

Ampio Pharmaceuticals, Inc.  
Form 10-Q  
May 10, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**For the Quarterly Period Ended: March 31, 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  No

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

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

Large Accelerated Filer  Accelerated Filer   
Non-Accelerated Filer  (Do not check if a smaller reporting company) Smaller reporting company   
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

As of May 8, 2018, there were 86,320,968 shares of Common Stock outstanding, par value \$0.0001, of the registrant.

**AMPIO PHARMACEUTICALS, INC.**

**FOR THE QUARTER ENDED MARCH 31, 2018**

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- projected operating or financial results, including anticipated cash flows used in operations;*
- expectations regarding clinical trials for our product candidates, capital expenditures, research and development expense and other payments;*
- our beliefs and assumptions relating to our liquidity position, including our ability to obtain additional financing;*
- our ability to obtain regulatory approvals for our pharmaceutical drugs and diagnostics;*
- our future dependence on third party manufacturers or strategic partners to manufacture any of our pharmaceutical drugs and diagnostics that receive regulatory approval, and our ability to identify strategic partners and enter into beneficial license, co-development, collaboration or similar arrangements; and*
- progress of our manufacturing facility/clean room.*

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

- the loss of key management personnel or sponsored research partners on whom we depend;*
- the progress and results of clinical trials for our product candidates;*
- our ability to navigate the regulatory approval process in the U.S. and other countries, and our success in obtaining required regulatory approvals for our product candidates;*
- commercial developments for products that compete with our product candidates;*
- the actual and perceived effectiveness of our product candidates, and how those product candidates compare to competitive products;*
- the strength of our intellectual property protection, and our success in avoiding infringing the intellectual property rights of others;*
- adverse developments in our research and development activities;*
- potential liability if our product candidates cause illness, injury or death, or adverse publicity from any such events;*
-

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

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

*This Quarterly Report on Form 10-Q includes trademarks, such as Ampion and Optina, which are protected under applicable intellectual property laws and are our property. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report on Form 10-Q may appear without the ® or TM 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**

	March 31, 2018 (unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	\$7,517,476	\$8,209,071
Trading security in Aytu BioScience, Inc.	3,256	11,398
Prepaid expenses and other	383,325	222,417
Total current assets	7,904,057	8,442,886
Fixed assets, net (Note 3)	6,725,525	6,837,861
Deposits	33,856	33,856
Total assets	\$14,663,438	\$15,314,603
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	\$2,492,948	\$2,785,529
Accrued compensation	982,449	1,033,261
Deferred rent - current portion	59,579	59,579
Total current liabilities	3,534,976	3,878,369
Long-term deferred rent	523,824	537,364
Warrant derivative liability	19,461,450	45,075,755
Total liabilities	23,520,250	49,491,488
Commitments and contingencies (Note 5)		
Stockholders' equity		
Preferred Stock, par value \$.0001; 10,000,000 shares authorized; none issued	-	-
Common Stock, par value \$.0001; 200,000,000 shares authorized; shares issued and outstanding - 86,011,751 in 2018 (unaudited) and 80,060,345 in 2017	8,601	8,006
Additional paid-in capital	174,083,789	170,803,783



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Accumulated deficit	(182,949,202)	(204,988,674)
Total stockholders' equity	(8,856,812 )	(34,176,885 )
Total liabilities and stockholders' equity	\$ 14,663,438	\$ 15,314,603

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

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

	Three Months Ended March 31,	
	2018	2017
Operating expenses		
Research and development	\$ 2,044,476	\$ 1,604,386
Research and development - related party (Note 8)	-	35,951
General and administrative	1,522,215	1,362,668
Total operating expenses	3,566,691	3,003,005
Other income (expense)		
Interest income	-	3,033
Derivative gain	25,614,305	1,126,473
Unrealized loss on trading security	(8,142 )	(30,711 )
Total other income	25,606,163	1,098,795
Net income (loss)	\$ 22,039,472	\$ (1,904,210 )
Basic and diluted net income (loss) per common share	\$ 0.27	\$ (0.03 )
Weighted average number of common shares outstanding	82,943,340	57,240,081

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
	Shares	Amount	Capital	Deficit	Stockholders' Equity
Balance - 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)	249,666	25	400,734	-	400,759
Warrants exercised, net (unaudited)	5,684,499	568	2,699,651	-	2,700,219
Stock-based compensation, net (unaudited)	-	-	119,623	-	119,623
Net income (unaudited)	-	-	-	22,039,472	22,039,472
Balance - March 31, 2018 (unaudited)	86,011,751	\$ 8,601	\$ 174,083,789	\$(182,949,202)	\$(8,856,812 )

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

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

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities		
Net income (loss)	\$ 22,039,472	\$ (1,904,210 )
Adjustments to reconcile net income (loss) to net cash used in operating activities		
Stock-based compensation and warrant modification	119,623	205,328
Depreciation and amortization	300,884	303,522
Write-off of advances to stockholder	-	25,160
Amortization of prepaid research and development - related party (Note 8)	-	35,951
Common stock issued for services	60,000	60,000
Derivative gain	(25,614,305 )	(1,126,473 )
Unrealized loss on trading security in Aytu BioScience, Inc.	8,142	30,711
Changes in operating assets and liabilities		
Increase in prepaid expenses and other	(160,908 )	(234,445 )
(Decrease) increase in accounts payable	(292,581 )	56,180
Decrease in deferred rent	(13,540 )	(11,123 )
Decrease in accrued compensation	(50,812 )	(61,641 )
Net cash used in operating activities	(3,604,025 )	(2,621,040 )
Cash flows used in investing activities		
Purchase of fixed assets	(188,548 )	(17,453 )
Net cash used in investing activities	(188,548 )	(17,453 )
Cash flows from financing activities		
Proceeds from option and warrant exercises	3,100,978	-
Net cash provided by financing activities	3,100,978	-
Net change in cash and cash equivalents	(691,595 )	(2,638,493 )
Cash and cash equivalents at beginning of period	8,209,071	4,894,834
Cash and cash equivalents at end of period	\$ 7,517,476	\$ 2,256,341

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

**AMPIO PHARMACEUTICALS, INC.**

**Notes to Financial Statements**

**(unaudited)**

**Note 1 - Basis of Presentation**

These unaudited financial statements represent the financial statements of Ampio Pharmaceuticals, Inc. (“Ampio” or “the Company”). These unaudited financial statements should be read in conjunction with Ampio’s Annual Report on Form 10-K for the year ended December 31, 2017, which included all disclosures required by U.S. Generally Accepted Accounting Principles (“GAAP”). In the opinion of management, these unaudited financial statements contain all adjustments necessary to present fairly the financial position of Ampio for the balance sheet and the results of operations and cash flows for the interim periods presented. The results of operations for the period ended March 31, 2018 are not necessarily indicative of expected operating results for the full year. The information presented throughout this report as of and for the period ended March 31, 2018 is unaudited.

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 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. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. 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. The Company is currently evaluating the impact of its pending adoption of this standard on its financial statements.

In July 2017, the FASB issued ASU 2017-11, “*Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*”. The amendments require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. Companies that provide earnings per share (EPS) data will adjust their basic EPS calculation for the effect of the feature when triggered (i.e., when the exercise price of the related equity-linked financial instrument is adjusted downward because of the down round feature) and will also recognize the effect of the trigger within equity. The new standard is 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.

Other accounting standards that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the financial statements upon adoption. 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 \$7.5 million as of March 31, 2018 with net income of \$22.0 million for the period ended March 31, 2018. The net income is attributable to the non-cash derivative gain of \$25.6 million that was recognized during the first quarter of 2018. The Company used net cash in operations of \$3.6 million for the period ended March 31, 2018. The Company ended the quarter with an accumulated deficit of \$182.9 million and a deficit in stockholders’ equity of \$8.9 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.

In the first quarter of 2018, the Company received a total of \$3.1 million from investor warrants and stock options being exercised (see Note 7). Ampio expects that current cash resources and operating cash flows will be sufficient to sustain operations into the third quarter of 2018. 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 the 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 March 31, 2018	As of December 31, 2017
Manufacturing facility/clean room	3 - 8	\$2,926,000	\$2,773,000
Leasehold improvements	10	6,075,000	6,075,000
Office furniture and equipment	3 - 10	557,000	557,000
Lab equipment	5 - 10	1,095,000	1,059,000
Less accumulated depreciation and amortization		(3,927,000)	(3,626,000)
Fixed assets, net		\$6,726,000	\$6,838,000

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

	Three Months Ended March 31,	
	2018	2017
Depreciation and amortization expense	\$ 301,000	\$ 304,000



#### Note 4 - Fair Value Considerations

The Company's financial instruments include cash and cash equivalents, trading security in Aytu, accounts payable and accrued expenses, and warrant derivative liability. The carrying amounts of financial instruments, including cash and cash equivalents, accounts payable and accrued expenses are carried at cost which approximates fair value due to the short maturity of these instruments. The fair value of trading securities is based on quoted market prices, if available, or estimated discounted future cash flows. Warrants were 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 March 31, 2018 and December 31, 2017, by level within the fair value hierarchy:

	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
March 31, 2018				
ASSETS				
Trading security Aytu	\$3,300	\$ -	\$-	\$3,300
LIABILITIES				
Warrant derivative liability	\$-	\$ -	\$19,461,000	\$19,461,000
December 31, 2017				
ASSETS				
Trading security Aytu	\$11,400	\$ -	\$-	\$11,400
LIABILITIES				
Warrant derivative liability	\$-	\$ -	\$45,076,000	\$45,076,000

On August 25, 2017, Aytu announced a 1-for-20 stock split which automatically converted twenty shares of Aytu's common stock into one new share of common stock. The Company's investment, the trading security in Aytu, is recorded at estimated fair value which represents Ampio's ownership shares in Aytu of 5,111 multiplied by Aytu's closing stock price on March 31, 2018 and December 31, 2017, which is classified as Level 1 (quoted price is available).

	Maturity in Years	Fair Value at December 31, 2017	Unrealized Gains/losses	Fair Value at March 31, 2018
Trading security Aytu	Less than 1 year	\$ 11,400	\$- \$(8,100)	\$ 3,300

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 March 31, 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 valued hierarchy:

#### Derivative Instruments

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Balance as of December 31, 2017	\$ 45,076,000	
Warrants issuances	-	
Warrants exercises	(12,981,000	)
Change in fair value	(12,634,000	)
Balance as of March 31, 2018	\$ 19,461,000	

**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	2,672,000	1,852,000	820,000	-	-	-	-
Biologics License Application (BLA) consulting services	1,212,000	1,212,000	-	-	-	-	-
Facility lease	2,244,000	239,000	326,000	335,000	345,000	355,000	644,000
	\$13,778,000	\$5,853,000	\$3,696,000	\$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. Per an amendment to the original agreement, Ampio was not committed to purchase any product in 2017 and has extended the agreement to 2020.

***Clinical Research and Trial Obligation***

In November 2017, Ampio entered into an Open Label Extension study agreement which has a remaining commitment of \$2.7 million.

***Biologics License Application (BLA) Consulting Services***

In March 2018, Ampio entered into a BLA consulting services agreement which has a commitment of \$1.2 million.

***Facility Lease***

In December 2013, Ampio entered into a 125-month non-cancellable operating lease for office space and the manufacturing facility effective May 1, 2014. The lease has initial base rent of \$23,000 per month, with the total base rent over the term of the lease of approximately \$3.3 million and includes rent abatements and leasehold incentives. The Company recognizes rental expense of the facility on a straight-line basis over the term of the lease. Differences between the straight-line net expenses on rent payments are classified as liabilities between current deferred rent and long-term deferred rent.

Rent expense for the respective periods is as follows:

	Three Months Ended March 31,	
	2018	2017
Rent expense	\$ 65,000	\$ 65,000

**Note 6 - Common Stock**

***Capital Stock***

At March 31, 2018 and December 31, 2017, Ampio had 200.0 million shares of common stock authorized with a par value of \$0.0001 per share, respectively, and 10.0 million shares of preferred stock authorized with a par value of \$0.0001 per share.

At March 31, 2018 and December 31, 2017, Ampio had 86,011,751 and 80,060,345 shares of common shares 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 \$78.3 million remained available under the Form S-3 as of March 31, 2018. This shelf registration statement on Form S-3 expires in March of 2020.

### ***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. There is 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 expires on June 2, 2019. 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 additional derivative feature of the investor warrants, they 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 \$4.6 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 and a termination date of June 1, 2022. These warrants had a value of \$369,000 when they were issued and are 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 cost of \$292,000.

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. 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 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 is entitled to purchase additional shares, such that the aggregate purchase price of \$5.0 million for the warrant shares remains unchanged. The investor warrants also include a provision for redemption at the Black-Scholes value at the request of the holder upon a change of control. Based on these derivative features of the investor warrants, they must be accounted for as a liability at fair value under ASC 480. On the date of issuance, these warrants were valued at \$4.1 million.

In connection with the offering, the placement agent received a 6% commission totaling \$225,000 and 150,000 warrants with an exercise price of \$0.9375 and a termination date of September 1, 2021. These warrants had a value of \$89,000 when they were issued and 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 cost of \$113,000.

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 it entered the transaction. The loss on the transaction was \$804,000 and was included in derivative expense on the statement of operations.

On March 27, 2017, the Company entered into a Waiver and Consent Letter Agreement with the investor from September 2016, 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 <sup>SM</sup> Sales Agreement (the "Agreement") with a placement agent to implement an "at-the-market" equity program under which Ampio, from time to time may offer and sell shares of its common stock having an aggregate offering price of up to \$25.0 million through the placement agent. The Company has no obligation to sell any of the shares and may at any time suspend sales under the Agreement or terminate the Agreement in accordance with 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 three months ended March 31, 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 three months ended March 31, 2018, the Company did not grant options to officers, directors or employees. Former employees and executives exercised 249,666 options with a weighted average exercise price of \$1.61. The Company received \$400,800 as of March 31, 2018 related to these option exercises. A total of 3,334 options were forfeited and 145,000 expired as of March 31, 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 December 31, 2017	7,247,165	\$ 2.87	5.16	12,739,512
Granted	-	\$ -		
Exercised	(249,666 )	\$ 1.61		
Forfeited	(3,334 )	\$ 8.37		
Expired or Cancelled	(145,000 )	\$ -		
Outstanding March 31, 2018	6,849,165	\$ 2.81	5.11	8,528,722
Exercisable at March 31, 2018	6,135,830	\$ 3.04	4.65	6,634,118
Available for grant at March 31, 2018	3,042,262			

Stock options outstanding at March 31, 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	2,975,221	\$ 0.91	6.19

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\$2.01 - \$5.00	2,638,944	\$ 3.06	3.70
\$5.01 - \$8.93	1,235,000	\$ 6.86	5.51
	6,849,165	\$ 2.81	5.11

Ampio computes the fair value of all options granted 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 valuation. Ampio calculates its volatility assumption using the actual changes in the market value of its stock. Ampio adopted ASU 2016-09 in 2017 and no longer estimates a forfeiture rate. Instead, forfeitures are recognized as they occur. Ampio estimates the expected term based on the average of the vesting term and the contractual term of the options. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. Ampio did not grant any options but did compute the fair value for an option modification during the period ending March 31, 2018, using the following assumptions:

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

Stock-based compensation expense related to the fair value of stock options was 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 months ended March 31, 2018 and 2017:

	Three Months Ended March 31,	
	2018	2017
Research and development expenses		
Stock-based compensation	\$ 23,000	\$ 42,000
General and administrative expenses		
Common stock issued for services	60,000	60,000
Stock-based compensation	96,000	89,000
	\$ 179,000	\$ 191,000
Unrecognized expense at March 31, 2018	\$ 176,000	
Weighted average remaining years to vest	1.13	

### ***Warrants***

In connection with the June 2017 registered direct offering, Ampio issued to investors warrants to purchase an aggregate of approximately 11.0 million shares of common stock at an exercise price of \$0.76 and 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 March 31, 2018, these warrants had a fair value of \$19,461,000 (see Note 4). Significant assumptions as of March 31, 2018 and at issuance were as follows:

	March 31, 2018	At Issuance
Assumptions for warrants issued June 2, 2017:		
Exercise price	\$ 0.76	\$0.76
Volatility	105.6	% 94.6 %
Equivalent term (years)	4.17	5.00
Risk-free interest rate	2.49	% 1.71 %
Number of shares	6,421,082	10,990,245

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 and a term of five years. Due to certain derivative features, these warrants are accounted for under liability accounting and are fair valued at each reporting period. As

March 31, 2018, no fair value was recorded as these warrants were exercised in full during the 2018 quarter (see Note 4).

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 December 31, 2017	13,332,243	\$ 0.73	4.01
Warrants issued	-	\$ -	
Warrants exercised	(5,684,499 )	\$ 0.48	
Outstanding March 31, 2018	7,647,744	\$ 0.93	3.90

During the quarter ending March 31, 2018, the Company issued 1,184,499 shares of common stock from the exercise of investor warrants with an exercise price of \$0.76. 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. After this exercise, the Company no longer has outstanding \$0.40 warrants. The Company received \$2.7 million as of March 31, 2018 related to these investor warrant exercises.

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.

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 have been exercised in full as of March 31, 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 Chief Scientific Officer, 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 contract for Dr. Bar-Or for an additional year. He will continue his current roles as the Chief Scientific Officer and a director.

***Service Agreement***

In June 2017, Ampio terminated the shared services agreement with Aytu. For the three months ended March 31, 2018 and 2017, the total shared overhead cost was \$0 and \$39,000, respectively.

### **Note 9 - Litigation**

From time to time, the Company is party to litigation arising in the ordinary course of its business. As of March 31, 2018, the Company is not currently a party to any material litigation.

### **Note 10 - Subsequent Events**

The Company received option exercise notices from former employees after the close of market on March 29, 2018, with a weighted average exercise price of \$2.75. Due to the market being closed on March 30, 2018, the shares of common stock were not transferred to the former employees until April 2018. The Company recorded a receivable of \$82,350 related to the exercise cost and an accrued liability for the trade in transfer for \$82,350 as of March 31, 2018.

The Company received a cashless option exercise notice from a former executive after the close of market on March 29, 2018. Due to the market being closed on March 30, 2018, the net shares of common stock totaling 14,117 shares were not transferred to the former executive until April 2018.

As of May 10, 2018, a total of 55,000 options were exercised by former employees at a weighted average exercise price of \$2.79. The Company received \$153,000 from the option exercises.

As of May 10, 2018, the Company issued 210,100 shares of common stock from the exercise of investor warrants with an exercise price of \$0.76. The Company received \$160,000 related to investor warrant exercises.

## **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 a robust portfolio of novel therapeutic candidates. These therapeutic candidates, if approved, will address significant inflammatory conditions for which limited treatment options exist. Our therapeutic product pipeline has been developed through more than two decades of study at leading hospital-based research centers. Rigorous preclinical and clinical research efforts have yielded a diverse portfolio of late-stage product candidates focusing on the world's most prevalent inflammatory conditions including osteoarthritis and diabetic macular edema.

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.

As 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.

While advancing into our next phase, we plan on creating a leaner and simpler operating model to streamline our operations and reallocate resources towards commercializing our lead product candidate Ampion.

### **Overview**

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

We 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 currently have two lead product candidates, which have advanced through late-stage clinical trials in the United States. During the fourth quarter of 2017, we successfully completed our confirmatory Phase III trial for Ampion, a biologic intra-articular injection being studied for the treatment of pain due to osteoarthritis of the knee. In addition, we have completed clinical trials for Optina, an oral agent being studied for the treatment of diabetic macular edema.

### **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, or HSA, a Food and Drug Administration, or 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 late 2017, we announced the publication of an integrated analysis of 417 severely diseased OAK patients, thought to be the largest study treating this patient population, as a feature article in *Orthopedics*, an international peer-reviewed journal. The publication detailed the safety and tolerability of a single intra-articular injection of Ampion into the knee and demonstrated that patients are significantly more likely to respond to treatment with Ampion with a longer duration of response compared to saline. This data suggests that Ampion can satisfy an unmet medical need for a population with few therapeutic treatment options and a debilitating symptomatic disease.

Additionally, we announced the beginning of an Open Label Extension, or OLE, study of the AP-003-C trial. The OLE study offers patients an opportunity to receive repeat injections of Ampion after they have completed the pivotal clinical trial. The OLE study will address the regulatory requirements to allow an expanded commercial label for repeat administration of Ampion.

We also intend to study Ampion for therapeutic applications other than osteoarthritis of the knee and hand. We may engage development partners to study Ampion in various conditions including: (i) acute and chronic inflammatory conditions; (ii) degenerative joint diseases; and (iii) respiratory disorders. 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 that we are developing to treat diabetic macular edema, or DME. Danazol is a synthetic derivative of modified testosterone ethisterone, and we believe it affects vascular endothelial cell linkage 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 organized into a cortical ring, filamentous actin, 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). The study could have significantly fewer patients than in our previous OptimEyes study, based on power calculations and guidance received from the FDA, and could include approximately 80 patients randomized 1:1 between placebo and Optina. Optina would be compared to placebo, not to other anti-vascular endothelial growth factor, or anti-VEGF, drugs, since we are addressing a population that failed these alternative treatments. The FDA will consider improved vision as measured by best corrected visual acuity, which is statistically and clinically meaningful, as determined by experts in the field. The duration of the study is expected to be a maximum of 12 months. We have also considered conducting a trial in combination with other 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, 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 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. There is 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 expires on June 2, 2019. 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 additional derivative feature of the investor warrants, they must be accounted for as a liability at fair value under Accounting Standards Codification, or ASC, 815 "Derivatives and Hedging". On the date of issuance, these warrants were valued at \$4.6 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 and a termination date of June 1, 2022. These warrants had a value of \$369,000 when they were issued and are 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 cost of \$292,000.

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. 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 is entitled to purchase additional shares, such that the aggregate purchase price of \$5.0 million for the warrant shares remains unchanged. The investor warrants also include a provision for redemption at the Black-Scholes value at the request of the holder upon a change of control. Based on these derivative features of the investor warrants, they must be accounted for as a liability at fair value under ASC 480. On the date of issuance, these warrants were valued at \$4.1 million.

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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 it entered the transaction. The loss on the transaction was \$804,000 and was included in derivative expense on the statement of operations.

On March 27, 2017, we entered into a Waiver and Consent Letter Agreement with the investor from September 2016, 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 \$182.9 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 March 31, 2018, we had \$7.5 million of cash. We expect our capital resources will last into the third quarter of 2018.

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.

Although we have raised capital with net proceeds of over \$100 million in the past five years through the sale of common stock and warrants, we cannot assure you that we will be able to secure such additional financing 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, the valuation of the Aytu BioScience trading security and the warrant derivative liability. 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 March 31, 2018) is contained in Note 1 to the Financial Statements.

## RESULTS OF OPERATIONS

### Results of Operations - March 31, 2018 Compared to March 31, 2017

Results of operations for the three months ended March 31, 2018, or the “2018 quarter,” and the three months ended March 31, 2017, or the “2017 quarter,” reflected net income from continuing operations of approximately \$22.0 million and a net loss of \$1.9 million, respectively. The net income is attributable to the non-cash derivative gain of \$25.6 million that was recognized during the 2018 quarter. Additional non-cash items that offset the derivative gain during the 2018 quarter include unrealized loss on trading security, stock-based compensation, depreciation and amortization and common stock issued for services. In the 2017 quarter, there was a \$1.1 million non-cash gain on the warrant derivative which decreased the net loss to \$1.9 million.

### *Operating Expenses*

#### *Research and Development*

Research and development costs are summarized as follows:

	Three Months Ended March 31,	
	2018	2017
Clinical trials and sponsored research	\$ 995,000	\$ 315,000
Labor	563,000	683,000
Consultants and other	463,000	564,000
Stock-based compensation	23,000	42,000
Sponsored research - related party	-	36,000

\$ 2,044,000      \$ 1,640,000

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 expense increased \$404,000, or 24.6%, for the 2018 quarter compared to the 2017 quarter. This increase is primarily attributable to the Open Label Extension study, which began during the fourth quarter of 2017. The Open Label Extension study will address the regulatory requirements to allow an expanded commercial label for repeat administration of Ampion. During the 2017 quarter, we were not conducting a clinical trial, however we incurred costs related to production runs to prepare for the AP-003-C trial that began in June 2017. Labor costs decreased due to a reduction in headcount, as well as implementation of a new paid time off, or PTO, policy. Consultants and other costs decreased as we continue to focus on cost reduction measures. However, we expect consultants and other costs to increase throughout 2018 as we incur costs to prepare to file the BLA with the FDA. During the 2018 quarter, we did not incur costs related to the sponsored research agreement with Trauma Research LLC as this agreement was terminated during July 2017.

*General and Administrative*

General and administrative costs are summarized as follows:

	Three Months Ended March 31,	
	2018	2017
Occupancy, travel and other	\$ 750,000	\$ 446,000
Labor	218,000	274,000
Patent costs	193,000	219,000
Stock-based compensation	156,000	148,000
Professional fees	155,000	192,000
Directors fees	50,000	84,000
	\$ 1,522,000	\$ 1,363,000

General and administrative costs consist of occupancy, travel and other, labor, patent costs, stock-based compensation, professional fees and director fees. General and administrative costs increased \$159,000, or 11.7%, for the 2018 quarter compared to the 2017 quarter. This increase is primarily attributable to occupancy, travel and other as we contracted with a firm to perform a strategic assessment of the osteoarthritis environment. Labor costs decreased due to a reduction in headcount, as well as implementation of a new PTO policy. Professional fees decreased due to a reduction in audit and legal fees as no S-3 filing was completed during the 2018 quarter. Director fees decreased as there were fewer board meetings during the 2018 quarter.

### ***Income from Operations***

We recognized net income from operations for the quarter ended March 31, 2018 of \$22.0 million compared to a net loss from operations of \$1.9 million for the same quarter in 2017. The net income is attributable to the non-cash derivative gain of \$25.6 million that was recognized during the first quarter of 2018. The investor warrant exercises and decrease in our stock price from \$4.07 as of December 31, 2017 to \$3.40 as of March 31, 2018, caused the valuation of the warrant liability to decrease during the first quarter of 2018. As stated previously, we expect our research and development consulting expenses to continue to increase throughout 2018 as we prepare to file the BLA with the FDA.

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

During the 2018 quarter, our operating activities used approximately \$3.6 million in cash, which was less than the net income of \$22.0 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 2017 quarter, our operating activities used approximately \$2.6 million in cash, which was more than the net loss of \$1.9 million primarily as a result of the non-cash gain in the warrant derivatives.

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

During the 2018 quarter, cash was used to acquire \$188,500 of manufacturing machinery and equipment.

During the 2017 quarter, cash was used to acquire \$17,000 of manufacturing machinery and equipment.

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

During the 2018 quarter, we received \$3.1 million from option and warrant exercises.

During the 2017 quarter, there were no financing activities.

### *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 March 31, 2018, we had \$7.5 million of cash. We expect our capital resources will last into the third quarter of 2018. 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 fixed, on-going expenses such as payroll, legal and accounting, patents and overhead at an average cash burn rate of approximately \$830,000 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 three years, volatility in the financial markets has adversely affected the market capitalizations of many pharmaceutical companies and generally made equity and debt financing more difficult to obtain. This volatility, coupled with other factors, may limit our access to additional financing 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 of time until we are able to raise additional capital. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. This may lead to impairment or other charges, which could materially affect our balance sheet and operating results.

### ***Off Balance Sheet Arrangements***

We do not have off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as “variable interest entities”.

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

We are not currently exposed to material market risk arising from financial instruments, changes in interest rates or commodity prices, or fluctuations in foreign currencies. We have no need to hedge against any of the foregoing risks and therefore currently engage in no hedging activities.

### **Item 4. Controls and Procedures.**

We maintain “disclosure controls and procedures,” as such term is 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 is 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.**

From time to time, the Company is party to litigation arising in the ordinary course of its business. As of March 31, 2018, the Company is not currently a party to any material litigation.



## **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, 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 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.**

None.

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**Item 6. Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
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31.1	<u>Certificate of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
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31.2	<u>Certificate of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
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32.1	<u>Certificate of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*.</u>
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101	XBRL (eXtensible Business Reporting Language). The following materials from Ampio Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 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.
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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.

**SIGNATURES**

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

AMPIO PHARMACEUTICALS, INC.

By: /s/ Michael Macaluso

**Michael Macaluso**

**Chairman and Chief Executive Officer**

**Date: May 10, 2018**

By: /s/ Thomas E. Chilcott, III

**Thomas E. Chilcott, III**

**Chief Financial Officer, Treasurer and Secretary**

**Date: May 10, 2018**