

Ampio Pharmaceuticals, Inc.
Form 10-Q
November 08, 2016

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, 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

Non-accelerated filer "Smaller Reporting Company"

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

As of November 1, 2016, there were 57,179,686 shares outstanding of Common Stock, par value \$0.0001, of the registrant.

AMPIO PHARMACEUTICALS, INC.

FOR THE QUARTER ENDED SEPTEMBER 30, 2016

INDEX

	Page
PART I—FINANCIAL INFORMATION	
Item 1. <u>Financial Statements</u>	M
<u>Balance Sheets as of September 30, 2016 (unaudited) and December 31, 2015</u>	M
<u>Statements of Operations for the three and nine months ended September 30, 2016 (unaudited) and the three and nine months ended September 30, 2015 (unaudited)</u>	N
<u>Statements of Stockholders' Equity (Deficit) (unaudited)</u>	O
<u>Statements of Cash Flows for the nine months ended September 30, 2016 (unaudited) and the nine months ended September 30, 2015 (unaudited)</u>	8
<u>Notes to Financial Statements (unaudited)</u>	9
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	J3
Item 4. <u>Controls and Procedures</u>	J3
PART II—OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	J3
Item 1A. <u>Risk Factors</u>	J4
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	J4
Item 3. <u>Defaults Upon Senior Securities</u>	J4
Item 4. <u>Mine Safety Disclosures</u>	J4
Item 5. <u>Other Information</u>	J4
Item 6. <u>Exhibits</u>	J4

SIGNATURES

J5

2

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), obtain financing when required and the dilutive effects that raising additional capital could have on our current shareholders; 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.

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

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	\$7,416,953	\$ 15,998,392
Trading security Aytu BioScience, Inc. (Note 3)	333,175	-
Receivable from Aytu BioScience, Inc.	-	38,451
Prepaid expenses	409,671	321,574
Prepaid research and development - related party (Note 8)	143,802	143,802
Current assets of discontinued operations (Note 9)	-	12,726,203
Total current assets	8,303,601	29,228,422
Fixed assets, net (Note 2)	8,271,022	9,187,620
Long-term portion of prepaid research and development - related party (Note 8)	215,702	323,553
Deposits	33,856	33,856
Other assets of discontinued operations, net (Note 9)	-	11,645,142
Total assets	\$16,824,181	\$50,418,593
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$1,146,881	\$1,804,369
Accrued compensation	1,205,839	885,517
Deferred rent	59,579	59,579
Current liabilities of discontinued operations (Note 9)	-	2,765,648
Total current liabilities	2,412,299	5,515,113
Long-term deferred rent	599,425	629,568
Warrant derivative liability	4,039,197	-
Liabilities of discontinued operations, net (Note 9)	-	6,346,924
Total liabilities	7,050,921	12,491,605

Commitments and contingencies (Note 5)

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 - 57,179,686 (unaudited) in 2016 and 51,998,306 in 2015	5,718	5,200
Additional paid-in capital	159,542,164	170,999,410
Advances to stockholders	(50,653)	(90,640)
Accumulated deficit	(149,723,969)	(133,914,812)
Total Ampio stockholders' equity	9,773,260	36,999,158
Non-controlling interests of discontinued operations	-	927,830
Total stockholders' equity	9,773,260	37,926,988
Total liabilities and stockholders' equity	\$ 16,824,181	\$ 50,418,593

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

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Operating expenses				
Research and development	\$1,752,273	\$3,617,793	\$8,796,848	\$10,579,569
Research and development - related party (Note 8)	35,951	35,950	107,851	107,851
General and administrative	1,555,527	1,646,625	5,229,436	6,186,091
Total operating expenses	3,343,751	5,300,368	14,134,135	16,873,511
Other (expense) income				
Interest income (expense)	3,080	(1,299)	19,789	55,600
Derivative expense	(715,732)	-	(715,732)	-
Unrealized gain on trading security	64,274	-	64,274	-
Loss from equity investment in Aytu BioScience, Inc.	-	-	(1,043,353)	-
Total other (expense) income	(648,378)	(1,299)	(1,675,022)	55,600
Net loss from continuing operations	(3,992,129)	(5,301,667)	(15,809,157)	(16,817,911)
Loss from discontinued operations (Note 9)	-	(2,276,189)	-	(6,273,823)
Net loss	(3,992,129)	(7,577,856)	(15,809,157)	(23,091,734)
Net loss applicable to non-controlling interests	-	421,095	-	1,087,184
Net loss applicable to Ampio	\$(3,992,129)	\$(7,156,761)	\$(15,809,157)	\$(22,004,550)
Basic and diluted Ampio net loss				
per common share				
From continuing operations	\$(0.07)	\$(0.10)	\$(0.30)	\$(0.32)
From discontinued operations and non-controlling interests	-	(0.04)	-	(0.10)
Net loss per share applicable to Ampio	\$(0.07)	\$(0.14)	\$(0.30)	\$(0.42)
Weighted average number of Ampio common shares outstanding	53,842,234	51,998,306	52,629,343	51,989,939

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

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

	Common Stock Shares	Common 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)
Common stock issued in registered direct offering, net of offering costs of \$426,535 (unaudited)	5,000,000	500	(500)	-	-	-	-
Warrants issued in connection with the registered direct offering to the placement agent (unaudited)	-	-	88,530	-	-	-	88,530
Common stock issued in controlled equity offering, net of offering costs of \$102,530 (unaudited)	163,254	16	50,767	-	-	-	50,783
Warrant modification (unaudited)	-	-	36,643	-	-	-	36,643
Stock-based compensation (unaudited)	-	-	1,326,003	-	-	-	1,326,003
	-	-	-	39,987	-	-	39,987

Repayment of advance (unaudited)							
Net loss (unaudited)	-	-	-	-	(15,809,157)	-	(15,809,157)
Changes in non-controlling interests (unaudited)	-	-	-	-	-	(927,830)	(927,830)
			-				
Balance - September 30, 2016 (unaudited)	57,179,686	\$5,718	\$159,542,164	\$(50,653)	\$(149,723,969)	\$-	\$9,773,260

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

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

	Nine Months Ended	
	September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	\$(15,809,157)	\$(23,091,734)
Stock-based compensation and warrant modification	1,362,646	3,657,987
Depreciation and amortization	916,598	618,095
Amortization of prepaid research and development - related party (Note 8)	107,851	107,852
Common stock issued for services	60,000	30,000
Derivative expense	715,732	-
Losses in equity investment in Aytu BioScience, Inc.	1,043,353	-
Unrealized gain on trading security	(64,274)	-
Repayment of advance to stockholder	39,987	-
Adjustments to reconcile net loss to net cash used in operating activities		
(Increase) decrease in prepaid expenses	(88,097)	42,320
Decrease in accounts receivable from Aytu BioScience, Inc.	38,451	-
Decrease in accounts payable	(657,486)	(1,712,718)
Decrease in deferred rent	(30,143)	(22,888)
Increase in accrued compensation	320,322	681,629
Net cash used in operating activities - continuing operations	(12,044,217)	(19,689,457)
Net cash provided by operating activities - discontinued operations	-	1,010,919
Net cash used in operating activities	(12,044,217)	(18,678,538)
Cash flows used in investing activities		
Purchase of fixed assets	-	(108,709)
Net cash used in investing activities - continuing operations	-	(108,709)
Net cash used in investing activities - discontinued operations	-	(1,006,442)
Net cash used in investing activities	-	(1,115,151)
Cash flows from financing activities		
Proceeds from sale of common stock related to the registered direct offering	3,750,000	-
Costs related to sale of common stock related to the registered direct offering	(338,005)	-
Proceeds from sale of common stock related to the controlled equity offering	153,313	-
Costs related to sale of common stock related to the controlled equity offering	(102,530)	-
Net cash provided by financing activities - continuing operations	3,462,778	-
Net cash provided by financing activities - discontinued operations	-	4,857,937
Net cash provided by financing activities	3,462,778	4,857,937

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

Net change in cash and cash equivalents	(8,581,439)	(14,935,752)
Cash and cash equivalents at beginning of period	26,957,938	50,159,751
Cash and cash equivalents - Aytu BioScience, Inc. at beginning of period	(10,959,546)	160,905
Cash and cash equivalents of Ampio Pharmaceuticals, Inc. at the beginning of period	15,998,392	50,320,656
Cash and cash equivalents at end of period	\$7,416,953	\$35,384,904
Non-cash transactions:		
Distribution to stockholders	\$13,018,687	\$-
Warrant derivative liability - registered direct offering	\$4,127,130	\$-
Warrants registered direct offering - placement agent	\$88,530	\$-

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

AMPIO PHARMACEUTICALS, INC.

Notes to Financial Statements

(unaudited)

Note 1—Basis of Presentation

These unaudited financial statements represent the financial statements of Ampio Pharmaceuticals, Inc. (“Ampio” or “the Company”). These unaudited financial statements should be read in conjunction with Ampio’s Annual Report on Form 10-K for the year ended December 31, 2015, which included all disclosures required by generally accepted accounting principles (“GAAP”). In the opinion of management, these unaudited financial statements contain all adjustments necessary to present fairly the financial position of Ampio for the balance sheet and the results of operations and cash flows for the interim periods presented. The results of operations for the period ended September 30, 2016 are not necessarily indicative of expected operating results for the full year. The information presented throughout this report as of and for the period ended September 30, 2016 is unaudited.

Ampio is 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.

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 (see Note 9 – Discontinued Operations). This transaction changed Ampio’s ownership from 81.5% to 8.6% of Aytu’s outstanding shares on that date. As of September 30, 2016, Ampio’s ownership has been reduced to 2.0% (see Note 3 – Investment in Aytu BioScience, Inc.). Ampio reclassified its remaining investment in Aytu as a trading security, recorded at fair value on the balance sheet with the change in fair value recorded as an unrealized gain on the statement of operations.

Adoption of Newly Issued Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-15 *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments*, which provides guidance on the presentation of certain cash receipts and cash payments in the statement of cash flows in order to reduce diversity in existing practice. ASU 2016-15 is effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted. During the quarter ended September 30, 2016, the Company early adopted this standard with no impact on the nine months ended September 30, 2016 cash flow categorization.

Recently Issued Accounting Pronouncements, Not Adopted as of September 30, 2016

In March 2016, the FASB issued ASU 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 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 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.

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 September 30, 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 amortization		(2,114,000)	(1,198,000)
Fixed assets, net		\$8,271,000	\$9,187,000

Note 3—Investment in Aytu BioScience, Inc.

On January 4, 2016, Ampio 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 (see Note 9 – Discontinued Operations). This transaction changed Ampio's ownership from 81.5% to 8.6% of Aytu's outstanding shares on that date. As of March 31 and June 30, 2016, Ampio had significant influence over Aytu subsequent to the spin-off due to the fact that Ampio's Chief Executive Officer was one of the three and one of four Aytu Board members, respectively.

In May 2016, Aytu completed an offering which was dilutive to the Aytu shares held by Ampio. In July 2016, Aytu added a fifth Board member. In July 2016, the Company determined that Ampio's influence is no longer significant

over Aytu's Board of Directors. As of September 30, 2016, Ampio's ownership in Aytu's outstanding shares was 2.0%. Ampio reclassified its remaining investment in Aytu as a trading security. The Aytu security is recorded at fair value on the balance sheet with the change in fair value recorded as an unrealized gain on the statement of operations.

Note 4—Fair Value Considerations

Ampio's financial instruments include cash and cash equivalents, trading security, accounts payable and accrued liabilities and warrant derivative liability. The carrying amounts of cash and cash equivalents, accounts payable and accrued liabilities approximate their fair value due to their short maturities. The valuation policies are determined by the Chief Financial Officer and approved by the Company's Board of Directors.

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 Ampio's 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.

The following table presents Ampio's financial assets and liabilities that were accounted for at fair value on a recurring basis as of September 30, 2016, by level within the fair value hierarchy:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
<u>September 30, 2016</u>				
ASSETS				
Trading security in Aytu BioScience, Inc.	\$ 333,000	\$ -	\$ -	\$ 333,000
LIABILITIES				
Warrant derivative liability	\$ -	\$ -	\$ 4,039,000	\$ 4,039,000

The trading security in Aytu BioScience, Inc. is recorded at fair value which represents Ampio's ownership shares in Aytu of 102,201 multiplied by the Aytu's closing stock price on September 30, 2016. The difference in value is recorded as an unrealized gain on the statement of operations.

The warrant derivative liability for the warrants was valued using the Monte Carlo valuation methodology because this model embodies all of the relevant assumptions to address the features underlying these instruments. Significant assumptions in valuing the warrant derivative liability are based on estimates of the value of Ampio's common stock and various factors regarding the warrants. These assumptions were as follows as of September 30, 2016 and at issuance:

	September 30, 2016	At Issuance
Warrants:		
Exercise price	\$1.00	\$1.00
Volatility	95.5 %	96.1 %
Equivalent term (years)	4.91	5.00
Risk-free interest rate	1.13 %	1.18 %
Number of shares	5,000,000	5,000,000

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 Instruments
Balance as of December 31, 2015	\$-
Warrant issuances	4,127,000
Change in fair value included in derivative expense	(88,000)
Balance as of September 30, 2016	\$4,039,000

Note 5—Commitments and Contingencies

Commitments and contingencies are described below and summarized by the following table as of September 30, 2016:

	Total	Remaining				
		2016	2017	2018	2019	2020
Ampion supply agreement	\$7,650,000	\$-	\$2,550,000	\$2,550,000	\$2,550,000	\$-
Facility lease	2,702,000	75,000	306,000	316,000	326,000	335,000
Sponsored research agreement with related party	812,000	81,000	325,000	325,000	81,000	-
Clinical research and trial obligations	453,000	108,000	345,000	-	-	-
	\$11,617,000	\$264,000	\$3,526,000	\$3,191,000	\$2,957,000	\$335,000

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 \$7,650,000. 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 2019.

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 remaining term of the lease of approximately \$2.7 million and includes rent abatements and leasehold incentives. The Company recognizes rental expense of the facility on a straight-line basis over the term of the lease. Differences between the straight-line net expenses on rent payments are classified as liabilities between current deferred rent and long-term deferred rent.

Rent expense for the respective periods is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Rent expense	\$64,000	\$64,000	\$194,000	\$192,000

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 8—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.

Clinical Research and Trial Obligations

In connection with current and recent clinical trials, as of September 30, 2016, Ampio has a remaining commitment of \$453,000 on contracts related to the completion of these Ampion clinical trials.

Note 6—Common Stock

Capital Stock

At September 30, 2016 and December 31, 2015, Ampio had 57,179,686 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 \$82.4 million remains available under the Form S-3 as of September 30, 2016.

Registered Direct Offering

On September 1, 2016, the Company completed a registered direct offering. In this offering, the Company issued directly to an institutional investor 5.0 million shares of its common stock and warrants to purchase up to 5.0 million shares of common stock. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. Each unit was sold to the investor in this offering at a negotiated price of \$0.75 per unit generating gross proceeds of \$3.75 million. The shares and the warrants were offered and sold pursuant to the Company’s shelf registration statement on Form S-3 which was declared effective by the SEC in January 2014.

The investor warrants have an exercise price of \$1.00 per share and are immediately exercisable with a term of five years from issuance. In addition, the investor warrants include provisions for the adjustment to the exercise price upon subsequent issuances of common stock by the Company at a price less than the warrant exercise price and the investor is entitled to purchase additional shares, such that the aggregate purchase price of \$5.0 million for the warrant shares remains unchanged. The investor warrants also include a provision for redemption at the Black-Scholes value upon the request of the holder upon a change of control. Based on these additional derivative features of the investor warrants, they must be accounted for as a liability at fair value under ASC 480. On the date of issuance, these warrants were valued at \$4.1 million.

In connection with the offering the placement agent received a 6% commission totaling \$225,000 and 150,000 warrants with an exercise price of \$0.9375 and a termination date of September 1, 2021. These warrants had a value of \$89,000 when they were issued and are accounted for as equity based warrants. The Company also incurred expenses related to legal, accounting, and other registration cost of \$113,000.

The Company’s net cash proceeds for the registered direct offering were \$3.4 million. When the additional non-cash charges of \$4.2 million related to the 5.0 million investor warrants and the 150,000 placement agent warrants were offset against the net cash transaction proceeds this exceeded 100% of the proceeds so the Company was required to

take the additional cost above the transaction proceeds and recognize them as a loss on the day it entered the transaction. The loss on the transaction was \$804,000 and is included in derivative expense on the statement of operations.

Controlled Equity Offering

In February 2016, Ampio entered into a Controlled Equity Offering SM 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 its 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.

The following table summarizes Ampio's total sales under the Agreement for the period indicated:

	Nine Months Ended September 30, 2016
Total shares of common stock sold	163,254
Average price per share	0.93
Gross proceeds	153,000
Commissions earned by placement agent	5,000
Other expenses	98,000

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.

Note 7—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 5.2% 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. Ampio has computed the fair value of all options granted during the nine months ended September 30, 2016 using the following assumptions:

Expected volatility	115.51% - 116.12 %
Risk free interest rate	0.61% - 1.20 %
Expected term (years)	1.0 - 5.5
Dividend yield	0.0 %
Forfeiture rate	5.2% - 5.3 %

Ampio stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Years Contractual Life
Outstanding December 31, 2015	7,315,832	\$ 3.71	6.58
Granted	350,000	\$ 1.11	9.68
Exercised	-	\$ -	
Forfeited	-	\$ -	
Expired or Cancelled	(490,000)	\$ 2.79	
Outstanding September 30, 2016	7,175,832	\$ 3.64	5.22
Exercisable at September 30, 2016	6,670,101	\$ 3.72	4.86
Available for grant at September 30, 2016	3,111,647		

Stock options outstanding and exercisable at September 30, 2016 are summarized in the table below:

Range of Exercise Prices	Number of Options Outstanding and Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Years Contractual Lives
\$1.02 - \$4.00	5,015,832	\$ 2.26	5.02
\$4.01 - \$7.00	1,225,000	\$ 6.16	5.20
\$7.01 - \$8.93	935,000	\$ 7.73	6.33
	7,175,832	\$ 3.64	5.22

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 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 and nine months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development expenses				
Stock options	\$ 162,000	\$ 354,000	\$ 317,000	\$ 1,411,000
General and administrative expenses				
Common stock issued for services	-	-	60,000	30,000
Stock options	281,000	340,000	1,009,000	2,069,000
	\$ 443,000	\$ 694,000	\$ 1,386,000	\$ 3,510,000
Unrecognized expense at September 30, 2016	\$ 428,633			
Weighted average remaining years to vest	1.11			

Warrants

Ampio has issued warrants in conjunction with private and public offerings. A summary of all Ampio warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Years Contractual Life
Outstanding December 31, 2015	499,076	\$ 3.24	1.19
Warrants issued in connection with the registered direct offering	5,150,000	\$ 1.00	4.92
Warrants exercised	-	\$ -	
Warrants expired	(500)	\$ 3.13	
Outstanding September 30, 2016	5,648,576	\$ 1.20	4.54

In connection with our September 2016 registered direct offering, we issued to an investor warrants to purchase an aggregate of 5,000,000 shares of common stock at an exercise price of \$1.00 and a term of five years. These warrants due to certain derivative features are accounted for under liability accounting and are fair valued at each reporting period (see Note 6). At September 30, 2016, these warrants had a fair value of \$4,039,000 (see Note 4).

Also in connection with our September 2016 registered direct offering, we issued to the placement agent warrants to purchase an aggregate of 150,000 shares of common stock at an exercise price of \$0.9375 with a term of five years. These warrants are accounted for as equity based awards (see Note 6). The 150,000 placement agent warrants issued in connection with the registered direct offering were valued using the Black-Scholes valuation methodology. Significant assumptions were as follows:

Expected volatility	96 %
Risk free interest rate	1.18%
Expected term (years)	5.0
Dividend yield	0.0 %

Note 8—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 former 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 September 30, 2016, advances of \$51,000 to stockholders remained outstanding.

Note 9—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.

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

For all periods presented, the operating results associated with the Aytu business have been reclassified into loss from discontinued operations in the statement of operations. Due to the limited operations during the first four days of January 2016, the Company deemed the operating results associated with Aytu to be immaterial for disclosure purposes. The following table provides a summary of Aytu amounts included in discontinued operations:

	Three Months Ended September 30, 201 6 015	Nine Months Ended September 30, 201 6 015
Revenue	\$- \$487,385	\$- \$693,249
Total operating expenses	- (2,650,448)	- (6,813,800)
Interest expense	- (113,126)	- (153,272)
Loss from discontinued operations	\$- \$(2,276,189)	\$- \$(6,273,823)

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 10—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 Court granted the motion to dismiss, with leave to amend, on August 4, 2016. On September 27, 2016, plaintiffs filed their second amended complaint, alleging the same claims set forth in the consolidated amended complaint during the same class period. 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 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. 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.

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

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 met with the FDA where a single injection clinical trial and a Special Protocol Assessment, or SPA, was recommended by the FDA as the second pivotal trial for the BLA. A 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. A SPA can significantly de-risk the path to market due to insufficient data or unexpected safety concerns. In September of 2015, the FDA awarded us a SPA for the second PHASE III pivotal trial of Ampion (PIVOT study). The PIVOT study, which included 480 patients, was a randomized, double-blind, saline-controlled, PHASE III clinical study conducted at 20 sites across the US to examine the safety and efficacy of Ampion intra-articular injection in patients with pain due to osteoarthritis of the knee. The clinical stage of osteoarthritis of knee severity is defined by the Kellgren Lawrence scale, or KL. In March 2016, we announced that enrollment in the PIVOT study was complete. The results stating the PIVOT study did not meet its primary endpoint were announced in June 2016. The primary endpoint was the change in WOMAC A pain score at week 12 as compared to saline. Although the PIVOT study did not meet its primary endpoint, it did show a large reduction in pain from Baseline over 12 weeks. Ampion improved (reduced) WOMAC A pain scores significantly over baseline in all KL grades (reductions in pain: KL 2: 52%, KL 3: 36%, and KL 4: 33%). Additional analyses included adverse events, Patient Global Assessment, and responder status defined as 20% improvement in pain at week 12. Ampion was demonstrated to be safe and well-tolerated with no drug-related serious adverse events and an overall adverse event rate that was similar in both the Ampion and saline groups. We observed the largest differentiation between Ampion and saline in the most severe osteoarthritis of the knee patients (KL 4), where no available non-surgical therapy exists. KL 4 patients have been historically excluded from osteoarthritis of the knee trials because of the advanced stage of their condition. We are pleased with the consistent clinical effect Ampion has demonstrated in all of our clinical trials. In September 2016, we met with the CBER Division of the FDA to seek guidance on the best path forward to obtain a Biological License for Ampion™ to treat patients suffering from pain caused by severe osteoarthritis of the knee. As a result of this meeting, we are continuing our discussions with the FDA while analyzing the best way to proceed towards filling our BLA for Ampion. If another Ampion trial is needed prior to filing our BLA we believe that this trial could be smaller, with fewer patients, than our PIVOT study and could be completed in the first half of 2017. If we are successful in moving our plan forward, we believe that we could potentially file the Ampion BLA in the second half of 2017.

In May of 2016, we announced that patient dosing had begun in the exploratory, PHASE I clinical trial evaluating the safety of a single intra-articular injection of Ampion in adults with pain due to osteoarthritis of the hand, specifically of the first carpo-metacarpal joint of the thumb (basal thumb joint). This trial is a randomized, double-blind, placebo-controlled, single-center study in one of the largest hand surgery clinics in the US. In September 2016, we announced completion of enrollment. We expect to release the results once all patients have completed the trial.

We also intend to study Ampion for therapeutic applications outside of osteoarthritis of the knee and hand. 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.

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 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 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, The Association for Research in Vision and Ophthalmology Conference in May 2016, and the 49th Annual RETINA Society Meeting in September 2016.

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 process of producing the FDA required registration batches. We believe that these steps could shorten our regulatory timelines and significantly reduce our time to commercialize Ampion. The facility was placed in service during the first quarter of 2016. We 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 \$150.0 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. 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.

Although we have raised capital in the past with net proceeds of over \$100 million in the past five years through the sale of common stock and warrants, 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 September 1, 2016, we completed a registered direct offering. In the offering, we issued directly to an institutional investor 5.0 million shares of our common stock and warrants to purchase up to 5.0 million shares of our common stock. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. Each unit was sold to the investor in this offering at a negotiated price of \$0.75 per unit generating gross proceeds of \$3.75 million. The shares and the warrants were offered and sold pursuant to our shelf registration statement on Form S-3 which was declared effective by the SEC in January 2014.

The investor warrants have an exercise price of \$1.00 per share and are immediately exercisable with a term of five years from issuance. In addition, the investor warrants include provisions for the adjustment to the exercise price upon subsequent issuances of common stock at a price less than the warrant exercise price and the investor is entitled to purchase additional shares, such that the aggregate purchase price of \$5.0 million for the warrant shares remains unchanged. The investor warrants also include a provision for redemption at the Black-Scholes value upon the request of the holder upon a change of control. Based on these additional divertive features of the investor warrants they must be accounted for as a liability at fair value under ASC 480. On the date of issuance of these warrants they were valued at \$4.1 million and \$4.0 million at September 30, 2016. The fair value adjustment of \$88,000 is included in derivative expense on the statement of operations.

In connection with the offering the placement agent received a 6% commission totaling \$225,000 and 150,000 warrants with an exercise price of \$0.9375 and a termination date of September 1, 2021. We also incurred expenses related to legal, accounting, and other registration cost of \$113,000.

Our net cash proceeds for the registered direct offering were \$3.4 million. When the additional non-cash charges of \$4.2 million related to the 5.0 million investor warrants and the 150,000 placement agent warrants were offset against the net cash transaction proceeds this exceeded 100% of the proceeds so we were required to take the additional cost above the transaction proceeds and recognize them as a loss on the day we entered the transaction. The loss on the transaction was \$804,000 and is included in derivative expense on the statement of operations.

The Board of Directors determined that this transaction that generated net cash proceeds of \$3.4 million was in the best interest of the Company as we had less than six months of cash based on our current burn rate when the transaction was completed, that raising money would give us time to advance our clinical trial efforts and the absence of more favorable alternative sources of financing.

We also have access to a \$25.0 million controlled equity offering which we used to generate \$153,000 of gross proceeds by selling 163,254 common shares in the month of August 2016. The placement agent received a fixed commission of 3.0% of the gross proceeds from the shares sold. We could use the controlled equity offering to generate additional funding in the near future.

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.

RESULTS OF OPERATIONS

Results of Operations—September 30, 2016 Compared to September 30, 2015

Results of operations for the three months ended September 30, 2016 or the “2016 quarter” and the three months ended September 30, 2015 or the “2015 quarter” reflected net losses from continuing operations of approximately \$4.0 million and \$5.3 million, respectively. These losses include in part non-cash charges related to stock-based compensation, depreciation and amortization, amortization of prepaid research and development - related party, and derivative expense offset by the unrealized gain on trading securities collectively in the amount of \$1.5 million in the 2016 quarter and \$1.1 million in the 2015 quarter. The non-cash charges increased in the 2016 quarter primarily due to the increase in derivative expense partially offset by the decrease in stock-based compensation and warrant modification expense.

Results of operations for the nine months ended September 30, 2016 or the “2016 period” and the nine months ended September 30, 2015 or the “2015 period” reflected net losses from continuing operations of approximately \$15.8 million and \$16.8 million, respectively. These losses include in part non-cash charges related to losses in our stock-based compensation, depreciation and amortization, amortization of prepaid research and development - related party, common stock issued for services, derivative expense, losses in equity investment and unrealized gain on the trading security collectively in the amount of \$4.1 million in the 2016 period and \$4.4 million in the 2015 period. The non-cash charges decreased in the 2016 period primarily due to the decrease in stock-based compensation which were partially offset by the increase in depreciation and amortization, the unrealized gain on the trading security, losses on the equity investment and derivative expense.

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 (see Note 9 – Discontinued Operations). This transaction changed our ownership from 81.5% to 8.6% of Aytu’s outstanding shares on that date. As of March 31 and June 30, 2016, we had significant influence over Aytu subsequent to the spin-off due to the fact that our Chief Executive Officer was one of the three and one of four Aytu Board members, respectively.

In May 2016, Aytu completed an offering which was dilutive to the Aytu shares held by us. In July 2016, Aytu added a fifth Board member. In July 2016, we determined that our influence is no longer significant over Aytu’s Board of Directors. As of September 30, 2016, our ownership in Aytu’s outstanding shares was 2.0%. We reclassified our remaining investment in Aytu as a trading security, recorded at fair value on the balance sheet with the change in fair value recorded as an unrealized gain on the statement of operations.

Operating Expenses

Research and Development

Research and development costs are summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Clinical trials and sponsored research	\$493,000	\$2,200,000	\$4,663,000	\$5,920,000
Labor	514,000	734,000	2,109,000	2,172,000
Consultants and other	583,000	330,000	1,708,000	1,076,000

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

Stock-based compensation	162,000	354,000	317,000	1,411,000
Sponsored Research - related party	36,000	36,000	108,000	108,000
	\$1,788,000	\$3,654,000	\$8,905,000	\$10,687,000

Costs of research and development expense decreased \$1.9 million, or 51.1%, for the quarter ended September 30, 2016 compared to the same quarter in 2015 and decreased \$1.8 million, or 16.7%, for the nine-month period ended September 30, 2016 compared to the same period in 2015. The decrease in the 2016 quarter is primarily due to the decrease in clinical trials and sponsored research expenses as our Ampion PHASE III PIVOT study was substantially completed on June 30, 2016. The decrease in the 2016 nine-month period is primarily due to a decrease in clinical trials and sponsored research expenses and a decrease in stock-based compensation offset by an increase in consultants and other. During the last quarter of 2016, we expect our clinical trials and sponsored research expense to continue to decline as we concluded the Ampion PHASE III PIVOT study and we are evaluating future Ampion and Optina studies, as well as initial pilot evaluations of Ampion in additional indications.

General and Administrative

General and administrative costs are summarized as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2016	2015	September 30, 2016	2015
Occupancy, travel and other	\$ 308,000	\$ 390,000	\$ 1,200,000	\$ 1,009,000
Labor	346,000	268,000	1,083,000	1,245,000
Stock-based compensation	281,000	340,000	1,069,000	2,099,000
Professional fees	278,000	137,000	942,000	674,000
Patent costs	282,000	453,000	764,000	964,000
Directors fees	61,000	59,000	171,000	195,000
	\$ 1,556,000	\$ 1,647,000	\$ 5,229,000	\$ 6,186,000

General and administrative costs decreased \$91,000, or 5.5%, for the quarter ended September 30, 2016 compared to the same quarter in 2015 and decreased \$957,000, or 15.5%, for the nine-month period ended September 30, 2016 compared to the same period in 2015. The decrease in the 2016 quarter is primarily due to a decrease in stock-based compensation and patent costs partially offset by the increase in professional fees. The decrease in the 2016 nine-month period is due to a decrease in stock-based compensation. We expect that our general and administrative expense will remain fairly consistent during the last quarter of 2016.

Loss from Continuing Operations

The loss from continuing operations for the quarter ended September 30, 2016 of \$4.0 million is less than the loss from continuing operations of \$5.3 million for the same quarter in 2015. The loss from continuing operations during the nine months ended September 30, 2016 of \$15.8 million is less than the loss from continuing operations of \$16.8 million for the same period in 2015. As stated previously, we expect our clinical trial expense to decline in the last quarter of 2016 as we concluded the Ampion PHASE III PIVOT study and evaluate future Ampion and Optina studies, as well as initial pilot evaluations of Ampion in additional indications. We believe this could make our loss from continuing operations slightly decline in the last quarter of 2016 compared to the September 30, 2016 quarter.

Net Cash Used in Operating Activities

During the nine-month period ended September 30, 2016, our operating activities used approximately \$12.0 million in cash which was less than the net loss of \$15.8 million primarily as a result of the non-cash items such as stock-based compensation, depreciation and amortization, unrealized loss on the trading security and derivative expense partially offset by a decrease in accounts payable.

In the 2015 period, the use of cash was \$20.0 million which was less than the net loss of \$23.1 million principally as a result of non-cash stock-based compensation partially offset by the decrease in accounts payable.

Net Cash Used in Investing Activities

During the nine-month period ended September 30, 2015, cash was used to acquire \$109,000 of manufacturing machinery and equipment.

Net Cash from Financing Activities

Net cash provided by financing activities in the nine-month period ended September 30, 2016 reflects gross proceeds from the registered direct offering and controlled equity offering of \$3.9 million with net proceeds of \$3.5 million.

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 September 30, 2016, we had cash and cash equivalents totaling \$7.4 million available to fund our operations and \$2.4 million in accounts payable and accrued compensation (which includes approximately \$996,000 of accrued bonuses, payment of which is subject to FDA approval of Ampion and final Compensation Committee approval). Based upon our current plans, we believe our capital resources at September 30, 2016 will be sufficient to fund our currently planned operations into mid-2017. If we decide to complete another smaller Ampion trial in the first half of 2017 prior to filing our BLA, we would need to generate approximately \$10.0 million of additional funding to continue operations through 2017 and into 2018. 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 need additional capital within the next few months to fund future operations, which may include funding for a new clinical trial for Ampion, and to maintain minimum cash balances that we deem reasonable and prudent. We intend to evaluate the capital markets from time to time to determine when and how to raise additional capital.

We have prepared a budget for 2016 and 2017 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 in the near term. At this time, we expect to satisfy our future cash needs through our Controlled Equity OfferingTM Sales Agreement that we entered into in February 2016, private or public sales of our equity securities or convertible or straight debt financings. We cannot be certain that financing will be available to us on acceptable terms, or at all. If obtained, such financing may result in substantial dilution to our stockholders or the imposition of covenants and other terms or restrictions that may adversely affect our business or the manner in which we have operated our company. 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, particularly for small biotechnology companies, such as Ampio. 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 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 Court granted the motion to dismiss, with leave to amend, on August 4, 2016. On September 27, 2016, plaintiffs filed their second amended complaint, alleging the same claims set forth in the consolidated amended complaint during the same class period. 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 Number	Description
4.1	Form of Warrant to Purchase Common Stock. (1)
4.2	Form of Warrant to Purchase Common Stock. (1)
10.1	Purchase Agreement between Ampio Pharmaceuticals, Inc. and the investor named therein, dated August 29, 2016. (1)
31.1	Certificate of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certificate of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certificate of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*.
101	XBRL (eXtensible Business Reporting Language). The following materials from Ampio Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 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 August 29, 2016.

SIGNATURES

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

AMPIO PHARMACEUTICALS, INC.

By: /s/ Michael Macaluso

Michael Macaluso

Chairman and Chief Executive Officer

Date: November 8, 2016

By: /s/ Gregory A. Gould

Gregory A. Gould

**Chief Financial Officer, Treasurer and
Secretary**

Date: November 8, 2016