Ampio Pharmaceuticals, Inc.
Form 10-Q
November 14, 2018

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, 2018

or

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

For the transition period from _____ to _____

Commission File No. 001-35182

AMPIO PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-0179592**

(State or other jurisdiction of (IRS Employer

incorporation or organization) Identification No.)

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)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ¨

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

Large Accelerated Filer¨ Accelerated Filer ¨

Non-Accelerated Filer x Smaller reporting company x

Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

As of November 12, 2018, there were 106,716,516 shares of Common Stock outstanding, par value $0.0001, of the registrant.

AMPIO PHARMACEUTICALS, INC.

FOR THE QUARTER ENDED SEPTEMBER 30, 2018

INDEX

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. 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 expenses 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;*
- *our future dependence on third party manufacturers or strategic partners to manufacture any of our pharmaceutical drugs 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 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 on a timely basis;*
- *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.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

AMPIO PHARMACEUTICALS, INC.

Balance Sheets

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$8,672,062	$8,209,071
Prepaid expenses and other	512,481	233,815
Total current assets	9,184,543	8,442,886
Fixed assets, net (Note 3)	6,355,577	6,837,861
Deposits	33,856	33,856
Total assets	$15,573,976	$15,314,603
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	$1,534,259	$2,785,529
Accrued compensation	130,054	1,033,261
Deferred rent - current portion	59,579	59,579
Total current liabilities	1,723,892	3,878,369
Long-term deferred rent	492,712	537,364
Warrant derivative liability	11,120,495	45,075,755
Total liabilities	13,337,099	49,491,488
Commitments and contingencies (Note 5)		
Stockholders' equity		
Preferred Stock, par value $0.0001; 10,000,000 shares authorized; none issued	-	-
Common Stock, par value $0.0001; 200,000,000 shares authorized; shares issued and outstanding - 106,591,516 in 2018 (unaudited) and 80,060,345 in 2017	10,659	8,006
Additional paid-in capital	174,753,998	170,803,783
Accumulated deficit	(172,527,780)	(204,988,674)

Total stockholders' equity	2,236,877	(34,176,885)
Total liabilities and stockholders' equity	$15,573,976	$15,314,603

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

AMPIO PHARMACEUTICALS, INC.

Statements of Operations

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses				
Research and development	$ 1,184,194	$ 1,992,825	$ 5,343,452	$ 6,659,349
Research and development - related party (Note 8)	-	-	-	323,554
General and administrative	756,104	1,113,312	3,303,315	3,878,850
Total operating expenses	1,940,298	3,106,137	8,646,767	10,861,753
Other income (expense)				
Interest (expense) income	(3,190)	-	(3,190)	3,086
Derivative gain (loss)	7,744,708	(1,146,772)	41,110,851	2,092,994
Total other income (expense)	7,741,518	(1,146,772)	41,107,661	2,096,080
Net income (loss)	$ 5,801,220	$ (4,252,909)	$ 32,460,894	$ (8,765,673)
Basic and diluted net income (loss) per common share	$ 0.06	$ (0.06)	$ 0.37	$ (0.14)
Weighted average number of Ampio common shares outstanding	96,930,270	68,232,409	88,782,837	62,072,354

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

AMPIO PHARMACEUTICALS, INC.

Statements of Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2017	80,060,345	$8,006	$170,803,783	$(204,988,674)	$(34,176,885)
Common stock issued for services (unaudited)	17,241	2	59,998	-	60,000
Options exercised, net (unaudited)	348,783	35	636,375	-	636,410
Warrants exercised, net (unaudited)	6,165,147	616	2,968,503	-	2,969,119
Stock-based compensation, net (unaudited)	-	-	287,339	-	287,339
Common stock issued in connection with the confidentially marketed public offering, net of offering costs of $844,409 (unaudited)	20,000,000	2,000	(2,000)	-	-
Net income (unaudited)	-	-	-	32,460,894	32,460,894
Balance at September 30, 2018 (unaudited)	106,591,516	$10,659	$174,753,998	$(172,527,780)	$2,236,877

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

AMPIO PHARMACEUTICALS, INC.

Statements of Cash Flows

(unaudited)

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities		
Net income (loss)	$32,460,894	$(8,765,673)
Adjustments to reconcile net income (loss) to net cash used in operating activities		
Stock-based compensation and warrant modification	287,339	683,195
Depreciation and amortization	968,034	910,725
Write-off of advances to stockholder	-	25,160
Amortization of prepaid research and development - related party (Note 8)	-	323,554
Common stock issued for services	60,000	60,000
Derivative gain	(41,110,851)	(2,092,994)
Changes in operating assets and liabilities		
Increase in prepaid expenses and other	(278,666)	(79,884)
(Decrease) increase in accounts payable and accrued expenses	(1,251,270)	318,479
Decrease in deferred rent	(44,652)	(37,398)
Decrease in accrued compensation	(903,207)	(181,383)
Net cash used in operating activities	(9,812,379)	(8,836,219)
Cash flows used in investing activities		
Purchase of fixed assets	(485,750)	(33,326)
Net cash used in investing activities	(485,750)	(33,326)
Cash flows from financing activities		
Proceeds from sale of common stock related to the Equity Offering	8,000,000	6,594,148
Costs related to sale of common stock related to the Equity Offering	(844,409)	(812,288)
Proceeds from option and warrant exercises	3,605,529	-
Net cash provided by financing activities	10,761,120	5,781,860
Net change in cash and cash equivalents	462,991	(3,087,685)
Cash and cash equivalents at beginning of period	8,209,071	4,894,834
Cash and cash equivalents at end of period	$8,672,062	$1,807,149
Non-cash transactions:		
Warrant derivative liability in connection with the confidentially marketed public offering	$8,008,500	$4,618,318
Warrants issued to placement agent in connection with the registered offering	-	369,465

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

AMPIO PHARMACEUTICALS, INC.

Notes to Financial Statements

(unaudited)

Note 1 - Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, the financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the financial position and of the results of operations and cash flows of Ampio Pharmaceuticals, Inc. ("Ampio" or the "Company") for the periods presented.

These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K filed with the SEC. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The balance sheet at December 31, 2017 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements.

Ampio is a biopharmaceutical company primarily focused 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. The Company has not generated revenue to date.

Adoption of Recent Accounting Pronouncements

In May 2017, the FASB issued ASU 2017-09, *"Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting"*. The amendments provide guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award changes as a result of the change in terms or conditions. For all entities, this standard is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company adopted ASU 2017-09 during the first quarter of 2018 and the adoption of this guidance did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncements

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. Lessees are required to use a modified retrospective transition approach for capital and operating leases existing at, or entered after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. In July 2018, the FASB issued ASU 2018-10, *"Codification Improvements to Topic 842, Leases,"* to clarify how to apply certain aspects of the new lease standard. In July 2018, the FASB also issued ASU 2018-11, *"Leases (Topic 842): Targeted Improvements,"* to give entities another option for transition. The additional option for transition allows an entity to apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The new standards are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact of its pending adoption of this standard on its financial statements and plans to finalize implementation by the end of fiscal 2018. As of September 30, 2018, the Company had minimum operating lease payments of $2.1 million that are being evaluated. The Company is working on gathering all key lease data elements to meet the requirements of the new guidance.

In June 2018, the FASB issued ASU 2018-07, *"Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting"*. The amendment expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Companies should apply the requirements of Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within those fiscal years. Early adoption is permitted, but no earlier than the Company's adoption date of ASU 2014-09 "*Revenue from Contracts with Customers (Topic 606)"*. The Company does not expect the adoption of this ASU will have a significant impact on its financial statements.

In July 2018, the FASB issued ASU 2018-09, *"Codification Improvements"*, which facilitates amendments to a variety of topics to clarify, correct errors in, or make minor improvements to the accounting standards codification. The effective date of the standard is dependent on the facts and circumstances of each amendment. Some amendments do not require transition guidance and will be effective upon the issuance of this standard. A majority of the amendments in ASU 2018-09 will be effective for fiscal years beginning after December 15, 2018. The Company does not expect the adoption of this ASU will have a significant impact on its financial statements.

In August 2018, the FASB issued ASU 2018-13, *"Fair Value Measurement - Disclosure Framework (Topic 820)"*. The updated guidance improves the disclosure requirements on fair value measurements. The updated guidance is effective for fiscal years beginning after December 15, 2019, including interim reporting periods within those fiscal years. Early adoption is permitted for any removed or modified disclosures. The Company does not expect the adoption of this ASU will have a significant impact on its financial statements.

The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

Note 2 - Going Concern

As reflected in the accompanying financial statements, the Company had cash of $8.7 million as of September 30, 2018 with net income of $32.5 million for the nine months ended September 30, 2018. The net income is primarily attributable to the non-cash derivative gain of $41.1 million that was recognized, which was offset by the operating expenses of $8.6 million during the period ended September 30, 2018. The Company used net cash in operations of $9.8 million for the period ended September 30, 2018. As of September 30, 2018, the Company ended with an accumulated deficit of $172.5 million and stockholders' equity of $2.2 million. In addition, the Company is a clinical stage biopharmaceutical company and has not generated any revenues or profits to date. These factors raise substantial doubt about the Company's ability to continue as a going concern.

During the nine months ending September 30, 2018, the Company received a total of $3.6 million from investor warrants and stock options being exercised (see Note 7). In addition, the Company raised gross proceeds of $8.0 million in a confidentially marketed public offering (see Note 6). Ampio expects that current cash resources and operating cash flows will be sufficient to sustain operations into the second quarter of 2019. The ability of the Company to continue its operations is dependent on management's plans, which includes continuing to raise equity-based and debt financing, as well as encouraging additional warrant exercises. The Company is currently in negotiation with potential investors for financing. However, there is no assurance that the Company will be successful in raising sufficient capital.

The accompanying unaudited interim financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments relating to the recovery of recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

Note 3 - Fixed Assets

Fixed assets are recorded at cost and, once placed in service, are depreciated on the straight-line method over their estimated useful lives. Leasehold improvements are accreted over the shorter of the estimated economic life or related lease terms. Fixed assets consist of the following:

	Estimated Useful Lives in Years	As of September 30, 2018	As of December 31, 2017
Manufacturing facility/clean room	3 - 8	$ 3,197,000	$ 2,773,000
Leasehold improvements	10	6,075,000	6,075,000
Office furniture and equipment	3 - 10	511,000	557,000
Lab equipment	5 - 8	1,095,000	1,059,000
Less accumulated depreciation and amortization		(4,522,000)	(3,626,000)
Fixed assets, net		$ 6,356,000	$ 6,838,000

Depreciation and amortization expense for the respective periods is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Depreciation and amortization expense	$ 347,000	$ 304,000	$ 968,000	$ 911,000

Note 4 - Fair Value Considerations

The Company’s financial instruments include cash and cash equivalents, accounts payable and accrued expenses, and warrant derivative liability. The carrying amounts of cash and cash equivalents and accounts payable and accrued expenses are carried at cost which approximates fair value due to the short maturity of these instruments. Warrants are recorded at estimated fair value based on a Black-Scholes warrant pricing model. 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 based on market data obtained from sources independent of Ampio. Unobservable inputs are inputs that reflect the Company's assumptions of what market participants would use in pricing the asset or liability 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, 2018 and December 31, 2017, by level within the fair value hierarchy:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
September 30, 2018				
LIABILITIES				
Warrant derivative liability	$-	$ -	$11,120,000	$11,120,000
December 31, 2017				
LIABILITIES				
Warrant derivative liability	$-	$ -	$45,076,000	$45,076,000

The warrant derivative liability was valued using the Black-Scholes valuation methodology because that model embodies all the relevant assumptions that address the features underlying these instruments. For significant assumptions in valuing the warrant derivative liability as of September 30, 2018 and at issuance see Note 7.

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

	Derivative Instruments
Balance as of December 31, 2017	$ 45,076,000
Warrants issuances	8,008,000
Warrants exercises	(13,925,000)
Change in fair value	(28,039,000)
Balance as of September 30, 2018	$ 11,120,000

Note 5 - Commitments and Contingencies

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

	Total	Remaining 2018	2019	2020	2021	2022	Thereafter
Ampion supply agreement	$7,650,000	$2,550,000	$2,550,000	$2,550,000	$-	$-	$-
Clinical research and trial obligations	327,000	277,000	50,000	-	-	-	-
Biologics License Application (BLA) consulting services	1,166,000	45,000	1,121,000	-	-	-	-
Facility lease	2,085,000	80,000	326,000	335,000	345,000	355,000	644,000
	$11,228,000	$2,952,000	$4,047,000	$2,885,000	$345,000	$355,000	$644,000

Ampion Supply Agreement

In October 2013, Ampio entered into a human serum albumin ingredient and purchase sale agreement which has a remaining commitment of $7.7 million. In November 2017, Ampio amended this agreement, which extended the contractual terms to 2020.

Clinical Research and Trial Obligations

In November 2017, Ampio entered into an Open Label Extension (OLE) study agreement. In August 2018, the Company canceled the OLE study. The Company will continue to incur close-out costs for the study through the beginning of fiscal 2019. As of September 30, 2018, there is an outstanding commitment of $327,000.

Biologics License Application (BLA) Consulting Services

In March 2018, Ampio entered into a BLA consulting services agreement, which has an outstanding commitment of $1.2 million. This contract is an open-ended contract and the Company incurs costs as sections of the BLA are

completed.

Facility Lease

In December 2013, Ampio entered into a 125-month non-cancellable operating lease for office space and a manufacturing facility. The effective date for the lease was May 1, 2014. The initial base rent of the lease was $23,000 per month. The total base rent over the term of the lease is approximately $3.3 million, which includes rent abatements and leasehold incentives. The Company recognizes rent expense on a straight-line basis over the term of the lease. The Company recognizes deferred rent when the straight-line rent expense exceeds the actual lease payments and reduces deferred rent when the actual lease payments exceed the straight-line rent expense. Deferred rent is classified between current and long-term.

Rent expense for the respective periods is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Rent expense	$ 65,000	$ 65,000	$ 195,000	$ 195,000

Note 6 - Common Stock

Capital Stock

At September 30, 2018 and December 31, 2017, Ampio had 200.0 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.

At September 30, 2018 and December 31, 2017, Ampio had 106,591,516 and 80,060,345 shares of common stock outstanding, respectively. As of these same dates, Ampio had no preferred shares outstanding.

Shelf Registration

In March 2017, Ampio filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission ("SEC") to register Ampio common stock and warrants in an aggregate amount of up to $100.0 million for offerings from time to time, as well as 5.0 million shares of common stock available for sale by selling shareholders. The shelf registration was declared effective in April 2017 by the SEC. As a result of equity raises, approximately $78.7 million remained available under the Form S-3 as of September 30, 2018. This shelf registration statement on Form S-3 expires in March of 2020.

Confidentially Marketed Public Offering

In August 2018, the Company completed a confidentially marketed public offering. In this offering, the Company issued 20.0 million shares of its common stock and warrants to purchase up to 20.0 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 investors in this offering at a negotiated price of $0.40 per unit generating gross proceeds of $8.0 million. In connection with the offering, the underwriter received a 7% commission totaling $560,000. The Company also incurred expenses related to legal, accounting, and other registration costs of $284,000. The shares and the warrants were offered and sold pursuant to the Company's shelf registration statement on Form S-3 that was declared effective by the SEC in April 2017.

The warrants have an exercise price of $0.40 per share and are exercisable immediately with a term of five years from issuance. The warrants include a provision where the warrant holder has the contractual right to request a cash exercise if the effectiveness of the registration statement is not maintained, but securities law would prevent the Company from issuing registered shares in a cash exercise. Therefore, the Company could be forced to cash settle the warrants. Based on this derivative feature, these warrants must be accounted for as a liability at fair value under Accounting Standards Codification ("ASC") 815 "Derivatives and Hedging". On the date of issuance, these warrants were valued at $8.0 million.

The Company's net cash proceeds from the confidentially marketed public offering totaled $7.2 million. When the additional non-cash charges of $8.0 million related to the 20.0 million warrants are offset against the net cash transaction proceeds, the non-cash charges exceeded 100% of the proceeds. Therefore, the Company is required to take the additional cost above the transaction proceeds and recognize a loss on the day it entered into the transaction. The loss on the transaction was $853,000 and this amount is included in the derivative gain on the statement of operations.

Registered Direct Offering

In October 2017, the Company entered into a Securities Purchase Agreement, with certain investors, pursuant to which the Company sold approximately 7.7 million shares of common stock at a price per share of $0.875. The gross proceeds from the offering were approximately $6.7 million. The costs associated with the offering were approximately $490,000. The shares were offered and sold pursuant to the Company's shelf registration statement on Form S-3 that was declared effective by the SEC in April 2017.

In June 2017, the Company completed a registered direct offering. In this offering, Ampio issued directly to multiple investors approximately 11.0 million shares of its common stock and approximately 11.0 million warrants to purchase 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 investors in this offering at a negotiated price of $0.60 per unit generating gross proceeds of $6.6 million. In connection with the offering, the placement agent received an 8% commission totaling $533,000 and approximately 879,000 warrants with an exercise price of $0.76. The expiration date of these warrants is June 1, 2022. At issuance, these warrants had a value of $369,000 and were accounted for as equity-based warrants. The placement agent warrants provide for cashless exercise, which the placement agents may elect if there is no effective registration statement. The Company also incurred expenses related to legal, accounting, and other registration costs of $292,000.

There was a participation right of 35% for any proposed or intended issuance or sale or exchange of securities being offered until the second anniversary of the closing date, which would have expired on June 2, 2019. However, in July 2018, the Company obtained the required number of waivers necessary to eliminate the participation rights from the June 2017 registered direct offering. The shares and the warrants were offered and sold pursuant to the Company's shelf registration statement on Form S-3 that was declared effective by the SEC in April 2017.

The investor warrants have an exercise price of $0.76 per share and were exercisable starting on December 7, 2017 with a term of five years from issuance. The investor warrants include a provision where the warrant holder has the contractual right to request a cash exercise if the effectiveness of the registration statement is not maintained, but securities law would prevent the Company from issuing registered shares in a cash exercise. Therefore, the Company could be forced to cash settle the warrant. Based on this derivative feature, these warrants must be accounted for as a liability at fair value under ASC 815 "Derivatives and Hedging". On the date of issuance, these warrants were valued at $4.6 million.

In September 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. 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. The expiration date of these warrants is September 1, 2021. At issuance, these warrants had a value of $89,000 and were accounted for as equity-based warrants. The placement agent warrants provide for cashless exercise,

which the placement agents may elect if there is no effective registration statement. The Company also incurred expenses related to legal, accounting, and other registration costs of $113,000.

There was a participation right of 30% for any proposed or intended issuance or sale or exchange of securities being offered until the first anniversary of the closing date, which expired on September 1, 2017. 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 Form S-3 expired in January of 2017 and the Company filed a new Form S-3 in April 2017.

The investor warrants had an exercise price of $1.00 per share and were immediately exercisable with a term of five years from issuance. In addition, the investor warrants included a provision for an 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 was entitled to purchase additional shares, such that the aggregate purchase price of $5.0 million for the warrant shares remained unchanged. The investor warrants also included a provision for redemption at the Black-Scholes value at the request of the holder upon a change of control. Based on these derivative features, these warrants were accounted for as a liability at fair value under ASC 480 "Distinguishing Liabilities from Equity". On the date of issuance, these warrants were valued at $4.1 million.

The Company's net cash proceeds from 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 a loss on the day of the transaction. The loss on the transaction was $804,000 and was included in derivative loss on the statement of operations.

On March 27, 2017, the Company entered into a Waiver and Consent Letter Agreement with the investor from the September 2016 registered direct offering, amending the terms of the warrants previously issued. Under the Waiver and Consent Agreement, the investor waived the right to have the warrant exercise price reduced and the number of shares of common stock underlying the warrant increased in the event the Company secures any financing, including debt, which includes issuing or selling shares of common stock for a price per share less than the warrant exercise price. The investor also waived the prohibition on the Company's ability to issue or sell shares of its common stock, options or convertible securities at a price which varies or may vary with the market price of the common stock or pursuant to an equity credit line or similar "at-the-market" offering. The waivers are permanent. In return, the Company agreed to reduce the exercise price of the warrants from $1.00 to $0.40 and to not issue or sell any shares of its capital stock for a period of 10 trading days following the execution of the Waiver and Consent Agreement. All other terms of the warrants remained the same. Based upon the amendment to this warrant agreement, the Company recognized a non-cash derivative gain of $1.1 million during the quarter ended March 31, 2017.

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.

No shares were sold under the Agreement during fiscal 2017 or the nine months ended September 30, 2018.

Common Stock Issued for Services

Ampio issued 17,241 and 62,478 shares of common stock valued at $60,000 and $60,000, respectively, for non-employee directors as part of their director fees for fiscal years 2018 and 2017, 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.

During the nine months ended September 30, 2018, the Company granted 115,000 options at a weighted average exercise price of $0.51 to an officer and five employees. Former employees and executives exercised 409,666 options with a weighted average exercise price of $2.06. The Company received $636,400 as of September 30, 2018 related to these option exercises. A total of 3,334 options were forfeited and 355,000 expired as of September 30, 2018.

The following table summarizes Ampio's stock option activity:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregated Intrinsic Value
Outstanding at December 31, 2017	7,247,165	$ 2.87	5.16	12,739,512
Granted	115,000	$ 0.51	-	-
Exercised	(409,666)	$ 2.06	-	-
Forfeited	(3,334)	$ 1.02	-	-
Expired or Cancelled	(355,333)	$ 5.09	-	-
Outstanding at September 30, 2018	6,593,832	$ 2.77	4.13	7,784
Exercisable at September 30, 2018	6,242,164	$ 2.88	3.89	7,411
Available for grant at September 30, 2018	3,198,478			

Stock options outstanding at September 30, 2018 are summarized in the table below:

Range of Exercise Prices	Number of Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Lives
$0.48 - $2.00	3,083,554	$ 0.89	5.28

$2.01 - $5.00	2,285,278	$ 3.10	3.43
$5.01 - $8.93	1,225,000	$ 6.86	2.56
	6,593,832	$ 2.77	4.13

Ampio computes the fair value for all options granted or modified using the Black-Scholes option pricing model. 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 the valuation. Ampio calculates its volatility assumption using the actual changes in the market value of its stock. Ampio adopted ASU 2016-09 in fiscal 2017 and no longer estimates a forfeiture rate. Instead, forfeitures are recognized as they occur. The Company’s historical option exercises do not provide a reasonable basis to estimate an expected term due to the lack of sufficient data. Therefore, the Company estimates the expected term by using the simplified method. The simplified method calculates the expected term as the average time to vest and the contractual life 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 for options granted and modified during the period ended September 30, 2018, using the following assumptions:

Expected volatility	100.66% - 127.60	%
Risk free interest rate	1.86% - 2.96	%
Expected term (years)	0.32 - 5.00	
Dividend yield	0.0	%

15

Stock-based compensation expense related to the fair value of stock options is included in the statements of operations as research and development expenses or general and administrative expenses as set forth in the table below. The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development expenses				
Stock-based compensation	$ 20,000	$ 179,000	$ 73,000	$ 255,000
General and administrative expenses				
Common stock issued for services	-	-	60,000	60,000
Stock-based compensation	75,000	127,000	214,000	354,000
	$ 95,000	$ 306,000	$ 347,000	$ 669,000
Unrecognized expense at September 30, 2018	$ 68,000			
Weighted average remaining years to vest	1.26			

Warrants

In connection with the August 2018 confidentially marketed public offering, Ampio issued warrants to purchase an aggregate of 20.0 million shares of common stock at an exercise price of $0.40 with a term of five years. Due to certain derivative features, these warrants are accounted for under liability accounting and are recorded at fair value each reporting period. As of September 30, 2018, these warrants had a fair value of $8.7 million. Significant assumptions as of September 30, 2018 and at issuance were as follows:

	September 30, 2018		At Issuance	
Exercise Price	$ 0.40		$0.40	
Volatility	123.7	%	121.8	%
Equivalent term (years)	4.87		5.00	
Risk-free interest rate	2.94	%	2.75	%
Number of shares	19,950,000		20,000,000	

In connection with the June 2017 registered direct offering, Ampio issued investor warrants to purchase an aggregate of approximately 11.0 million shares of common stock at an exercise price of $0.76 with a term of five years. Due to certain derivative features, these warrants are accounted for under liability accounting and are recorded at fair value

each reporting period. As of September 30, 2018, these warrants had a fair value of $2.4 million. Significant assumptions as of September 30, 2018 and at issuance were as follows:

	September 30, 2018		At Issuance	
Exercise Price	$ 0.76		$0.76	
Volatility	137.2	%	94.6	%
Equivalent term (years)	3.67		5.00	
Risk-free interest rate	2.90	%	1.71	%
Number of shares	6,093,582		10,990,245	

The combined value for the warrant liability as of September 30, 2018 is $11.1 million (see Note 4).

In connection with the 2016 registered direct offering, Ampio issued to an investor warrants to purchase an aggregate of 5.0 million shares of common stock at an exercise price of $1.00 with a term of five years. In March 2017, the exercise price of these warrants was reduced from $1.00 to $0.40. Due to certain derivative features, these warrants were accounted for under liability accounting and are recorded at fair value each reporting period. As of September 30, 2018, no fair value was recorded as these warrants were exercised in full during the first quarter of 2018.

During the 2017 registered direct offering, Ampio issued placement agent warrants to purchase an aggregate of approximately 879,000 shares of common stock at an exercise price of $0.76 with a term of five years. These warrants were accounted for as equity-based awards (see Note 6). They were valued using the Black-Scholes methodology.

During the 2016 registered direct offering, Ampio 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 were accounted for as equity-based awards (see Note 6). They were valued using the Black-Scholes methodology.

The following table summarizes Ampio's warrant activity:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding at December 31, 2017	13,332,243	$ 0.73	4.01
Warrants issued	20,000,000	$ 0.40	
Warrants exercised	(6,200,476)	$ 0.50	
Warrants expired	(498,576)	$ 3.24	
Outstanding at September 30, 2018	26,633,191	$ 0.49	4.56

During the nine months ended September 30, 2018, the Company issued 50,000 shares of common stock from the exercise of investor warrants with an exercise price of $0.40 from the 2018 confidentially marketed public offering. The Company also issued 1,511,999 shares of common stock from the exercise of investor warrants with an exercise price of $0.76 from the 2017 registered direct offering. In addition, the Company issued 4,500,000 shares of common stock from the exercise of investor warrants at an exercise price of $0.40 from the 2016 registered direct offering. After this warrant exercise, the Company no longer has outstanding $0.40 warrants from the 2016 registered direct offering. The Company has received approximately $3.0 million as of September 30, 2018 related to these investor warrant exercises.

In July 2018, 138,477 of the placement agent warrants from the 2017 direct offering were cashlessly exercised, which resulted in the issuance of 103,148 shares of common stock.

In March 2017, the Company modified 498,576 of its outstanding warrants which extended the expiration until June 30, 2018. The $75,000 additional expense related to this modification was recognized in the quarter ended March 31, 2017. These warrants all expired as of June 30, 2018.

In March 2017, the Company modified the five million warrants issued in conjunction with the Company's September 2016 registered direct offering with an original strike price of $1.00 down to $0.40. The $1.1 million gain related to this modification was recognized in the quarter ended March 31, 2017 (see Note 6). As noted above, these warrants were exercised in full during the first quarter of 2018.

Note 8 - Related Party Transactions

Sponsored Research Agreement

Ampio entered into a sponsored research agreement with Trauma Research LLC, an entity controlled by Ampio's Director and former Chief Scientific Officer ("CSO"), Dr. Bar-Or, in September 2009, which was amended seven times with the last amendment occurring in June 2017. The agreement was terminated effective July 5, 2017. The remaining prepaid of $252,000 was expensed during the quarter ended June 30, 2017. In conjunction with terminating this agreement, the Company extended the employment agreement for Dr. Bar-Or until July 2018. In July 2018, the Company extended Dr. Bar-Or's employment agreement for an additional month. On August 29, 2018, Dr. Bar-Or notified the Company of his decision to retire from his role as CSO, effective September 30, 2018. Dr. Bar-Or will continue to serve as a member of the Board of Directors and the Scientific Advisory Board of the Company.

Service Agreement

In June 2017, Ampio terminated the shared services agreement with Aytu. For the nine months ended September 30, 2018 and 2017, the total shared overhead cost was $0 and $77,000, respectively.

Note 9 - Litigation

On August 25, 2018 and August 31, 2018, two purported stockholders of the Company brought putative class action lawsuits in the United States District Court for the Central District of California, Shi v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:18-cv-07476-SJO-RAO, and in the United States District Court for the District of Colorado, Shaffer v. Ampio Pharmaceuticals, Inc., et al., Case No. 1:18-cv-02252-KLM (the "Securities Class Actions"). Plaintiffs in the Securities Class Actions allege that the Company and certain of its current officers violated federal securities laws by misrepresenting and/or omitting information regarding the AP-003 Phase III clinical trials of Ampion. Plaintiffs in the Securities Class Actions assert claims under Sections 10(b) and 20(a) and Rule 10b-5 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") on behalf of a putative class of purchasers of the Company's common stock from December 14, 2017 through August 7, 2018. The Securities Class Actions seek unspecified damages, pre-judgment and post-judgment interest, and attorneys' fees and costs.

On September 10, 2018, a purported stockholder of the Company brought a derivative action in the United States District Court for the Central District of California, Cetrone v. Macaluso et al., Case No. 2:18-cv-05970-SJO-RAO (the "Cetrone Action"), alleging primarily that the directors and officers of Ampio breached their fiduciary duties because of their alleged misstatements and/or omissions regarding the AP-003 Phase III clinical trials of Ampion.

On October 5, 2018, a purported stockholder of the Company brought a derivative action in the United States District Court for the District of Colorado, Theise v. Macaluso et al., 1:18-cv-02558, which closely parallels the allegations in the Cetrone Action.

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.

Note 10 - Subsequent Events

As of November 14, 2018, the Company issued 125,000 shares of common stock from the exercise of investor warrants with an exercise price of $0.40. The Company has received $50,000 related to these warrant exercises.

See Note 9 for litigation updates.

Effective October 1, 2018, EKS&H LLLP ("EKS&H"), the independent registered public accounting firm for the Company combined with Plante & Moran PLLC ("Plante Moran"). As a result of this transaction, on October 1, 2018, EKS&H resigned as the independent registered public accounting firm for the Company. Concurrent with such resignation, the Company's audit committee approved the engagement of Plante Moran as the new independent registered public accounting firm for the Company.

On October 1, 2018, the Compensation Committee of the Board of Directors of the Company approved a one-time option repricing (the "Option Repricing") where the exercise price of each Relevant Option (as defined below) was amended to reduce such exercise price to $0.75 per share, 44% above the closing price of the Company's common stock on October 1, 2018 and 88% above the price per share of common stock sold in the Company's recently completed public offering (not including the value of the accompanying warrants). "Relevant Options" are all outstanding stock options as of October 1, 2018 (vested or unvested) to acquire shares of the Company's common stock that had exercise prices above $0.75 per share; provided, however, that the maximum dollar value of the repricing for any individual did not exceed $500,000 (with such value calculated by multiplying (i) the difference between the initial exercise price and $0.75 by (ii) the number of options being repriced). In conjunction with the repricing, the Compensation Committee determined to eliminate all outstanding accrued bonuses, which amount to approximately $813,000. The Compensation Committee believes that the Option Repricing is in the best interests of the Company, as the amended stock options will provide added incentives to retain and motivate key contributors of the Company at this critical juncture without incurring the stock dilution resulting from significant option grants. The Compensation Committee also believes that the repricing better aligns the interests of the key contributors with the goals of the Company. The Company's Board of Directors, along with the Chairman and Chief Executive Officer, Michael Macaluso, did not participate in the Option Repricing.

In October 2018, the Company retained a law firm to represent its interests in a lobbying effort with the Food and Drug Administration, or FDA.

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 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 March 6, 2018.

EXECUTIVE SUMMARY

We are an innovative drug discovery and development company combining scientific, regulatory, and business capabilities to efficiently develop our main therapeutic candidate, Ampion. If approved, Ampion will address significant inflammatory conditions for which limited treatment options exist. Ampion has been developed through more than two decades of study at leading hospital-based research centers.

The pharmaceutical market is a competitive industry with strict regulations that are time intensive and costly. However, we are committed to offer compelling therapeutic options for the patients most in need of new treatment options, and we operate every day to advance our product candidates.

Since we are in the research and development phase, we have not generated revenue to date. Our operations are funded through equity raises, which occur from time to time. To proceed with our operations, we will need to raise additional funds to support the advancement of our therapeutic candidates.

Moving forward, we plan on creating a leaner and more efficient operating model by streamlining our operations and reallocating resources towards commercializing our lead product candidate, Ampion.

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 focus primarily on developing compounds that decrease inflammation by (i) inhibiting specific pro-inflammatory compounds by affecting specific pathways at the protein expression and at the transcription level; (ii) activating specific phosphatase or depleting available phosphate needed for the inflammation process; and (iii) decreasing vascular permeability.

We have a lead product candidate, which has advanced through late-stage clinical trials in the United States. On August 3, 2018, the FDA informed us that our latest trial, AP-003-C, was not considered an adequate and well-controlled clinical trial. The FDA recommended that we design a randomized trial with a concurrent control group to gather additional evidence necessary to support a Biologics License Application, or BLA. In addition, the FDA recommended that we request a Special Protocol Assessment, or SPA, to obtain FDA concurrence on the trial design before beginning the study. We are in the process of designing a new pivotal clinical trial and requesting a SPA, but we do not agree with the FDA's initial conclusion regarding the insufficiency of AP-003-C. Consequently, we are engaged in a formal dispute with the FDA and will provide them with additional information in an effort to persuade them to reconsider their decision of rejecting the AP-003-C clinical trial, which they considered not adequate and well-controlled. The FDA has agreed to consider this additional information in a Type C meeting before the end of November 2018.

Product Update –

We continue to execute our business plan and advance our main drug candidates.

AMPION

Ampion for Osteoarthritis and Other Inflammatory Conditions

Ampion is the < 5 kDa ultrafiltrate of 5% Human Serum Albumin, an FDA approved biologic product. Ampion is a non-steroidal, low molecular weight, anti-inflammatory biologic, which has the potential to be used in a wide variety of acute and chronic inflammatory conditions, as well as immune-mediated diseases. Ampion and its known components have demonstrated a broad spectrum of anti-inflammatory and immune modulatory activity which support the mechanism of action. We have published several scientific papers and peer-reviewed publications on Ampion's mechanism of action.

We are currently developing Ampion as an intra-articular injection to treat the signs and symptoms of severe osteoarthritis of the knee, or OAK. Osteoarthritis is a growing epidemic in the United States and symptomatic OAK is expected to impact 1 in 2 Americans. OAK is a progressive disease characterized by gradual degradation and loss of cartilage due to inflammation of the soft tissue and bony structures of the knee joint. Progression of the most severe form of OAK leaves patients with little to no treatment options other than total knee arthroplasty. The FDA has stated that severe OAK is an 'unmet medical need' with no licensed therapies for this indication.

We have conducted multiple clinical studies which have included over 2,000 patients in the development of Ampion.

Clinical Development Pathway

In September 2018, the FDA provided a response to our Chemistry, Manufacturing, and Controls (CMC) request. The FDA agreed on the CMC data requirements and analytical characterization of Ampion based the limited data that was provided to them. In addition, the FDA notified us that the potency control and commercial release specifications of Ampion are questions that will be addressed during the BLA review.

In August 2018, the FDA reaffirmed that clinical study AP-003-A is an adequate and well-controlled pivotal trial and provides evidence of effectiveness of Ampion and can contribute to the substantial evidence of effectiveness necessary for the approval of a BLA. The FDA has requested two pivotal trials in support of an Ampion BLA. Despite our belief that the AP-003-C trial design was based on FDA guidance and feedback, and consistent with FDA precedent for similar products (in intended use, in origin, and in regulatory pathway), which we reiterated with the FDA multiple times, the FDA does not consider the AP-003-C trial to be an adequate and well-controlled pivotal clinical trial. The FDA recommended that we perform an additional randomized trial with a concurrent control group. Discussions are on-going with the FDA regarding the necessity of conducting an additional trial, as we believe the

current body of data is sufficient to submit the BLA. Should another trial be required, we will move quickly to meet the FDA requirements under a SPA. The SPA will provide written agreement between us and the FDA indicating concurrence by the FDA with the adequacy and acceptability of critical elements of the overall protocol design for a study intended to support a BLA for Ampion. These elements of the protocol are critical to ensure the study can be considered an adequate and well-controlled pivotal trial in support of marketing approval. Under the Prescription Drug User Fee Act and Biosimilar User Fee Amendments, the FDA has committed to send a SPA letter to the sponsor within 45 calendar days of receipt of the SPA submission. As of the filing date of this quarterly report, we have not submitted a SPA.

In November 2017, we started the Open Label Extension, or OLE, study of the AP-003-C trial, which was designed to support the safety and tolerability of repeat injections of Ampion (up to five injections) over the course of one year. No serious drug-related adverse events have been reported, and all patients have demonstrated a sustained reduction in pain over the course of the trial. In August 2018, we canceled the OLE study. We will continue to incur close-out costs for the study through the beginning of fiscal 2019.

We also intend to study Ampion for therapeutic applications other than 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. 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 for Diabetic Macular Edema

Optina is a low-dose formulation of danazol to treat diabetic macular edema, or DME. Danazol is a synthetic derivative of modified testosterone ethisterone, and we believe it affects vascular endothelial cell leakage in a biphasic manner. 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. Steroid hormones control a variety of functions through slow genomic and rapid non-genomic mechanisms. Danazol immediately increases intracellular cyclic adenosine monophosphate through the rapid activation of membrane-associated androgen, steroid binding globulin, and calcium channel receptors. At lower concentrations danazol binds to androgen and steroid binding globulin receptors stimulating the formation of a cortical actin ring. At higher concentrations, activation of the calcium channels shifts the balance towards stress fiber formation and increases vascular permeability.

When filamentous actin is organized into a cortical ring, Optina increases the barrier function of endothelial cells by tethering adhesion molecule complexes to the cytoskeleton. In this orientation, increased cortical actin improves tight junctions which strengthen cell-to-cell adhesions. Formation of the cortical actin ring thereby restricts leakage across the cell membrane.

Clinical Development Pathway

We met with the Division of the Transplant and Ophthalmology Products of the FDA in late 2015 to discuss the results of the OptimEyes clinical trial of Optina and to seek guidance on the next steps for approval. The guidance from the FDA was that we perform a confirmatory study on patients with DME who are refractory to the currently available drugs, which if successful, would qualify Optina as a rescue medication for patients who have no treatment options (failed available therapies). We have also considered conducting a trial in combination with other anti-vascular endothelial growth factor, or anti-VEGF, drugs as we believe the effect of Optina with the anti-VEGF drugs could be cumulative.

The FDA has indicated that, for §505(b)(2) NDAs, complete studies of the safety and effectiveness of a product candidate may not be necessary if appropriate bridging studies provide an adequate basis for reliance upon the FDA’s findings of safety and effectiveness for a previously approved product.

While Optina shows promise, we are currently focusing our resources and clinical development efforts on Ampion to treat osteoarthritis of the knee, which is our highest priority. We plan to explore partnerships and/or development agreements related to Optina, pending further progress on Ampion related to osteoarthritis of the knee.

Recent Financing Activities

In August 2018, we completed a confidentially marketed public offering. In this offering, we issued 20.0 million shares of common stock and warrants to purchase up to 20.0 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 investors in this offering at a negotiated price of $0.40 per unit generating gross proceeds of $8.0 million. In connection with the offering, the underwriter received an 7% commission totaling $560,000. We also incurred expenses related to legal, accounting, and other registration costs of $284,000. The shares and the warrants were offered and sold pursuant to our shelf registration statement on Form S-3 that was declared effective by the SEC in April 2017.

The warrants have an exercise price of $0.40 per share and are exercisable immediately with a term of five years from issuance. The warrants include a provision where the warrant holder has the contractual right to request a cash exercise if the effectiveness of the registration statement is not maintained, but securities law would prevent us from issuing registered shares in a cash exercise. Therefore, we could be forced to cash settle the warrants. Based on this derivative feature, these warrants must be accounted for as a liability at fair value under Accounting Standards Codification (“ASC”) 815 “Derivatives and Hedging”. On the date of issuance, these warrants were valued at $8.0 million.

Our net cash proceeds from the confidentially marketed public offering totaled $7.2 million. When the additional non-cash charges of $8.0 million related to the 20.0 million investor warrants are offset against the net cash transaction proceeds, the non-cash charges exceeded 100% of the proceeds. Therefore, we are required to take the additional cost above the transaction proceeds and recognize a loss on the day it entered into the transaction. The loss on the transaction was $853,000 and this amount is included in the derivative gain on the statement of operations.

In October 2017, we entered into a Securities Purchase Agreement, with certain investors, pursuant to which we sold approximately 7.7 million shares of common stock at a price per share of $0.875. The gross proceeds from the offering were approximately $6.7 million. The costs associated with the offering were approximately $490,000. The shares were offered and sold pursuant to our shelf registration statement on Form S-3 that was declared effective by the SEC in April 2017.

In June 2017, we completed a registered direct offering. In this offering, we issued directly to multiple investors approximately 11.0 million shares of our common stock and approximately 11.0 million warrants to purchase 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 investors in this offering at a negotiated price of $0.60 per unit generating gross proceeds of $6.6 million. In connection with the offering, the placement agent received an 8% commission totaling $533,000 and approximately 879,000 warrants with an exercise price of $0.76. The expiration date of these warrants is June 1, 2022. At issuance, these warrants had a

value of $369,000 and were accounted for as equity-based warrants. The placement agent warrants provide for cashless exercise, which the placement agents may elect if there is no effective registration statement. We also incurred expenses related to legal, accounting, and other registration costs of $292,000.

There was a participation right of 35% for any proposed or intended issuance or sale or exchange of securities being offered until the second anniversary of the closing date, which would have expired on June 2, 2019. However, in July 2018, we obtained the required number of waivers necessary to eliminate the participate rights from the June 2017 registered direct offering. The shares and the warrants were offered and sold pursuant to our shelf registration statement on Form S-3 that was declared effective by the SEC in April 2017.

The investor warrants have an exercise price of $0.76 per share and were exercisable starting on December 7, 2017 with a term of five years from issuance. The investor warrants include a provision where the warrant holder has the contractual right to request a cash exercise if the effectiveness of the registration statement is not maintained, but securities law would prevent us from issuing registered shares in a cash exercise. Therefore, we could be forced to cash settle the warrant. Based on this derivative feature, these warrants must be accounted for as a liability at fair value under ASC 815 “Derivatives and Hedging”. On the date of issuance, these warrants were valued at $4.6 million.

In September 2016, we completed a registered direct offering. In this 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 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. 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. The expiration date of these warrants is September 1, 2021. At issuance, these warrants had a value of $89,000 and were accounted for as equity-based warrants. The placement agent warrants provide for cashless exercise, which the placement agents may elect if there is no effective registration statement. We also incurred expenses related to legal, accounting, and other registration costs of $113,000.

There was a participation right of 30% for any proposed or intended issuance or sale or exchange of securities being offered until the first anniversary of the closing date, which expired on September 1, 2017. 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 Form S-3 expired in January of 2017 and we filed a new Form S-3 in April 2017.

The investor warrants had an exercise price of $1.00 per share and were immediately exercisable with a term of five years from issuance. In addition, the investor warrants included a provision for an adjustment to the exercise price upon subsequent issuances of common stock by us at a price less than the warrant exercise price and the investor was entitled to purchase additional shares, such that the aggregate purchase price of $5.0 million for the warrant shares remained unchanged. The investor warrants also included a provision for redemption at the Black-Scholes value at the request of the holder upon a change of control. Based on these derivative features, these warrants were accounted for as a liability at fair value under ASC 480 “Distinguishing Liabilities from Equity”. On the date of issuance, these warrants were valued at $4.1 million.

Our net cash proceeds from 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 a loss on the day of the transaction. The loss on the transaction was $804,000 and was included in derivative loss on the statement of operations.

On March 27, 2017, we entered into a Waiver and Consent Letter Agreement with the investor from the September 2016 registered direct offering, amending the terms of the warrants previously issued. Under the Waiver and Consent Agreement, the investor waived the right to have the warrant exercise price reduced and the number of shares of common stock underlying the warrant increased in the event we secure any financing, including debt, which includes issuing or selling shares of common stock for a price per share less than the warrant exercise price. The investor also waived the prohibition on our ability to issue or sell shares of our common stock, options or convertible securities at a price which varies or may vary with the market price of the common stock or pursuant to an equity credit line or similar "at-the-market" offering. The waivers are permanent. In return, we agreed to reduce the exercise price of the warrants from $1.00 to $0.40 and to not issue or sell any shares of our capital stock for a period of 10 trading days following the execution of the Waiver and Consent Agreement. All other terms of the warrants remained the same. Based upon the amendment to this warrant agreement, we recognized a non-cash derivative gain of $1.1 million during the quarter ended March 31, 2017.

Known Trends or Future Events; Outlook

We are a clinical stage company that has not generated revenues and therefore have incurred significant net losses totaling $172.5 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. As of September 30, 2018, we had $8.7 million in cash. We expect our capital resources will last into the second quarter of 2019.

On September 1, 2017, we received a letter from the NYSE American stating that they had determined that we were not in compliance with Sections 1003(a)(ii) and (iii) of the NYSE American Company Guide, or the Guide, since we reported stockholders' equity of $3,734,756 as of June 30, 2017 and net losses in our five most recent fiscal years ended December 31, 2016. Prior to this, we were exempt from Section 1003(a) of the Guide since our market capitalization was above $50 million. We submitted a plan on October 2, 2017 advising the NYSE American of the actions that will be taken to regain compliance with the continued listing standards by March 19, 2019. On November 9, 2017, we received a letter from the NYSE American stating that the NYSE American had accepted our plan to regain compliance with the continued listing standards. On April 12, 2018, we received a letter from NYSE American stating that we are again in compliance with all the NYSE American continued listing standards set forth in Part 10 of the Guide, specifically Sections 1003(a)(ii) and (iii). Going forward, we will be subject to continued listing monitoring.

With respect to FDA review of Ampion and our completed and ongoing clinical trials, including the AP-003-A and AP-003-C trials, we have been and expect to continue to be engaged in meetings and correspondence with the FDA about the product, its manufacturing, and the preclinical and clinical testing necessary to support Ampion's safety and efficacy. We met with the FDA in July 2018 and have received a letter in response thereto. In the letter, the FDA stated that it considers the AP-003-A trial to be an adequate and well-controlled clinical trial that provides evidence of the effectiveness of Ampion and can contribute to the substantial evidence of effectiveness necessary for approval of a

BLA, but that as a single trial the AP-003-A study alone does not appear to provide sufficient evidence of effectiveness to support a BLA. Despite our belief that the APC-003-C trial design was based on FDA guidance and feedback and consistent with FDA precedent for similar products (in intended use, in origin, and in regulatory pathway), which we reiterated with the FDA multiple times, the FDA does not consider the AP-003-C trial to be an adequate and well-controlled clinical trial. The FDA recommended that we perform an additional randomized trial with a concurrent control group and that we request a Special Protocol Assessment to obtain FDA concurrence of the trial design before beginning the study. We plan to continue to discuss with the FDA the necessity of conducting this additional trial, as we believe the current body of data is sufficient to submit the BLA.

Although we have raised capital with net proceeds of over $138 million in the past ten years through the sale of common stock and warrants, we cannot assure you that we will be able to secure such additional financing 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.

Our primary focus for the remainder of fiscal 2018 is raising additional capital and advancing the clinical development and BLA preparation of our core asset, Ampion.

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 allowance, useful lives of assets, accrued compensation, stock compensation, warrant derivative liability and going concern. 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 2017 Annual Report on Form 10-K, filed with the SEC on March 6, 2018.

Newly Issued Accounting Pronouncements

Information regarding the recently issued accounting standards (adopted and not adopted as of September 30, 2018) is contained in Note 1 to the Financial Statements.

RESULTS OF OPERATIONS

Results of Operations – September 30, 2018 Compared to September 30, 2017

We recognized net income for the quarter ended September 30, 2018 of $5.8 million compared to a net loss of $4.3 million for the same quarter in 2017. The net income during the 2018 quarter was attributable to the non-cash derivative gain of $7.7 million that was recognized, which was offset by the operating expenses of $1.9 million. The net loss during the 2017 quarter was primarily attributable to the $3.1 million in operating expenses, as well as the $1.1 million non-cash derivative loss. The investor warrant exercises and decrease in our stock price from $2.20 as of June 30, 2018 to $0.51 as of September 30, 2018 caused the valuation of the warrant liability to decrease resulting in a derivative gain during the 2018 quarter. The increase in our stock price from $0.52 as of June 30, 2017 to $0.61 as of September 30, 2017 caused the valuation of the warrant liability to increase resulting in a derivative loss during the 2017 quarter. The operating expenses decreased $1.2 million from the 2017 quarter to the 2018 quarter primarily due to a $809,000 decrease in research and development costs and a $357,000 decrease in general and administrative costs, which is further explained below.

We recognized net income for the period ended September 30, 2018 of $32.5 million compared to a net loss of $8.8 million for the same period in 2017. The net income during the 2018 period is attributable to the non-cash derivative gain of $41.1 million that was recognized, which was offset by the operating expenses of $8.6 million. The net loss during the 2017 period was attributable to $10.9 million in operating expenses, which was offset by the $2.1 million non-cash derivative gain. The investor warrant exercises and decrease in our stock price from $4.07 as of December 31, 2017 to $0.51 as of September 30, 2018 caused the valuation of the warrant liability to decrease resulting in a derivative gain during the 2018 period. The decrease in our stock price from $0.90 as of December 31, 2016 to $0.61 as of September 30, 2017 caused the valuation of the warrant liability to decrease resulting in a derivative gain during the 2017 period. The operating expenses decreased $2.2 million from the 2017 period to the 2018 period primarily due to a $1.6 million decrease in research and development costs and a $576,000 decrease in general and administrative costs, which is further explained below.

Operating Expenses

Research and Development

Research and development costs are summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Clinical trials and sponsored research	$ 557,000	$ 854,000	$ 2,363,000	$ 3,089,000
Labor	105,000	476,000	1,277,000	1,767,000
Consultants and other	502,000	484,000	1,630,000	1,548,000
Stock-based compensation	20,000	179,000	73,000	255,000
Sponsored research - related party	-	-	-	324,000
	$ 1,184,000	$ 1,993,000	$ 5,343,000	$ 6,983,000

Research and development costs consist of clinical trials and sponsored research, labor, consultants and other, stock-based compensation and sponsored research - related party. Research and development costs decreased $809,000, or 40.6%, for the 2018 quarter compared to the 2017 quarter. This decrease is primarily attributable to clinical trials and sponsored research expense, labor costs and stock-based compensation. During the 2017 quarter, we incurred expenses related to the AP-003-C study. During the 2018 quarter, we were conducting the Open Label Extension (OLE) study, which was an extension of the AP-003-C study. However, the number of patients enrolled in the OLE study was approximately 40% less than the number of patients that were enrolled in the AP-003-C study, causing the expenses for the OLE study to be lower. Labor costs decreased for the 2018 quarter compared to the 2017 quarter primarily due to the elimination of the bonus accrual related to the option repricing discussed within the Subsequent Event footnote. Consultants and other costs are consistent for the 2018 quarter compared to the 2017 quarter. The decrease in stock-based compensation is a result of fewer options being granted at lower stock prices and previously awarded high priced options becoming fully vested during 2017.

Research and development costs decreased $1.6 million, or 23.5%, for the nine months ended September 30, 2018 compared to the same period in 2017. The decrease is primarily attributable to clinical trials and sponsored research expense, labor costs and stock-based compensation, as well as the sponsored research-related party. We incurred initial costs and clinical trial development expenses related to the AP-003-C study during the 2017 period. These costs were not incurred during the 2018 period, as the OLE study was an extension of the AP-003-C study. In addition, the number of patients enrolled in the OLE study was less than the AP-003-C study, causing the expenses for the OLE study to be lower. As noted above, labor costs for the 2018 period decreased from the 2017 period primarily due to the elimination of the bonus accrual related to the option repricing discussed within the Subsequent Event footnote. The decrease in stock-based compensation is a result of fewer options being granted at lower stock prices and previously awarded high priced options becoming fully vested during 2017. In addition, the sponsored research – related party expense also contributed to the decrease in the research and development costs due to the termination of the Trauma Research Agreement. Consultants and other costs increased as we incurred costs related to discussions with the FDA surrounding our clinical trials.

23

General and Administrative

General and administrative costs are summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Occupancy, travel and other	$ 390,000	$ 615,000	$ 1,463,000	$ 1,475,000
Labor	(109,000)	202,000	344,000	743,000
Professional fees	244,000	94,000	645,000	573,000
Patent costs	99,000	12,000	412,000	447,000
Stock-based compensation	75,000	127,000	274,000	414,000
Directors fees	57,000	63,000	165,000	227,000
	$ 756,000	$ 1,113,000	$ 3,303,000	$ 3,879,000

General and administrative costs consist of occupancy, travel and other, labor, professional fees, patent costs, stock-based compensation and director fees. General and administrative costs decreased $357,000, or 32.1%, for the 2018 quarter compared to the 2017 quarter. The decrease is primarily attributable to occupancy, travel and other expenses and labor costs. The decrease in occupancy, travel and other expenses relates to the termination of a contractual agreement that was supposed to assist us with potential partnerships, as well as a decrease in insurance premiums from the 2018 quarter compared to the 2017 quarter. Labor costs decreased for the 2018 quarter compared to the 2017 quarter primarily due to the elimination of the bonus accrual related to the option repricing, which is discussed within the Subsequent Event footnote. The decrease in stock-based compensation is a result of fewer options being granted at lower stock prices and previously awarded high priced options becoming fully vested during 2017. Professional fees increased for the 2018 quarter compare to the 2017 quarter due to an increase in legal fees related to current litigation, as well as amortization of a retainer related to a debt financing deal that is not expected to occur. Patent costs for the 2018 quarter have increased compared to the 2017 quarter due to a credit memo received from the patent attorney during the 2017 quarter.

General and administrative costs decreased $576,000, or 14.8%, for the nine months ended September 30, 2018 compared to the same period in 2017. The decrease is primarily attributable to labor, stock-based compensation and directors fees. As noted above, labor costs decreased for the 2018 period compared to the 2017 period primarily due to the elimination of the bonus accrual related to the option repricing, which is discussed within the Subsequent Event footnote. The decrease in stock-based compensation is a result of fewer options being granted at lower stock prices and previously awarded high priced options becoming fully vested during 2017. Director fees also decreased as there have been fewer board meetings during the 2018 period. There was an increase in professional fees due to an increase in legal fees related to current litigation, as well as the amortization of a retainer related to a debt financing deal that is not expected to occur.

24

Net Cash Used in Operating Activities

During the nine months ended September 30, 2018, our operating activities used approximately $9.8 million in cash, which was less than the net income of $32.4 million primarily as a result of the non-cash gain in the warrant derivatives, a decrease in accounts payable and accrued compensation and an increase in prepaid expenses, which was offset by stock-based compensation, depreciation and amortization and common stock issued for services.

During the nine months ended September 30, 2017, our operating activities used approximately $8.8 million in cash, which was equal to the net loss of $8.8 million primarily as a result of the non-cash gain in the warrant derivative, a decrease in accrued compensation and an increase in prepaid expenses, which was offset by increases in accounts payable, stock-based compensation, depreciation and the acceleration of the related-party amortization.

Net Cash Used in Investing Activities

During the nine months ended September 30, 2018, cash was used to acquire $486,000 of manufacturing machinery and equipment.

During the nine months ended September 30, 2017, cash was used to acquire $33,000 of manufacturing machinery and equipment.

Net Cash from Financing Activities

During the nine months ended September 30, 2018, we received $3.6 million from option and warrant exercises. We also received gross proceeds from the sale of common stock in a confidentially marketed public offering of $8.0 million, which was offset by offering costs of $844,000.

During the nine months ended September 30, 2017, we received gross proceeds from the sale of common stock in a registered direct offering of $6.6 million, which was offset by offering costs of $812,000.

Liquidity and Capital Resources

To date, we have not generated revenues or profits. Our primary activities are focused on research and development, advancing our primary product candidates, and raising capital. As of September 30, 2018, we had $8.7 million of cash. We expect our capital resources will last into the second quarter of 2019. This projection is based on several assumptions that may prove to be incorrect, and we could exhaust our available cash and cash equivalents earlier than presently anticipated. We will be required to seek additional capital to continue our clinical and commercial development activities for Ampion. We intend to evaluate the capital markets from time to time to determine whether to raise additional capital in the form of equity, convertible debt or otherwise, depending on market conditions relative to our need for funds at such time, and we are in negotiations with potential investors for near-term financing.

We have prepared a budget for 2018 which reflects cash requirements for routine monthly expenses such as payroll, legal, accounting, patents and overhead costs 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 private or public sales of our securities, debt financings, partnering/licensing transaction or our Controlled Equity Offering Sales Agreement that we entered into in February 2016. We cannot be certain that financing will be available to us on acceptable terms, or at all. Over the last couple of 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 and/or make the additional financing dilutive to our current shareholders.

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 or suspend operations for a period until we are able to raise additional capital. We also may be required to relinquish our 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.

We maintain “disclosure controls and procedures,” as such terms are defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, or the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of senior management, including the chief executive officer and the chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15(b) and 15d-15(b). Based upon this evaluation, the chief executive officer and the chief financial officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

On August 25, 2018 and August 31, 2018, two purported stockholders of the Company brought putative class action lawsuits in the United States District Court for the Central District of California, Shi v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:18-cv-07476-SJO-RAO, and in the United States District Court for the District of Colorado, Shaffer v. Ampio Pharmaceuticals, Inc., et al., Case No. 1:18-cv-02252-KLM (the "Securities Class Actions"). Plaintiffs in the Securities Class Actions allege that the Company and certain of its current officers violated federal securities laws by misrepresenting and/or omitting information regarding the AP-003 Phase III clinical trials of Ampion. Plaintiffs in the Securities Class Actions assert claims under Sections 10(b) and 20(a) and Rule 10b-5 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") on behalf of a putative class of purchasers of the Company's common stock from December 14, 2017 through August 7, 2018. The Securities Class Actions seek unspecified damages, pre-judgment and post-judgment interest, and attorneys' fees and costs.

On September 10, 2018, a purported stockholder of the Company brought a derivative action in the United States District Court for the Central District of California, Cetrone v. Macaluso et al., Case No. 2:18-cv-05970-SJO-RAO (the "Cetrone Action"), alleging primarily that the directors and officers of Ampio breached their fiduciary duties because of their alleged misstatements and/or omissions regarding the AP-003 Phase III clinical trials of Ampion. On October 5, 2018, a purported stockholder of the Company brought a derivative action in the United States District Court for the District of Colorado, Theise v. Macaluso et al., 1:18-cv-02558, which closely parallels the allegations in the Cetrone Action.

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, 2017, as filed with the SEC and as updated by our Quarterly Reports on Form 10Q 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, except as noted below, 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, 2017.

Risks Related to Our Business

The FDA is requiring an additional clinical trial of Ampion for OAK.

We have been engaged in discussions with the FDA relating to the nonclinical development and clinical evaluation of Ampion. Following our meeting with the FDA in July 2018, we received a response letter thereto. In the letter, the FDA stated that it considers the AP-003-A trial to be an adequate and well-controlled clinical trial that provides evidence of the effectiveness of Ampion and can contribute to the substantial evidence of effectiveness necessary for approval of a BLA, but that as a single trial the AP-003-A study alone does not appear to provide sufficient evidence of effectiveness to support a BLA. The FDA did not consider the AP-003-C trial to be an adequate and well-controlled clinical trial and recommended that we perform an additional randomized trial with a concurrent control group and that we request a Special Protocol Assessment to obtain FDA concurrence of the trial design before beginning the study. We plan to continue to discuss the data and our BLA with the FDA and we cannot ensure the outcome of such subsequent discussions with the FDA. We also cannot ensure that the data derived from a subsequent trial will be sufficient to support a submission to the FDA of a BLA for Ampion. We will also continue to address with the FDA the validation of manufacturing processes and controls and we cannot ensure when or whether we will receive validation.

Risks Related to Our Common Stock

We may not be able to comply with the listing requirements of, and may be delisted from, the NYSE American

Our common stock trades on the NYSE American, or the Exchange. The Exchange imposes various quantitative and qualitative requirements to maintain listing, including minimum stockholders' equity requirements. On September 1, 2017, we received a letter from the Exchange stating that the Exchange had determined that we were not in compliance with Sections 1003(a)(iii) of the Exchange Company Guide and the stockholder's equity continued listing standards applicable to us due to our recently reported stockholder's equity of $3,734,756 as of June 30, 2017 and net losses in our five most recent fiscal years ended December 31, 2016. Prior to this, we were exempt from Section 1003(a) of the Guide since our market capitalization was above $50 million. We submitted a plan on October 2, 2017 advising the NYSE American of the actions that will be taken to regain compliance with the continued listing standards by March 19, 2019. On November 9, 2017, we received a letter from the NYSE American stating that the NYSE American had accepted our plan to regain compliance with the continued listing standards. On April 12, 2018, we received a letter from NYSE American stating that we are back in compliance with all the NYSE American continued listing standards set forth in Part 10 of the Guide, specifically Sections 1003(a)(ii) and (iii). Even though we are back in compliance with the Exchange's listing standards, there can be no assurances that we will be able to continue to comply with the Exchange listing requirements.

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.

On November 12, 2018, the Board of Directors approved an amendment to our bylaws providing for a disclosure committee.

Item 6. Exhibits.

Exhibit Number	Description
1.1	Underwriting Agreement, dated August 9, 2018, by and between the Company and Canaccord Genuity LLC (1).
1.2	Amendment No. 1, dated August 10, 2018, to the Underwriting Agreement by and between the Company and Canaccord Genuity LLC (1).
3.1	Amended and Restated Bylaws.
4.1	Form of Warrant (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, 2018 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 8-K filed on August 13, 2018.

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 14, 2018

By: /s/ Thomas E. Chilcott, III
Thomas E. Chilcott, III
Chief Financial Officer, Treasurer and Secretary
Date: November 14, 2018

29