

Ampio Pharmaceuticals, Inc.

Form 10-Q

May 06, 2016

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**For the Quarterly Period Ended: March 31, 2016**

**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 May 1, 2016, there were 52,016,432 shares outstanding of Common Stock, par value \$0.0001, of the registrant.

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**AMPIO PHARMACEUTICALS, INC.  
FOR THE QUARTER ENDED MARCH 31, 2016**

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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 and Optina, which are protected under applicable intellectual property laws and are our property. Solely for convenience, our trademarks and trade names 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 trade names.*

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

	March 31, 2016 (Unaudited)	December 31, 2015
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 11,114,654	\$ 15,998,392
Receivable from Aytu BioScience, Inc.		38,451
Prepaid expenses	432,709	321,574
Prepaid research and development - related party (Note 6)	143,802	143,802
Current assets of discontinued operations (Note 7)		12,726,203
Total current assets	11,691,165	29,228,422
Fixed assets, net (Note 2)	8,882,087	9,187,620
Equity investment in Aytu BioScience, Inc.	959,734	
Long-term portion of prepaid research and development - related party (Note 6)	287,603	323,553
Deposits	33,856	33,856
Other assets of discontinued operations, net (Note 7)		11,645,142
Total assets	\$ 21,854,445	\$ 50,418,593
<b>Liabilities and Stockholders Equity</b>		
Current liabilities		
Accounts payable	\$ 2,210,872	\$ 1,804,369
Accrued compensation	1,040,919	885,517
Deferred rent	59,579	59,579
Current liabilities of discontinued operations (Note 7)		2,765,648
Total current liabilities	3,311,370	5,515,113
Long-term deferred rent	620,864	629,568
Liabilities of discontinued operations, net (Note 7)		6,346,924
Total liabilities	3,932,234	12,491,605
Commitments and contingencies (Note 3)		

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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 - 52,016,432 (unaudited) in 2016 and 51,998,306 in 2015

	5,202	5,200
Additional paid-in capital	158,687,250	170,999,410
Advances to stockholders	(90,640)	(90,640)
Accumulated deficit	(140,679,601)	(133,914,812)
Total Ampio stockholders' equity	17,922,211	36,999,158
Non-controlling interests of discontinued operations		927,830
Total stockholders' equity	17,922,211	37,926,988
Total liabilities and stockholders' equity	\$ 21,854,445	\$ 50,418,593

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

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

	Three Months Ended March 31,	
	2016	2015
Operating expenses		
Research and development	\$ 4,275,577	\$ 3,884,488
Research and development - related party (Note 6)	35,950	35,950
General and administrative	2,110,896	1,873,270
Total operating expenses	6,422,423	5,793,708
Other income (expense)		
Interest income	10,154	44,477
Loss from equity investment in Aytu BioScience, Inc.	(352,520)	
Total other (expense) income	(342,366)	44,477
Net loss from continuing operations	(6,764,789)	(5,749,231)
Loss from discontinued operations (Note 7)		(1,842,189)
Net loss	(6,764,789)	(7,591,420)
Net loss applicable to non-controlling interests		307,837
Net loss applicable to Ampio	\$ (6,764,789)	\$ (7,283,583)
Basic and diluted Ampio net loss per common share		
From continuing operations	\$ (0.13)	\$ (0.11)
From discontinued operations and non-controlling interests	\$	\$ (0.03)
Net loss per share applicable to Ampio	\$ (0.13)	\$ (0.14)
Weighted average number of Ampio common shares outstanding	52,016,034	51,981,340

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



**Table of Contents****AMPIO PHARMACEUTICALS, INC.****Statements of Stockholders' Equity (Deficit)**

	Common Shares	Stock Amount	Additional Paid in Capital	Advances to Stockholders	Accumulated Deficit	Non-controlling Interests	Total Stockholders' Equity
Balance - December 31, 2015	51,998,306	5,200	170,999,410	(90,640)	(133,914,812)	927,830	37,926,988
Common stock issued for services (unaudited)	18,126	2	59,998				60,000
Distribution to stockholders (unaudited)			(13,018,687)				(13,018,687)
Warrant modification (unaudited)			36,643				36,643
Stock-based compensation (unaudited)			609,886				609,886
Net loss (unaudited)					(6,764,789)		(6,764,789)
Changes in non-controlling interests (unaudited)						(927,830)	(927,830)
Balance - March 31, 2016	52,016,432	\$ 5,202	\$ 158,687,250	\$ (90,640)	\$ (140,679,601)	\$	\$ 17,922,211

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

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

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities		
Net loss	\$ (6,764,789)	\$ (7,591,420)
Losses in equity investment in Aytu BioScience, Inc.	352,520	
Stock-based compensation and warrant modification	646,529	1,144,803
Depreciation and amortization	305,533	206,426
Amortization of prepaid research and development - related party (Note 6)	35,950	35,950
Common stock issued for services	60,000	30,000
Adjustments to reconcile net loss to net cash used in operating activities		
(Increase) decrease in prepaid expenses	(111,135)	418,456
Decrease in accounts receivable	38,451	
Increase (decrease) in accounts payable	406,505	(2,017,840)
Decrease in deferred rent	(8,704)	(6,286)
Increase in accrued compensation	155,402	297,227
Net cash used in operating activities - continuing operations	(4,883,738)	(7,482,684)
Net cash provided by operating activities - discontinued operations		476,546
Net cash used in operating activities	(4,883,738)	(7,006,138)
Cash flows used in investing activities		
Purchase of fixed assets		(43,060)
Net cash used in investing activities - continuing operations		(43,060)
Net cash provided by investing activities - discontinued operations		
Net cash provided by (used in) investing activities		(43,060)
Cash flows from financing activities		
Net cash used in financing activities - continuing operations		
Net cash provided by financing activities - discontinued operations		
Net cash used in financing activities		
Net change in cash and cash equivalents	(4,883,738)	(7,049,198)
Cash and cash equivalents at beginning of period	26,957,938	50,159,751

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Cash and cash equivalents - Aytu BioScience, Inc. at beginning of period	(10,959,546)	160,905
Cash and cash equivalents at the beginning of period	15,998,392	50,320,656
Cash and cash equivalents at end of period	\$ 11,114,654	\$ 43,271,458
Non-cash transactions:		
Distribution to stockholders	\$ 13,018,687	\$
Fixed asset purchases included in accounts payable	\$	\$ 44,612

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

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**AMPIO PHARMACEUTICALS, INC.**

**Notes to Financial Statements**

**(unaudited)**

**Note 1 Basis of Presentation**

These financial statements represent the financial statements of Ampio Pharmaceuticals, Inc. ( Ampio or the Company ). Ampio is 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.

Ampio's activities have been primarily related to research and development and raising capital and have not generated revenue to date.

On January 4, 2016, Ampio completed the spin-off of Aytu BioScience, Inc. ( Aytu ) by distributing a majority of its shares of common stock of Aytu to the Ampio shareholders on a pro rata basis. This transaction changed Ampio's ownership from 81.5% to 8.6% of Aytu's outstanding shares on that date. Ampio believes it continues to have significant influence over Aytu subsequent to the spin-off due to the fact that Ampio's Chief Executive Officer was Aytu's only Board member until mid-January 2016 when he became one of three Aytu Board of Directors members. Therefore, Ampio has accounted for its remaining investment in Aytu based on the equity method of accounting. As of March 31, 2016 Ampio's ownership in Aytu's outstanding shares was 5.5% (see Note 7 *Discontinued Operations*). Ampio made reclassification adjustments to its December 31, 2015 balance sheet and our results of operations for the three months ended March 31, 2015 to reflect the effect of the Aytu business as discontinued operations.

***Recent Accounting Pronouncements***

In March 2016, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share Based Payment Accounting*. The standard includes multiple provisions intended to simplify various aspects of the accounting for share based payments. The amendments are expected to significantly impact net income, earnings per share, and the statement of cash flows. Implementation and administration may present challenges to companies with significant share based payment activities. The amendments are effective for public entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. The Company is currently evaluating the impact of this standard on its financial statements.

In March 2016, the FASB issued ASU No. 2016-07, *Investments - Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting*. The amendments affect all entities that have an investment that becomes qualified for the equity method of accounting as a result of an increase in the level of ownership interest or degree of influence. The amendments eliminate the requirement that when an investment qualifies for use of the equity method as a result of an increase in the level of ownership interest or degree of influence, an investor must adjust the investment, results of operations, and retained earnings retroactively on a step-by-step basis as if the equity method had been in effect during all previous periods that the investment had been held. The amendments require that the equity method investor add the cost of acquiring the additional interest in the investee to the current basis of the investor's previously held interest and adopt the equity method of accounting as of

the date the investment becomes qualified for equity method accounting. Therefore, upon qualifying for the equity method of accounting, no retroactive adjustment of the investment is required. The amendments are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. The amendments should be applied prospectively upon their effective date to increases in the level of ownership interest or degree of influence that result in the adoption of the equity method. Earlier application is permitted. The Company is currently evaluating the impact of this standard on its financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*. The new standard establishes a right-of-use ( ROU ) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of this standard on its financial statements.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments – Overall (Subtopic 825-10): Recognition Measurement of Financial Assets and Financial Liabilities*, which requires that all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under equity method of accounting or those that result in consolidation of the investee). The amendments in this update also require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when

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the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. In addition, the amendments in this update eliminate the requirement to disclose the fair value of financial instruments measured at amortized cost for entities that are not public business entities and the requirement to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet for public business entities. The amendment is effective for financial statements issued for fiscal years beginning after December 15, 2017. Early adoption is not permitted. The Company is currently evaluating the impact of this standard on its financial statements.

In August 2014, the FASB issued ASU 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*. The standard 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 ending after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact of this standard on its financial statements.

In May 2014, the 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. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers: Deferral of the Effective Date*, which deferred the effective date of the new revenue standard for periods beginning after December 15, 2017, with early adoption permitted. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. The Company is currently evaluating the impact of this standard on its financial statements.

**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:

	Estimated Useful Lives in years	As of March 31, 2016	As of December 31, 2015
Manufacturing Facility/Clean Room	8	\$ 2,734,000	\$ 2,734,000
Leasehold improvements	10	6,075,000	6,075,000
Office furniture and equipment	3 - 10	557,000	557,000
Lab equipment	5 - 10	1,019,000	1,019,000
Less accumulated depreciation and accretion		(1,503,000)	(1,198,000)
Fixed assets, net		\$ 8,882,000	\$ 9,187,000

**Note 3 Commitments and Contingencies**

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

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	Total	Remaining 2016	2017	2018	2019	2020	Thereafter
Ampion supply agreement	\$ 5,100,000	\$	\$ 2,550,000	\$ 2,550,000	\$	\$	\$
Clinical research and trial obligations	1,738,000	1,705,000	33,000				
Facility lease	2,851,000	224,000	306,000	316,000	326,000	335,000	1,344,000
Sponsored research agreement with related party	975,000	244,000	325,000	325,000	81,000		
	\$ 10,664,000	\$ 2,173,000	\$ 3,214,000	\$ 3,191,000	\$ 407,000	\$ 335,000	\$ 1,344,000

***Ampion Supply Agreement***

In October 2013, Ampio entered into an agreement to purchase human serum albumin, the starting raw material for the Company's Ampion product. Under this agreement, the Company still has a remaining commitment of \$5,100,000. Per an amendment to the original agreement, Ampio is not committed to purchase any human serum albumin during 2016 and has extended the agreement to 2018.

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

In connection with current and recent clinical trials, as of March 31, 2016, Ampio has a remaining commitment of \$1,738,000 on contracts related to the active Ampion clinical trial.

***Facility Lease***

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 March 31,	
	2016	2015
Rent expense	\$ 73,000	\$ 64,000

***Sponsored Research Agreement with Related Party***

Ampio entered into a Sponsored Research Agreement with Trauma Research LLC ( "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 6 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.

**Note 4 Common Stock*****Capital Stock***

At March 31, 2016 and December 31, 2015, Ampio had 52,016,432 and 51,998,306 common shares outstanding, respectively. As of these same dates, Ampio had no preferred shares outstanding. Ampio has 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***

In December 2013, Ampio filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission (the "SEC") 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 in January 2014 by the SEC. As a result of prior equity raises, approximately \$86.3 million remains available under the Form S-3 as of March 31, 2016.



***Controlled Equity Offering***

In February 2016, Ampio entered into a Controlled Equity Offering <sup>SM</sup> Sales Agreement (the Agreement ) with a placement agent to implement an at-the-market equity program under which Ampio, from time, to time may offer and sell shares of its common stock having an aggregate offering price of up to \$25.0 million through the placement agent. The Company has no obligation to sell any of the shares and may at any time suspend sales under the Agreement or terminate the Agreement in accordance with the terms. The Company has provided the placement agent with customary indemnification rights. The placement agent will be entitled to a fixed commission of 3.0% of the gross proceeds from shares sold. No sales were made under the Agreement during the quarter ended March 31, 2016.

***Common Stock Issued for Services***

Ampio issued 18,126 and 7,998 shares valued at \$60,000 and \$30,000, respectively, for non-employee directors as part of their director fees for fiscal years 2016 and 2015, respectively.

**Table of Contents****Note 5 Equity Instruments****Options**

In 2010, Ampio shareholders approved the adoption of a stock and option award plan (the 2010 Plan), under which shares were reserved for future issuance under restricted stock awards, options, and other equity awards. The 2010 Plan permits grants of equity awards to employees, directors and consultants. The shareholders have approved a total of 11.7 million shares reserved for issuance under the 2010 plan. 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 its stock. Ampio has estimated a forfeiture rate of 5.3% 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 March 31, 2016, Ampio granted 5,000 options at a price of \$6.53 to a former employee to replace 5,000 options that were forfeited due to the spin-off of Aytu. The \$6.53 price represented the fair market value on the original date of the grant. In January 2016, Aytu accelerated the vesting of 335,000 Aytu options to employees of Ampio. The Company recognized expense in the amount of \$312,000 related to this modification during the quarter ended March 31, 2016. Ampio has computed the fair value of all options granted during the three months ended March 31, 2016 using the following assumptions:

Expected volatility	124%
Risk free interest rate	0.61%
Expected term (years)	1.0
Dividend yield	0.0%

Ampio stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding December 31, 2015	7,315,832	\$ 3.71	6.58
Granted	5,000	\$ 6.53	
Exercised		\$	
Forfeited		\$	
Expired or Cancelled	(5,000)	\$ 6.53	
Outstanding March 31, 2016	7,315,832	\$ 3.71	5.54
Exercisable at March 31, 2016	6,336,607	\$ 3.71	5.22
Available for grant at March 31, 2016	2,971,647		



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Stock options outstanding and exercisable at March 31, 2016 are summarized in the table below:

Range of Exercise Prices	Number of Options Outstanding and Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Contractual Lives
\$1.03 - \$4.00	5,140,832	\$ 2.38	5.28
\$4.01 - \$7.00	1,240,000	\$ 6.17	5.64
\$7.01 - \$8.93	935,000	\$ 7.73	6.83
	7,315,832	\$ 3.71	5.54

Stock-based compensation expense related to the fair value of stock options was included in the statements of operations as research and development expenses and selling, 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 model and expenses the fair value ratably over the vesting period. The following table summarizes stock-based compensation expense for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
	2016	2015
Research and development expenses		
Stock options	\$ 90,000	\$ 608,000
General and administrative expenses		
Common stock issued for services	60,000	30,000
Stock options	520,000	537,000
	\$ 670,000	\$ 1,175,000
Unrecognized expense at March 31, 2016	\$ 836,613	
Weighted average remaining years to vest	0.25	

**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, 2015	499,076	\$ 3.24	1.19
Warrants exercised		\$	

Outstanding March 31, 2016	499,076	\$	3.24	1.03
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In March 2016, the Company modified 45,300 of its outstanding warrants which extended the expiration for an additional year from March 31, 2016 to March 31, 2017. The \$37,000 expense related to this modification was recognized in the quarter ended March 31, 2016.

**Note 6 Related Party Transactions**

Ampio entered into a sponsored research agreement with TRLLC, an entity controlled by Ampio's director and Chief Scientific Officer, Dr. Bar-Or, in September 2009, which has been amended six times with the last amendment occurring in January 2015. Under the amended terms of the research agreement, Ampio will provide personnel with an equivalent value of \$325,000 per year. With the fifth amendment, Ampio also paid \$725,000 in 2014 which is being amortized over the contractual term of 60.5 months and is divided between current and long-term on the balance sheet. In return, TRLLC will assign any intellectual property rights it develops on Ampio's behalf under the research agreement and undertake additional activities to support Ampio's commercial activities and business plan. This agreement is set to expire in March 2019 and cannot be terminated prior to March 2017.

The Company has advances to one executive and three employees that were used to purchase stock in the Company when it was formed during 2010. These advances are non-interest bearing and due on demand and are classified as a reduction to stockholders' equity. As of March 31, 2016 and December 31, 2015, advances of \$91,000 to stockholders remained outstanding.

**Note 7 Discontinued Operations**

On January 4, 2016, the Company completed the spin-off of Aytu by distributing a majority of its shares of common stock of Aytu to the Ampio shareholders on a pro rata basis. The Aytu business has been included in Ampio's financial results as discontinued operations for all periods presented. Please refer to *Note 1 Basis of Presentation* for additional information concerning discontinued operations.

For all periods presented, the operating results associated with the Aytu business have been reclassified into loss from discontinued operations in the condensed statement of operations. Due to the holiday on January 1, 2016, and January 2<sup>nd</sup> and 3<sup>rd</sup> 2016 falling on weekend days, the Company deemed the operating results associated with Aytu for January 1 - 3, 2016 immaterial for disclosure purposes. The following table provides a summary of Aytu amounts included in discontinued operations:

	Three Months Ended March 31,	
	2016	2015
Revenue	\$	\$ 23,829
Total operating expenses		(1,829,966)
Interest (expense)		(36,052)
Loss from discontinued operations	\$	\$ (1,842,189)

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Assets and liabilities of discontinued operations consisted of the following at December 31, 2015:

	December 31, 2015
Cash and cash equivalents	\$ 10,959,546
Prepaid expenses and other	1,644,674
Prepaid research and development - related party	121,983
Current assets of discontinued operations	12,726,203
Fixed assets, net	143,826
In-process research and development	7,500,000
Developed technology, customer contracts and trade names, net	2,909,583
Goodwill	221,000
Patents, net	593,382
Long-term portion of prepaid research and development - related party	274,463
Deposits	2,888
Other assets of discontinued operations	11,645,142
Assets of discontinued operations	\$ 24,371,345
Accounts payable	\$ 1,076,293
Primsol payable	1,111,057
Accrued compensation	492,584
Deferred revenue	85,714
Current liabilities of discontinued operations	2,765,648
Convertible promissory notes, net of unamortized discount of \$253,448	4,921,552
Interest payable	161,988
Contingent consideration	687,685
Long-term deferred rent	11,694
Long-term deferred revenue	383,036
Warrant derivative liability	180,969
Liabilities of discontinued operations	6,346,924
Liabilities of discontinued operations	\$ 9,112,572

**Note 8 Litigation**

As previously disclosed, on May 8, 2015 and May 14, 2015, purported stockholders of the Company brought two putative class action lawsuits in the United States District Court in the Central District of California, Napoli v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03474-TJH and Stein v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03640-TJH (the "Securities Class Actions"), alleging that Ampio and certain of its current and former officers violated federal securities laws by misrepresenting and/or omitting information regarding the STEP study. The cases were consolidated, and on February 8, 2016, plaintiffs filed a consolidated amended complaint alleging claims under Sections 10(b) and 20(a) and Rule 10b-5 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Sections 11 and 15 under the Securities Act of 1933 on behalf of a putative class of purchasers of common stock from January 13, 2014 through August 21, 2014, including purchasers in the Company's offering on February 28, 2014. On April 8, 2016, Ampio and the other defendants moved to dismiss the consolidated amended complaint. The lawsuits seek unspecified damages, pre-judgment and post-judgment interest, and attorneys' fees and costs.

On August 6, 2015 and September 25, 2015, purported stockholders of the Company brought derivative actions in the United States District Court in the Central District of California, Oglina v. Macaluso et al., Case No. 2:15-cv-05970-TJH-PJW ("Oglina action") and the Colorado state court in Denver, Loyd v. Giles et al., Case No. 2015CV33429 ("Loyd action"), alleging primarily that the directors and officers of Ampio breached their fiduciary duties because of their alleged misstatements and/or omissions regarding the STEP study. Pursuant to the parties' stipulation, the United States District Court in the Central District of California has stayed the proceedings in the Oglina action at the present time in accordance with the terms of the parties' stipulation. Pursuant to the parties' stipulation, the Colorado state court in Denver has stayed the Loyd action at the present time in accordance with the terms of the parties' stipulation.



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The Company believes these claims are without merit and intends to defend these lawsuits vigorously. The Company currently believes the likelihood of a loss contingency related to these matters 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 our 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 our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 26, 2016.*

### **Overview**

We maintain an Internet website at [www.ampiopharma.com](http://www.ampiopharma.com). Information on or linked to our 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).

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.

### **Product Update**

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

### **AMPION**

Ampion is the < 5 kDa ultrafiltrate of 5% Human Serum Albumin, or HSA, an approved biologic product. Ampion is produced by ultrafiltration, and is provided as a sterile solution for dose administration as an injection directly into the osteoarthritic knee joint. Ampion is proposed for the treatment of pain due to osteoarthritis of the knee.

We have completed multiple clinical trials in the development of Ampion. Clinical trial development began in 2011 with a Phase I/II study. In 2013, we announced the results of the single injection Phase III Spring study, which met its primary endpoint, and was deemed by the United States Food and Drug Administration, or the FDA, as one of the two pivotal trials required to support a Biologics License Application, or BLA. Results of the Spring study have been published. Multiple injection clinical investigations were evaluated in the first and second quarter of 2015. The multiple injection Phase II Strut study demonstrated a 64% reduction in pain over baseline at 20 weeks. The Phase III multiple injection Stride study did not reach its primary endpoint, though it did demonstrate a significant reduction in pain over baseline at 20 weeks. In July 2015, we announced that we had a meeting with the FDA where a single injection clinical trial and a Special Protocol Assessment, or SPA, was recommended by the FDA as the second, and final, pivotal trial for the BLA. An SPA is a process by which the FDA provides written agreement on the design and size of a clinical protocol for the purpose of BLA filing. An SPA can significantly de-risk the path to market due to

insufficient data or unexpected safety concerns. In September of 2015, we announced that the FDA had awarded us a SPA for the second Phase III pivotal trial of Ampion, the Pivot study. On March 29, 2016, we announced that enrollment in the Pivot study was complete. We expect final results to be available mid-year 2016.

## **OPTINA**

Optina is a low-dose formulation of danazol, an FDA approved therapeutic when used at 100 to 800 mg per day. Danazol is a synthetic derivative of modified testosterone ethisterone. At low doses, danazol decreases vascular permeability by increasing the barrier function of endothelial cells. The lipophilic low-molecular-weight weak androgen has the potential to treat multiple angiopathies. Optina is proposed for the treatment of Diabetic Macular Edema, or DME.

During 2014 and 2015, we conducted the OptimEyes multicenter, placebo-controlled, randomized, dose ranging trial to evaluate the safety and efficacy of oral Optina, which included 355 patients. The trial showed Optina was safe and well tolerated with no drug related adverse events and no differences in side effect rates between placebo and Optina groups. The trial did not meet its primary endpoint for all patients, however we believe we have successfully identified an optimal dose for a body mass index subgroup of patients who are refractory to currently available therapies and also utilize RAS inhibitors as a medication. As more than 70% of all DME patients are utilizing RAS inhibitors to control their blood pressure, we believe this combination of drugs shows promise as a

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painless, safe and efficacious oral treatment for DME, and a rescue medication following anti-vascular endothelial growth factor therapy failure. These patients showed a +6.2 letter improvement in visual acuity at three months. We presented these results at the World Ophthalmology Congress in February 2016 and plan to present the results at The Association for Research in Vision and Ophthalmology Conference in May 2016.

## **Future Development**

We also intend to study Ampion for therapeutic applications outside of osteoarthritis of the knee. We may engage development partners to study Ampion in various conditions including: (i) acute and chronic inflammatory conditions; (ii) degenerative joint diseases; and (iii) respiratory 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.

## **AMPION MANUFACTURING FACILITY**

In December 2013, we entered into a ten-year lease of a multi-purpose facility containing approximately 19,000 square feet. This facility includes an FDA compliant clean room to manufacture Ampion, research laboratories and our corporate offices.

We moved into our new manufacturing facility in the summer of 2014. Since that time we have implemented a quality system, validated the facility for human-use products and produced the product used in the PIVOT study clinical trial. We presented on single use technology in manufacturing at the 24th Annual Aseptic Processing Technology Conference for the International Society for Pharmaceutical Engineers in February of 2015. We are now in the final stages of the FDA required registration batches and have begun to manufacture product that could potentially be used commercially. We believe that these steps could shorten our regulatory timelines and significantly reduce our time to commercialize Ampion. The facility was fully placed in service during the first quarter of 2016. We have manufactured the Ampion drug and placebo (Saline) for the second Phase III Ampion trial in our facility.

## **KNOWN TRENDS OR FUTURE EVENTS**

We are a development stage company that has not generated revenues and have therefore incurred significant net losses totaling \$140.7 million since our inception in December 2008. We expect to generate operating losses for the foreseeable future, but intend to try to limit the extent of these losses by entering into co-development or collaboration agreements with one or more strategic partners. Although we have raised capital in the past with net proceeds of \$63.4 million, \$28.9 million and \$15.4 million through the sale of common stock in 2014, 2013 and 2012, 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.

On January 4, 2016, we distributed to our shareholders the majority of our shares in Aytu, and since we no longer own a majority of Aytu's stock, our focus will be solely on the Ampio products, Ampion and Optina, in fiscal 2016.

## **ACCOUNTING POLICIES**

### **Significant Accounting Policies and Estimates**

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to recoverability of long-lived assets, valuation analysis, useful lives of assets, stock compensation and the valuation of the Aytu BioScience investment. 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 2015 Annual Report reported on Form 10-K, filed with the SEC on February 26, 2016.

#### **Newly Issued Accounting Pronouncements**

Information regarding the recently issued accounting standards is in Note 1 of the Financial Statements.

**Table of Contents****RESULTS OF OPERATIONS****Results of Operations March 31, 2016 Compared to March 31, 2015**

Results of operations for the three months ended March 31, 2016 or the 2016 quarter and the three months ended March 31, 2015 or the 2015 quarter reflected net losses from continuing operations of approximately \$6.8 million and \$5.8 million, respectively. These losses include in part non-cash charges related to losses in our equity investment in Aytu, stock-based compensation, depreciation and amortization, amortization of prepaid research and development - related party and common stock issued for services, collectively in the amount of \$1.4 million in each of the 2016 quarter and the 2015 quarter. The non-cash charges increased in the 2016 quarter primarily due to the losses in the equity investment in Aytu and offset by the decrease in stock-based compensation.

As previously disclosed, on January, 4, 2016, we completed the spin-off of Aytu by distributing a majority of our shares of common stock of Aytu to our shareholders on a pro rata basis. This transaction changed Ampio's ownership from 81.5% to 8.6% of Aytu's outstanding shares on that date. We believe we continue to have significant influence over Aytu subsequent to the spin-off due to the fact that our Chief Executive Officer was Aytu's only Board of Directors member until mid-January 2016 when he became one of three Aytu Board of Directors members. Therefore, we have accounted for our remaining investment in Aytu based on the equity method of accounting. As of March 31, 2016, our ownership in Aytu's outstanding shares was 5.5%. We made reclassification adjustments to our results of operations for the three months ended March 31, 2015 to reflect the effect of the Aytu business as discontinued operations. Thus, the Aytu business is not included in research and development or general and administrative costs.

***Operating Expenses******Research and Development***

Research and development costs are summarized as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Clinical trials and sponsored research	\$ 2,807,000	\$ 2,158,000
Labor	898,000	713,000
Consultants and other	480,000	405,000
Stock-based compensation	90,000	608,000
Sponsored Research - related party	36,000	36,000
	\$ 4,311,000	\$ 3,920,000

Research and development costs consist of clinical trials and sponsored research, labor, consultants and other, stock-based compensation and sponsored research - related party. Costs of research and development expense increased \$391,000, or 10.0%, for the 2016 quarter compared to the 2015 quarter. The increase is primarily due to an increase in clinical trials and sponsored research expenses related to our Ampio Phase III Pivot study partially offset by the decrease in stock-based compensation. During the second half of 2016, we expect our clinical trial expense to decline as we conclude the Ampion Phase III Pivot study and evaluate future Optina studies, as well as initial pilot evaluations of Ampion in additional indications.



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

General and administrative costs are summarized as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Stock-based compensation	\$ 580,000	\$ 567,000
Professional fees	455,000	234,000
Occupancy, travel and other	447,000	239,000
Labor	388,000	538,000
Patent costs	181,000	232,000
Directors fees	60,000	63,000
	<b>\$ 2,111,000</b>	<b>\$ 1,873,000</b>

General and administrative costs increased \$238,000, or 12.7%, for the 2016 quarter compared to the 2015 quarter. The increase is due to the increase in professional fees and occupancy, travel and other which was partially offset by the decrease in labor and patent costs. Occupancy, travel and other increased as Aytu relocated to their own rental space adjacent to Ampio and we are now absorbing all of the facility costs. We expect that our general and administrative expense will remain consistent during the remainder of 2016 compared to the first quarter of 2016.

*Loss from Operations*

The loss from continuing operations during the three months ended March 31, 2016 of \$6.8 million is greater than the loss from continuing operations of \$5.8 million for the same period in 2015. The increase in the losses was primarily caused by the increase in our clinical trial expenses specifically for our Ampion Phase III Pivot trial as well as the increase in general and administrative costs. As stated previously, we expect our clinical trial expense to decline in the second half of 2016 as we conclude the Ampion Phase III Pivot study and evaluate future Optina studies, as well as initial pilot evaluations of Ampion in additional indications.

*Net Cash Used in Operating Activities*

During the 2016 quarter, our operating activities used approximately \$4.9 million in cash which was less than the net loss of \$6.8 million primarily as a result of the increase in accounts payable and prepaid expenses partially offset by the decrease in stock-based compensation and the losses in our equity investment in Aytu.

In the 2015 quarter, the use of cash was \$7.5 million which was less than the net loss of \$7.6 million principally as a result of non-cash stock-based compensation offset by prepaid research and development related party, accrued compensation and accounts payable.

*Net Cash Used in Investing Activities*

During the 2015 quarter, cash was used to acquire manufacturing machinery and equipment.

*Net Cash from Financing Activities*

We had no financing activity during the first quarter of 2016 or 2015.

***Liquidity and Capital Resources***

We have not generated revenue as our primary activities are focused on research and development, advancing our primary product candidates, and raising capital. As of March 31, 2016, we had cash and cash equivalents totaling \$11.1 million available to fund our operations and \$3.3 million in accounts payable and accrued compensation. Based upon our current plans, we believe our capital resources at March 31, 2016 will be sufficient to fund our currently planned operations through 2016 and into early 2017. This projection 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 will be required to seek additional capital within the next 9 months to expand our



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clinical and commercial development activities for Ampion based on the positive results of our ongoing clinical trials, if we face challenges or delays in connection with our clinical trials, or 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 depending on market conditions relative to our need for funds at such time, and we will seek to raise additional capital within the next 9 months when 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 2016 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 approximately \$800,000 per month. Additional funds are planned for regulatory approvals, clinical trials, outsourced research and development and commercialization consulting. Accordingly, 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 our Controlled Equity Offering™ Sales Agreement that we entered into in February 2016, 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. Over the last three 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 future 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.**

We are not currently exposed to material market risk arising from financial instruments, changes in interest rates or commodity prices, or fluctuations in foreign currencies. We have no need to hedge against any of the foregoing risks and therefore currently engage 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 our management, with the participation of the Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act. Based on such evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed in the reports we file or furnish under the Exchange Act 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.**

As previously disclosed, on May 8, 2015 and May 14, 2015, purported stockholders of the Company brought two putative class action lawsuits in the United States District Court in the Central District of California, Napoli v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03474-TJH and Stein v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03640-TJH (the "Securities Class Actions"), alleging that Ampio and certain of its current and former officers violated federal securities laws by misrepresenting and/or omitting information regarding the STEP study. The cases were consolidated, and on February 8, 2016, plaintiffs filed a consolidated amended complaint alleging claims under Sections 10(b) and 20(a) and Rule 10b-5 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Sections 11 and 15 under the Securities Act of 1933 on behalf of a putative class of purchasers of

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common stock from January 13, 2014 through August 21, 2014, including purchasers in the Company's offering on February 28, 2014. On April 8, 2016, Ampio and the other defendants moved to dismiss the consolidated amended complaint. The lawsuits seek unspecified damages, pre-judgment and post-judgment interest, and attorneys' fees and costs.

On August 6, 2015 and September 25, 2015, purported stockholders of the Company brought derivative actions in the United States District Court in the Central District of California, Oglina v. Macaluso et al., Case No. 2:15-cv-05970-TJH-PJW ( Oglina action ) and the Colorado state court in Denver, Loyd v. Giles et al., Case No. 2015CV33429 ( Loyd action ), alleging primarily that the directors and officers of Ampio breached their fiduciary duties because of their alleged misstatements and/or omissions regarding the STEP study. Pursuant to the parties' stipulation, the United States District Court in the Central District of California has stayed the proceedings in the Oglina action at the present time in accordance with the terms of the parties' stipulation. Pursuant to the parties' stipulation, the Colorado state court in Denver has stayed the Loyd action at the present time in accordance with the terms of the parties' stipulation.

The Company believes these claims are without merit and intends to defend these lawsuits vigorously. The Company currently believes the likelihood of a loss contingency related to these matters is remote and, therefore, no provision for a loss contingency is required.

### **Item 1A. Risk Factors.**

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC, which could materially affect our business, financial condition or future results. During the period covered by this Quarterly Report on Form 10-Q, there were no material changes to the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

### **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	Controlled Equity Offering <sup>TM</sup> Sales Agreement, dated February 10, 2016, by and between the Company and Cantor Fitzgerald Co. (1).
10.2	Agreement, dated March 2, 2016, by and between the Company and Vaughan Clift, M.D. (2).
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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**Exhibit**

<b>Number</b>	<b>Description</b>
101	XBRL (eXtensible Business Reporting Language). The following materials from Ampio Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 formatted in XBRL: (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Stockholders' Equity (Deficit), (iv) the Statements of Cash Flows, and (v) the Notes to Financial Statements.

- \* 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.
- (1) Incorporated by reference from the Company's Current Report on Form 8-K filed on February 10, 2016.
  - (2) Incorporated by reference from the Company's Current Report on Form 8-K filed on March 7, 2016.

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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: May 6, 2016**

By: /s/ Gregory A. Gould  
**Gregory A. Gould**  
**Chief Financial Officer, Treasurer and**  
**Secretary**  
**Date: May 6, 2016**