

Ampio Pharmaceuticals, Inc.  
Form 10-Q  
November 06, 2015  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**For the Quarterly Period Ended: September 30, 2015**

**or**

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

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

**Commission File No. 001-35182**

**AMPIO PHARMACEUTICALS, INC.**  
**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of**  
**incorporation or organization)**  
**373 Inverness Parkway, Suite 200**  
**Englewood, Colorado 80112**  
**(Address of principal executive offices, including zip code)**  
**(720) 437-6500**  
**(Registrant's telephone number, including area code)**

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

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

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

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller Reporting Company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 1, 2015, there were 51,998,306 shares outstanding of Common Stock, par value \$0.0001, of the registrant.

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**AMPIO PHARMACEUTICALS, INC.  
AND SUBSIDIARIES  
FOR THE QUARTER ENDED SEPTEMBER 30, 2015  
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**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

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

*expectations regarding clinical trials for our product candidates, capital expenditures, research and development expense and other payments;*

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

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

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

*progress of our manufacturing facility/clean room.*

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

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

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

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

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

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

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

*adverse developments in our research and development activities;*

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

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

*our expectations with respect to our acquisition activity.*

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

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

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

	September 30, 2015 (Unaudited)	December 31, 2014
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 35,384,904	\$ 50,320,656
Prepaid expenses and other	1,591,208	672,716
Prepaid research and development related party (Note 9)	265,785	265,785
Total current assets	37,241,897	51,259,157
Fixed assets, net (Note 2)		
In-process research and development	9,418,940	9,945,428
Developed technology, customer contracts and trade names, net	7,500,000	7,500,000
Goodwill	1,530,375	
Patents, net	74,000	
Long-term portion of prepaid research and development related party (Note 9)	611,079	664,169
Deposits	664,462	863,802
	38,742	35,854
	19,837,598	19,009,253
Total assets	\$ 57,079,495	\$ 70,268,410
<b>Liabilities and Stockholders Equity</b>		
Current liabilities		
Accounts payable	\$ 2,310,615	\$ 3,299,025
Accrued compensation	1,440,088	235,665
Deferred rent	59,579	59,579
Deferred revenue	85,714	85,714
Total current liabilities	3,895,996	3,679,983
Convertible promissory notes, net of amortization discount of \$349,690 (Note 6)	4,825,310	
Interest payable	57,637	
Contingent consideration	677,153	
Long-term deferred rent	649,651	661,160

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Long-term deferred revenue	404,464	468,749
Warrant derivative liability	102,803	
<b>Total liabilities</b>	<b>10,613,014</b>	<b>4,809,892</b>
Commitments and contingencies (Note 5)		
<b>Stockholders' equity</b>		
Preferred Stock, par value \$.0001; 10,000,000 shares authorized; none issued		
Common Stock, par value \$.0001; 100,000,000 shares authorized; shares issued and outstanding 51,998,306 in 2015 and 51,972,266 in 2014	5,200	5,197
Additional paid-in capital	168,916,720	168,108,278
Advances to stockholders	(90,640)	(90,640)
Accumulated deficit	(123,909,120)	(101,904,570)
<b>Total Ampio stockholders' equity</b>	<b>44,922,160</b>	<b>66,118,265</b>
Non-controlling interests	1,544,321	(659,747)
<b>Total stockholders' equity</b>	<b>46,466,481</b>	<b>65,458,518</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 57,079,495</b>	<b>\$ 70,268,410</b>

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

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

	Three Months Ended September 30, 2015		Nine Months Ended September 30, 2014	
	2015	2014	2015	2014
<b>Revenue</b>				
License revenue	\$ 21,429	\$ 21,429	\$ 64,285	\$ 55,358
Product and service revenue	465,956		628,964	
Total revenue	487,385	21,429	693,249	55,358
<b>Operating Expenses</b>				
Cost of sales	37,325		125,209	
Research and development	4,627,402	6,153,152	12,931,084	19,562,123
Research and development related party (Note 9)	83,948	66,446	251,845	143,967
Selling, general and administrative	3,410,920	3,299,043	10,379,173	9,261,938
Loss from operations	(7,672,210)	(9,497,212)	(22,994,062)	(28,912,670)
<b>Other income</b>				
Interest and other (expense) income	(114,425)	5,547	(97,672)	16,547
Total other (expense) income	(114,425)	5,547	(97,672)	16,547
Net loss	(7,786,635)	(9,491,665)	(23,091,734)	(28,896,123)
Net loss applicable to non-controlling interests	421,095	211,635	1,087,184	682,390
Net loss applicable to Ampio	\$ (7,365,540)	\$ (9,280,030)	\$ (22,004,550)	\$ (28,213,733)
<b>Weighted average number of Ampio common shares outstanding</b>				
	51,998,306	51,969,836	51,989,939	49,638,257
<b>Basic and diluted Ampio net loss per common share</b>				
	\$ (0.14)	\$ (0.18)	\$ (0.42)	\$ (0.57)

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



**Table of Contents****AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES****Consolidated Statements of Stockholders Equity (Deficit)**

	Common Stock		Additional	Advances to	Accumulated	Non-controlling	Total
	Shares	Amount	Paid-in Capital	Stockholders	Deficit	Interests	Stockholders Equity
Balance December 31, 2014	51,972,266	\$ 5,197	\$ 168,108,278	\$ (90,640)	\$ (101,904,570)	\$ (659,747)	\$ 65,458,518
Common stock issued for services (unaudited)	7,998	1	29,999				30,000
Options exercised, net (unaudited)	10,416	1	28,748				28,749
Warrants exercised, net (unaudited)	7,626	1					1
Stock-based compensation (unaudited)			4,088,437				4,088,437
Payments for equity-based transactions (unaudited)			(47,490)				(47,490)
Non-controlling interests on contributed assets (unaudited)			(3,291,252)			3,291,252	
Net loss (unaudited)					(22,004,550)	(1,087,184)	(23,091,734)
Balance September 30, 2015 (unaudited)	51,998,306	\$ 5,200	\$ 168,916,720	\$ (90,640)	\$ (123,909,120)	\$ 1,544,321	\$ 46,466,481

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

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

	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
<b>Cash flows from operating activities:</b>		
Net loss	\$ (23,091,734)	\$ (28,896,123)
Stock-based compensation expense	4,088,437	5,124,187
Depreciation, amortization and accretion	816,055	209,837
Loss on disposal of fixed assets		28,685
Amortization of prepaid research and development related party (Note 9)	199,340	143,967
Common stock issued for services	30,000	30,000
Adjustments to reconcile net loss to net cash used in operating activities:		
(Increase) in prepaid expenses and other	(918,492)	(973,352)
(Increase) in prepaid research and development related party (Note 9)		(1,190,000)
(Decrease) increase in accounts payable	(988,410)	174,662
Increase in interest payable	57,637	
(Decrease) increase in deferred rent	(11,509)	699,616
(Decrease) increase in deferred revenue	(64,285)	194,642
Increase (decrease) in accrued compensation	1,204,423	(522,056)
Net cash used in operating activities	(18,678,538)	(24,975,935)
<b>Cash flows used in investing activities:</b>		
Purchase of fixed assets	(112,263)	(7,925,198)
Purchase of ProstaScint business	(1,000,000)	
Proceeds from sale of fixed assets		2,385
(Increase) decrease in deposits	(2,888)	10,000
Net cash used in investing activities	(1,115,151)	(7,912,813)
<b>Cash flows from financing activities:</b>		
Proceeds from sale of common stock		68,409,531
Costs related to sale of common stock		(4,999,777)
Proceeds from convertible promissory notes (Note 6)	5,175,000	
Debt issuance costs	(298,322)	
Proceeds from option exercise	28,749	
Payments for equity-based transactions	(47,490)	
Net cash provided by financing activities	4,857,937	63,409,754

Net change in cash and cash equivalents	(14,935,752)	30,521,006
Cash and cash equivalents at beginning of period	50,320,656	26,309,449
Cash and cash equivalents at end of period	\$ 35,384,904	\$ 56,830,455
Non-cash transactions:		
Fixed asset purchases included in accounts payable	\$	\$ 769,394
Related party research and development liability included in prepaid research and development related party (Note 9)	\$	\$ 150,000
Contingent consideration related to ProstaScint (Note 1)	\$ 664,000	\$
Warrant derivative liability related to the issuance of the convertible promissory notes (Note 6)	\$ 102,931	\$

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

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**AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements**

**(unaudited)**

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

**Basis of Presentation**

These unaudited financial statements represent the consolidated financial statements of Ampio Pharmaceuticals, Inc. ( Ampio or the Company ) and Aytu BioScience, Inc. ( Aytu ), an 81.5% owned subsidiary. These unaudited consolidated financial statements should be read in conjunction with Ampio's Annual Report on Form 10-K for the year ended December 31, 2014, which included all disclosures required by generally accepted accounting principles ( GAAP ). In the opinion of management, these unaudited consolidated financial statements contain all adjustments necessary to present fairly the financial position of Ampio and its subsidiary on a consolidated basis and the consolidated results of operations and cash flows for the interim periods presented. The results of operations for the period ended September 30, 2015 are not necessarily indicative of expected operating results for the full year. The information presented throughout the document as of and for the period ended September 30, 2015 is unaudited. Ampio's activities, being primarily research and development and raising capital, have not generated significant revenue to date.

**Merger/Subsidiary**

**Aytu BioScience, Inc.**

On April 16, 2015, Luoxis Diagnostics, Inc. ( Luoxis ) and Vyrix Pharmaceuticals, Inc. ( Vyrix ), each previously a subsidiary of Ampio, entered into an Agreement and Plan of Merger (the Merger Agreement ) by and among Rosewind Corporation, a Colorado corporation and public company ( Rosewind ), Luoxis, Vyrix, two major stockholders of Rosewind and two subsidiaries of Rosewind created solely for the purposes of the Merger (as defined below), and which did not survive the Merger.

In the first stage of the transaction, each of Luoxis and Vyrix merged with and into one of Rosewind's merger subsidiaries. Luoxis and Vyrix survived these mergers. The outstanding shares of stock of Luoxis and the outstanding shares of stock of Vyrix were converted into the right to receive shares of common stock in Rosewind. The Luoxis stock and the Vyrix stock were each converted at an exchange factor. The exchange factor for each of them was determined upon the basis of a relative value opinion obtained by Ampio prior to the Merger. The outstanding shares of Rosewind's merger subsidiary that merged with Luoxis were converted into shares of Luoxis as the surviving corporation. The outstanding shares of Rosewind's merger subsidiary that merged with Vyrix were converted into shares of Vyrix as the surviving corporation. After completion of the first stage of the transaction, Luoxis and Vyrix were wholly-owned subsidiaries of Rosewind.

In the second stage of the transaction, which occurred on the same day as the first stage of the transaction, each of Luoxis and Vyrix was merged with and into Rosewind, with Rosewind surviving. The first and second stage mergers are referred to collectively as the Merger. Following the consummation of the Merger, Ampio became the holder of 81.5% of the common stock of Rosewind.

Pursuant to the Merger, Rosewind changed its fiscal year end from August 31 to June 30.

On June 1, 2015, the Rosewind shareholders voted to change the state of incorporation from Colorado to Delaware and to change Rosewind's name to Aytu BioScience, Inc., which was effective June 8, 2015. Along with the reincorporation, Aytu now has 300 million authorized shares of common stock with a par value of \$0.0001 per share and 50 million authorized shares of preferred stock with a par value of \$0.0001 per share. The Aytu shareholders also approved the 2015 Stock Option and Incentive Plan, which provides for the award of stock options, stock appreciation rights, restricted stock and other equity awards for up to an aggregate of 10 million shares of common stock. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by Aytu prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2015 Plan will be added back to the shares of common stock available for issuance under the 2015 Plan. As of September 30, 2015, one grant has been made under the 2015 Plan.

On June 1, 2015, the Rosewind shareholders voted and approved a reverse stock split that was in effect on June 8, 2015. The reverse stock split was at a ratio of one new share for every 12.174 shares outstanding.

**Table of Contents****Business Combination ProstaScint**

In May 2015, Aytu entered into and closed on an Asset Purchase Agreement with Jazz Pharmaceuticals, Inc. (the Seller ). Pursuant to the agreement, Aytu purchased assets related to the Seller s product known as ProstaScint (capromab pendetide), including certain intellectual property and contracts, and the product approvals, inventory and work in progress (together, the ProstaScint Business ), and assumed certain of the Seller s liabilities, including those related to product approvals and the sale and marketing of ProstaScint.

The purchase price consisted of the upfront payment of \$1.0 million. Aytu also agreed to pay an additional \$500,000 payable within five days after transfer for the ProstaScint-related product inventory and \$227,000 that was paid subsequent to September 30, 2015 (which represents a portion of certain FDA fees). Aytu also will pay 8% as contingent consideration on its net sales made after October 31, 2017, payable up to a maximum aggregate payment of an additional \$2.5 million. The contingent consideration was valued at \$664,000 using a discounted cash flow estimate as of the acquisition date. The total fair value consideration for the purchase was \$2.4 million.

The Company s allocation on consideration transferred for ProstaScint as of the purchase date of May 20, 2015 is as follows:

	Estimated Fair Value
Tangible assets	\$ 727,000
Intangible assets	1,590,000
Goodwill	74,000
 Total assets acquired	 \$ 2,391,000

Included in the intangible assets is Developed technology of \$790,000, Customer contracts of \$720,000 and Trade names of \$80,000 each of which will be amortized over a ten-year period.

As of September 30, 2015, the contingent consideration had increased to \$677,000 due to accretion.

**Newly Issued Accounting Pronouncements**

In September 2015, the Financial Accounting Standards Board, FASB issued Accounting Standards Update ( ASU ) 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments, which requires that an acquirer recognize adjustments to estimated amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments require that the acquirer record, in the same period s financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the estimated amounts, calculated as if the accounting had been completed at the acquisition date. The amendments also require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the estimated amounts had been recognized as of the acquisition date. The amendment is effective for financial statements issued for fiscal years beginning after December 15, 2015 and early adoption is permitted. As of September 30, 2015, the Company early adopted this standard.

In July 2015, the FASB issued ASU 2015-12, Plan Accounting: Defined Benefits Pension Plans (Topic 960), Defined Contribution Pension Plans (Topic 962) and Health and Welfare Benefit Plans (Topic 965): I. Fully Benefit-Responsive Investment Contracts; II. Plan Investment Disclosures; and III. Measurement Date Practical Expedient. This three-part ASU simplifies current benefit plan accounting and requires (i) fully benefit-responsive investment contracts to be measured, presented, and disclosed only at contract value and accordingly removes the requirement to reconcile their contract value to fair value; (ii) benefit plans to disaggregate their investments measured using fair value by general type, either on the face of the financial statements or in the notes to the financial statements; (iii) the net appreciation or depreciation in investments for the period to be presented in the aggregate rather than by general type, and removes certain disclosure requirements relevant to individual investments that represent five percent or more of net assets available for benefits. Further, the amendments in this ASU eliminate the requirement to disclose the investment strategy for certain investments that are measured using Net Asset Value ( NAV ) per share using the practical expedient in the FASB ASC Topic 820. Part III of the ASU provides a practical expedient to permit employee benefit plans to measure investments and investment-related accounts as of the month-end that is closest to the plan's fiscal year-end, when the fiscal period does not coincide with a month-end, while requiring certain additional disclosures. The amendments in Parts I and II of this standard are effective retrospectively for fiscal years beginning after December 15, 2015 and early adoption is permitted. The amendments in Part III of this standard are effective prospectively for fiscal years beginning after December 15, 2015 and early adoption is permitted. The Company is currently evaluating the impact of this standard on its financial statements.

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In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*. ASU 2015-11 clarifies that inventory should be held at the lower of cost or net realizable value. Net realizable value is defined as the estimated selling price, less the estimated costs to complete, dispose and transport such inventory. ASU 2015-11 will be effective for fiscal years and interim periods beginning after December 15, 2016. ASU 2015-11 is required to be applied prospectively and early adoption is permitted. The adoption of ASU 2015-11 is not expected to have a material impact on the Company's financial position or results of operations.

In June 2015, the FASB issued ASU 2015-10, *Technical Corrections and Improvements*. The amendments represent changes to clarify the codification, correct unintended application of guidance, or make minor improvements to the codification that are not expected to have a significant effect on current accounting practice or create a significant administrative cost. In addition, some of the amendments will make the codification easier to understand and easier to apply by eliminating inconsistencies, providing needed clarifications, and improving the presentation of guidance in the codification. The amendments that require transition guidance are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. All other amendments will be effective upon issuance. The Company is evaluating the impact of ASU 2015-10 on its financial statements.

In April 2015, the FASB issued ASU 2015-03, *Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* to simplify the presentation of debt issuance costs. The amendments in the update require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct reduction of the carrying amount of the debt. Recognition and measurement of debt issuance costs were not affected by this amendment. In August 2015, FASB issued ASU 2015-15, *Presentation and Subsequent Measurement of Debt Issuance Costs Associated With Line-of-Credit Arrangements* Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting which clarified that the SEC would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement. The amendments are effective for financial statements issued for fiscal years beginning after December 15, 2015. This standard does not have an impact on the Company's financial statements. As of September 30, 2015, the Company early adopted this standard and recorded debt issuance costs as a debt discount. There was no impact related to this adoption as the Company did not have any debt issuance costs previously.

In January 2015, the FASB issued ASU 2015-01, *Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*. The purpose of this amendment is to eliminate the concept of extraordinary items. As a result, an entity will no longer be required to separately classify, present and disclose extraordinary events and transactions. The amendment is effective for annual reporting periods beginning after December 15, 2015 and subsequent interim periods with early application permitted. The Company is evaluating the impact the adoption of ASU 2015-01 will have on its financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. The amendments in this ASU are effective for reporting periods beginning after December 15, 2016, with early adoption permitted. The Company is evaluating the impact the adoption of ASU 2014-15 will have on its financial statements.

In May 2014, the FASB issued ASU 2014-09 regarding ASC Topic 606, *Revenue from Contracts with Customers*. The standard provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services. In August



2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, which deferred the effective date of the new revenue standard for periods beginning after December 15, 2016 to December 15, 2017, with early adoption permitted but not earlier than the original effective date. The Company is currently evaluating the effect that the updated standard will have on its financial statements.

## **Business**

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

**Table of Contents****Note 2 Fixed Assets**

Fixed assets are recorded at cost and, once placed in service, are depreciated on the straight-line method over the estimated useful lives. Fixed assets consist of the following:

	Estimated Useful Lives in years	As of September 30, 2015	As of December 31, 2014
Manufacturing Facility/Clean Room in progress	8	\$ 2,734,000	\$ 2,684,000
Leasehold improvements	10	6,079,000	6,064,000
Office furniture and equipment	3 - 10	555,000	556,000
Lab equipment	5	1,109,000	1,060,000
Less accumulated depreciation and amortization		(1,058,000)	(419,000)
Fixed assets, net		\$ 9,419,000	\$ 9,945,000

**Note 3 Revenue Recognition**

The \$466,000 and \$629,000 product and service revenue recognized in the 2015 quarter and nine month period, respectively, represents sales from Ampio's Aytu segment which includes the ProstaScint product and the RedoxSYS System. We did not generate any product and service revenue in the respective 2014 quarter and period.

The \$21,000 license revenue recognized in the 2015 quarter and 2014 quarter, respectively, and the \$64,000 and \$55,000 license revenue recognized in the 2015 period and 2014 period, respectively, represents the amortization of the upfront payments received from Ampio's license agreements. The initial payment of \$500,000 from the license agreement of Zertane with a Korean pharmaceutical company was deferred and is being recognized over ten years. The initial payment of \$250,000 from the license agreement of Zertane with a Canadian-based supplier was deferred and is being recognized over seven years.

**Note 4 Fair Value Considerations Related to the Company's Subsidiary Aytu**

The Company's financial instruments include cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, convertible notes and warrant derivative liability. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their short maturities. The fair value of the convertible notes is approximately the face value of the notes, \$5,175,000 based upon the valuation that the Company had completed of all components of the convertible notes at inception and as of September 30, 2015. The valuation policies are determined by the Chief Financial Officer and approved by the Company's Board of Directors as deemed appropriate.

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

assumptions of what market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on reliability of the inputs as follows:

- Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to Ampio for identical assets or liabilities;
- Level 2: Inputs include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and
- Level 3: Unobservable inputs that are supported by little or no market activity.

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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 liabilities that were accounted for at fair value on a recurring basis as of September 30, 2015, by level within the fair value hierarchy:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
<u>September 30, 2015</u>				
<b>LIABILITIES</b>				
Warrant derivative liability	\$	\$	\$ 103,000	\$ 103,000

The warrant derivative liability for the warrants was valued using the Monte Carlo valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. Significant assumptions in valuing the warrant derivative liability based on estimates of the value of Ampio's common stock and various factors regarding the warrants, were as follows as of September 30, 2015 and at issuance:

	September 30, 2015	At Issuance
<u>Warrants:</u>		
Exercise price	\$1.51 - \$1.95	\$1.51 - \$1.95
Volatility	75.0%	75.0%
Equivalent term (years)	4.92	5.0 - 5.11
Risk-free interest rate	1.35%	1.54% - 1.74%
Potential number of shares	141,000 - 189,000	139,000 - 224,000

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

	Derivative Instruments
Balance as of December 30, 2014	\$
Warrant issuances	102,931
Included in earnings	(128)
Balance as of September 30, 2015	\$ 102,803

**Table of Contents****Note 5 Commitments and Contingencies**

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

	Total	Remaining 2015	2016	2017	2018	2019	Thereafter
Ampion supply agreement	\$ 5,100,000	\$	\$	\$ 2,550,000	\$ 2,550,000	\$	\$
Clinical research and trial obligations	4,385,000	1,901,000	2,443,000	41,000			
Facility lease	3,415,000	107,000	435,000	450,000	418,000	326,000	1,679,000
Sponsored research agreement with related party	1,505,000	99,000	395,000	395,000	395,000	151,000	70,000
	\$ 14,405,000	\$ 2,107,000	\$ 3,273,000	\$ 3,436,000	\$ 3,363,000	\$ 477,000	\$ 1,749,000

***Ampion Supply Agreement***

In connection with the manufacturing facility/clean room, in October 2013, Ampio entered into a human serum albumin ingredient and purchase sale agreement with a remaining commitment of \$5,100,000. Per an amendment to the original agreement, Ampio is not committed to take its full allocation in 2015 and no purchases in 2016 and has extended the agreement to 2018.

***Clinical Research and Trial Obligations***

In connection with upcoming clinical trials, as of September 30, 2015, Ampio has a remaining commitment of \$3,969,000 on contracts related to the Ampion study trial expense and \$150,000 remaining contract commitments related to the Optina study trial expense. The clinical trial and research studies related to Aytu have a remaining commitment of \$266,000.

***Facility Lease***

On December 13, 2013, Ampio entered into a 125 month non-cancellable operating lease for new office space and the manufacturing facility effective May 1, 2014. The new lease has initial base rent of \$23,000 per month, with the total base rent over the term of the lease of approximately \$3.3 million and includes rent abatements and leasehold incentives. The Company recognizes rental expense of the facility on a straight-line basis over the term of the lease. Differences between the straight-line net expenses on rent payments are classified as liabilities between current deferred rent and long-term deferred rent.

In June 2015, Aytu entered into a 37 month operating lease for a space in Raleigh, North Carolina. This lease has initial base rent of \$2,900 a month, with total base rent over the term of the lease of approximately \$112,000. In September 2015, the Company entered into a 37 month operating lease in Englewood, Colorado. This lease has an initial base rent of \$8,500 a month with a total base rent over the term of the lease of approximately \$318,000. The

Company recognizes rental expense of the facilities on a straight-line basis over the term of the lease. Differences between the straight-line net expenses on rent payments are classified as liabilities between current deferred rent and long-term deferred rent.

Rent expense for the respective periods is as follows:

	Three Months Ended September 30, 2015		Nine Months Ended September 30, 2014	
	2015	2014	2015	2014
Rent expense	\$ 81,000	\$ 98,000	\$ 219,000	\$ 221,000

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

Ampio entered into a Sponsored Research Agreement with Trauma Research LLC ( TRLLC ), a related party, in September 2009. Under the terms of the Sponsored Research Agreement, Ampio is to provide personnel and pay for leased equipment. The Sponsored Research Agreement may be terminated without cause by either party on 180 days notice. As further noted in Note 9 Related Party Transactions, in March 2014, the Sponsored Research Agreement was extended through March 2019, including a no termination period through March 2017. In a subsequent Addendum, the parties also agreed to increase the equivalent value of the personnel provided by Ampio from \$264,000 to \$325,000 per year.

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**Table of Contents****Note 6 Convertible Promissory Notes Pertaining to the Company's Subsidiary Aytu*****Convertible Promissory Notes***

During July and August 2015, Aytu closed on note purchase agreements with institutional and high net worth individual investors for the purchase and sale of convertible promissory notes ( Notes ) with an aggregate principal amount of \$5.2 million. The sale of the Notes was pursuant to a private placement. Debt issuance costs totaled \$401,000 which includes \$103,000 fair value of the warrants.

The Notes are an unsecured obligation. Unless earlier converted, the Notes will mature 18 months from their respective dates of issuance which will be on January 22, February 11 and February 28, 2017, with an option to extend the maturity date up to six months at Aytu's discretion (provided that in the event Aytu exercises such extension option, the then applicable interest rate shall increase by 2% for such extension period). Aytu does not have the right to prepay the Notes prior to the maturity date. Interest will accrue on the Notes in the following amounts: (i) 8% simple interest per annum for the first six months and (ii) 12% simple interest per annum thereafter if not converted during the first six months. If there has not been a registration statement on Form S-1 filed with the SEC for the registration of the shares of common stock underlying the Notes by the expiration of the first six-month period then (a) the interest rate will increase to 14% for the remainder of the period in which the Notes remain outstanding and (b) any Notes held by officers and directors of Aytu will be subordinated to the remaining Notes. Interest will accrue, is payable with the principal upon maturity, conversion or acceleration of the Notes and may be paid in kind or in cash, in Aytu's sole discretion.

The 4% increase in the interest rate is triggered automatically with the passage of time and is not a contingent feature, thus, there is no initial accounting for this feature. However, the periodic interest cost will be calculated using a constant effective interest over the life of the Notes. As Aytu's management does not intend to utilize the extension option, the expected life of the Notes is 18 months.

Aytu did not give recognition to the registration rights arrangement as management did not believe at issuance that probable payment under the contingent escalation clause would be required, thus there was no impact on the initial measurement of the Notes. Aytu satisfied the registration rights arrangement in October 2015 upon the effectiveness of a registration statement on Form S-1.

The Notes are convertible at any time at the noteholder's discretion into that number of shares of Aytu common stock equal in an amount equal to 120% of the number of shares of common stock calculated by dividing the then outstanding principal and accrued interest by \$4.63. A holder of Notes will be obligated to convert on the terms of Aytu's next public offering of its stock resulting in gross proceeds of at least \$5,000,000 (excluding indebtedness converted in such financing) prior to the maturity date of the Notes (a Qualified Financing ). The principal and accrued interest under the Notes will automatically convert into a number of shares of such equity securities of Aytu sold in the Qualified Financing equal to 120% of the principal and accrued interest under such Note divided by the lesser of (i) the lowest price paid by an investor in the Qualified Financing or (ii) \$4.63. In the event that Aytu sells equity securities to investors at any time while the Notes are outstanding in a financing transaction that is not a Qualified Financing, then the noteholders will have the option to convert in whole the outstanding principal and accrued interest as of the closing of such financing into a number of shares of Aytu capital stock in an amount equal to 120% of the number of such shares calculated by dividing the outstanding principal and accrued interest by the lesser of (i) the lowest cash price per share paid by purchasers of shares in such financing, or (ii) \$4.63.

Aytu determined that the conversion option is not required to be bifurcated and accounted for as an embedded derivative liability. There was no intrinsic value to the beneficial conversion feature as it was determined that the

effective conversion price exceeded the commitment date valuation price.

The Notes contained a purchase premium option in the event of a sale transaction as defined in the Notes. A holder of the Notes will be entitled to receive, at the holder's option, (i) repayment of the Note balance plus the amount equal to 25% of the original purchase amount or (ii) the consideration the holder would have received on an as-converted basis. Given that the payment under the purchase premium is contingent upon a sale transaction and involves a substantial premium of 25%, the purchase premium is an embedded derivative that must be bifurcated and accounted for as an embedded derivative. No value was recorded related to this derivative at issuance and September 30, 2015.

Newbridge Securities Corporation, a FINRA/IPC member, through Life Tech Capital, acted as sole placement agent for the institutional portion of the offering of the Notes. Aytu sold the balance of the Notes to individuals and entities with whom Aytu has an established relationship. For Notes sold by the placement agent, Aytu paid the placement agent 8% of the gross proceeds of Notes sold by the placement agent and is obligated to issue warrants for an amount of shares to be equal to 8% of the gross number of shares of Aytu stock issuable upon conversion of the Notes issued to investors introduced to Aytu by the private placement agents in the private placement, in addition to a previously paid non-refundable retainer fee of \$20,000. The placement agent warrant has a term of five years, will have an exercise price equal to the lowest conversion price per share at which the Notes are converted into common stock. Change in fair value is recorded in earnings. Fair value at the grant date was recorded as a debt discount and amortized over the term of the debt.



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The warrants were recorded at fair value as long-term liabilities on the Balance Sheet. See Note 4.

Per our adoption ASU 2015-3, the costs associated with the Notes were recorded as a long-term liability and are presented in the Balance Sheet as a direct reduction of the carrying amount of the Notes on their inception date.

As of September 30, 2015, the carrying value of the Notes was \$4.8 million inclusive of an unamortized debt discount of \$350,000.

## **Note 7 Common Stock**

### ***Capital Stock***

At September 30, 2015 and December 31, 2014, Ampio had 100.0 million shares of common stock authorized with a par value of \$0.0001 per share and 10.0 million shares of preferred stock authorized with a par value of \$0.0001 per share.

### ***Shelf Registration***

In December 2013, Ampio filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission to register Ampio common stock and warrants in an aggregate amount of up to \$100.0 million for offering from time to time in the future, as well as 1.5 million shares of common stock available for sale by selling shareholders. The shelf registration was declared effective in January 2014 by the Securities and Exchange Commission. As a result of equity raises, approximately \$86.3 million remains available under the Form S-3 filed in December 2013.

### ***Underwritten Public Offerings***

In March 2014, Ampio completed an underwritten public offering for the sale of 9,775,000 shares of common stock at a price of \$7.00 per share. Gross proceeds to the Company were \$68.4 million with net proceeds of \$63.4 million after underwriter fees and cash offering expenses.

### ***Common Stock Issued for Services***

Ampio issued 7,998 and 4,209 shares valued at \$30,000 for non-employee directors as part of their director fees for the nine months ended September 30, 2015 and 2014, respectively.

## **Note 8 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.

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Ampio has computed the fair value of all options granted using the Black-Scholes option pricing model. In order to calculate the fair value of the options, certain assumptions are made regarding components of the model, including the estimated fair value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield and expected option life. Changes to the assumptions could cause significant adjustments to valuation. Ampio calculates its volatility assumption using the actual changes in the market value of its stock. Ampio has estimated a forfeiture rate of 5.7% based upon historical experience; this is an estimate of options granted that are expected to be forfeited or cancelled before becoming fully vested. Ampio estimates the expected term based on the average of the vesting term and the contractual term of the options. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. During the nine months ended September 30, 2015, Ampio granted 30,000 options at a price of \$3.46, 33,000 at a price of \$2.47, 425,000 options at a price of \$2.60 and 170,000 at a price of \$2.68 to employees which represented the fair market value on date of the grants. Included in these options were 470,000 of performance-based options based upon the outcome of the ongoing Ampion trial. Also included in the total options granted during the nine months ended September 30, 2015 is the 275,000 of modified options held by a former executive. The expense related to this modification was recognized in the period ended June 30, 2015. These same modified options are considered forfeited then re-granted during the nine months ended September 30, 2015. Ampio has computed the fair value of all options granted during the nine months ended September 30, 2015 using the following assumptions:

Expected volatility	104% - 113%
Risk free interest rate	.05% - 1.62%
Expected term (years)	1.50 - 6.01
Dividend yield	0%

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Ampio stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Expected Life in years
Outstanding December 31, 2014	6,568,248	\$ 3.82	7.66
Granted	933,000	\$ 3.29	
Exercised	(10,416)	\$ 2.76	
Forfeited	(275,000)	\$ 4.80	
Expired or Cancelled	(60,000)	\$ 3.53	
Outstanding September 30, 2015	7,155,832	\$ 3.72	6.76
Exercisable at September 30, 2015	5,985,940	\$ 3.68	6.27
Available for grant at September 30, 2015	3,149,773		

Stock options outstanding and exercisable at September 30, 2015 are summarized in the table below:

Range of Exercise Prices	Number of Options Outstanding and Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Expected Life in years
\$1.03 - \$4.00	4,980,832	\$ 2.04	5.17
\$4.01 - \$7.00	1,240,000	\$ 6.17	7.99
\$7.01 - \$8.93	935,000	\$ 7.73	7.52
	7,155,832	\$ 3.72	6.76

The Luoxis options that were in the money and all outstanding Vyrix options issued under the 2013 Option Plans were accelerated and cancelled in connection with the Merger. Option holders received a cash payment per option share equal to the difference between the consideration payable per share of common stock pursuant to the Merger and the exercise price of the option, if the consideration paid to holders of common stock was less than the exercise price of such options, no amount was paid to the option holder in connection with the cancellation. The cash payment during the period ended June 30, 2015 was \$27,000. The Company recognized compensation of \$422,000 and \$189,000 related to the Luoxis and Vyrix options that had accelerated vesting as of the Merger date.

The Luoxis options that were not paid out were terminated pursuant to the terms of the 2013 Luoxis Option Plan. The Company treated these options as pre-vesting forfeitures and \$433,000 of previously recognized compensation was reversed.

On June 1, 2015, Aytu's stockholders approved the 2015 Stock Option and Incentive Plan (the "2015 Plan"), which provides for the award of stock options, stock appreciation rights, restricted stock and other equity awards for up to an aggregate of 10 million shares of common stock. The shares of common stock underlying any awards that are

forfeited, canceled, reacquired by Aytu prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2015 Plan will be added back to the shares of common stock available for issuance under the 2015 Plan. As of September 30, 2015, one grant has been made under the 2015 Plan.

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The fair value of the options was calculated using the Black-Scholes option pricing model. In order to calculate the fair value of the options, certain assumptions are made regarding components of the model, including the estimated fair value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield and expected option life. Changes to the assumptions could cause significant adjustments to valuation. Aytu 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. Aytu has computed the fair value of all options granted during the three months ended September 30, 2015 using the following assumptions:

Expected volatility	75.00%
Risk free interest rate	1.08% - 1.59%
Expected term (years)	3.0 - 4.5
Dividend yield	0%

Aytu stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Expected Life in Years
Outstanding December 31, 2014		\$	
Granted	50,000	\$ 4.63	
Exercised		\$	
Forfeited/Cancelled		\$	
Outstanding September 30, 2015	50,000	\$ 4.63	4.86
Exercisable at September 30, 2015		\$	
Available for grant at September 30, 2015	9,950,000		

Stock-based compensation expense related to the fair value of stock options was included in the consolidated statements of operations as research and development expenses and selling, general and administrative expenses as set forth in the table below. Ampio and its subsidiary determined the fair value as of the date of grant using the Black-Scholes option pricing model and expenses the fair value ratably over the vesting period. The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2015 and 2014:

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	Three Months Ended September 30, 2015		Nine Months Ended September 30, 2014	
Research and development expenses				
Stock options				
Ampio	\$ 354,000	\$ 1,724,000	\$ 1,411,000	\$ 2,761,000
Aytu	159,000	90,000	316,000	231,000
Selling, general and administrative expenses				
Common stock issued for services			30,000	30,000
Stock options				
Ampio	340,000	572,000	2,069,000	1,963,000
Aytu	87,000	112,000	292,000	169,000
	\$ 940,000	\$ 2,498,000	\$ 4,118,000	\$ 5,154,000
Unrecognized expense at September 30, 2015				
Ampio	\$ 1,223,000			
Aytu	\$ 10,000			
Weighted average remaining years to vest				
Ampio	0.56			
Aytu	3.55			

**Warrants**

Ampio issued warrants in conjunction with its Senior Convertible Debentures, 2011 Private Placements and an underwritten public offering. A summary of all Ampio warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in years
Outstanding December 31, 2014	516,329	\$ 3.26	1.44
Warrants exercised Private/Registered Direct Placements	(17,253)	\$ 3.94	
Outstanding September 30, 2015	499,076	\$ 3.24	0.66

Luoxis had 465,250 warrants with an exercise price of \$1.00 which were converted into Aytu warrants to purchase 102,613 shares of common stock at a price of \$4.53. This conversion occurred in April 2015 when the Aytu transaction closed. These warrants have been adjusted to reflect the reverse stock split which occurred in June 2015. All of these warrants remain outstanding with a weighted average remaining contractual life of 2.92 years.

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***Warrant Obligation related to the Convertible Promissory Notes Pertaining to the Company's Subsidiary Aytu***

Aytu has the obligation to issue warrants to the private placement agents as part of their fees for servicing in the convertible note financing. These warrants are classified as a derivative warrant liability due to the fact that the number of shares and the exercise price have not been set as of September 30, 2015. The number of shares of the Aytu stock that these warrants will convert into equal to 8% of the gross number of shares of Aytu stock issuable upon conversion of the Notes issued to investors introduced to Aytu by the private placement agents pursuant to the private placement memorandum. The exercise price will be the lowest conversion price per share at which the Notes are converted into Aytu common stock. The warrants have a term of five years from August 31, 2015.

**Note 9 Related Party Transactions**

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

In June 2013, the TRLLC agreement was amended to include Luoxis, which is now a part of Aytu. The agreement, which was amended again in January 2015, provides for Aytu to pay \$6,000 per month to TRLLC in consideration for services related to research and development of Aytu's RedoxSYS platform. In March 2014, Luoxis also agreed to pay \$615,000 which is being amortized over the contractual term of 60.5 months and is divided between current and long-term on the balance sheet; this amount has been paid in full. This agreement has the same termination and expiration as the agreement between Ampio and TRLLC.

The Company has advances to one executive and three employees that were used to purchase stock in the Company when it was formed during 2010. These advances are non-interest bearing and due on demand and are classified as a reduction to stockholders' equity. As of September 30, 2015 and December 31, 2014, advances of \$91,000 to stockholders remained outstanding.

The convertible promissory notes (see Note 6) include \$275,000 invested by relatives of senior management of Aytu.

**Table of Contents****Note 10 Segment Information**

We manage our Company and aggregate our operational and financial information in accordance with two reportable segments: Ampio and Aytu. The Ampio segment consists of our core biopharmaceuticals compounds and the clinical trials associated with them. The Aytu segment contains our men's health platform which consists of its diagnostic device platform and sexual dysfunction portfolio. Select financial information for our segments is as follows:

	Three Months Ended September 30, 2015		Nine Months Ended September 30, 2014	
	2015	2014	2015	2014
<b>Revenue:</b>				
Ampio	\$	\$	\$	\$
Aytu	487,000	21,000	693,000	55,000
Consolidated revenue	\$ 487,000	\$ 21,000	\$ 693,000	\$ 55,000
<b>Consolidated net loss:</b>				
Ampio	\$ (5,302,000)	\$ (7,363,000)	\$ (16,818,000)	\$ (22,773,000)
Aytu	(2,485,000)	(2,129,000)	(6,274,000)	(6,123,000)
Consolidated net loss	(7,787,000)	(9,492,000)	(23,092,000)	(28,896,000)
<b>Reconciliation of consolidated net loss attributable to Ampio:</b>				
Net loss applicable to non-controlling interests	421,000	212,000	1,087,000	682,000
Net loss attributable to Ampio	\$ (7,366,000)	\$ (9,280,000)	\$ (22,005,000)	\$ (28,214,000)

	September 30, 2015	December 31, 2014
<b>Total assets</b>		
Ampio	\$ 35,823,000	\$ 61,326,000
Aytu	21,256,000	8,942,000
Total assets	\$ 57,079,000	\$ 70,268,000

**Note 11 Litigation**

On May 8, 2015 and May 14, 2015, purported stockholders of the Company brought two putative class action lawsuits in the United States District Court in the Central District of California, Napoli v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03474-TJH and Stein v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03640-TJH (the Securities Class Actions), alleging that Ampio and certain of its current and former officers violated federal securities laws by misrepresenting and/or omitting information regarding the STEP study. The lawsuits seek unspecified damages, pre-judgment and post-judgment interest, and attorneys' fees and costs.



On August 6, 2015 and September 25, 2015, purported stockholders of the Company brought derivative actions in the United States District Court in the Central District of California, Oglina v. Macaluso et al., Case No. 2:15-cv-05970-TJH-PJW ( Oglina action ) and the Colorado state court in Denver, Loyd v. Giles et al., Case No. 2015CV33429 ( Loyd action ), alleging primarily that the directors and officers of Ampio breached their fiduciary duties because of their alleged misstatements and/or omissions regarding the STEP study. The United States District Court in the Central District of California has stayed the proceedings in the Oglina action because it is related to the pending Securities Class Actions. Counsel are also seeking a stay in the Loyd action for the same reason.

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

#### **Note 12 Subsequent Events**

On October 5, 2015, Aytu entered into and closed on an Asset Purchase Agreement with FSC Laboratories, Inc. (the Seller ). Pursuant to the agreement, Aytu purchased assets related to the Seller s product known as Primisol (trimethoprim solution), including certain intellectual property and contracts, inventory, work in progress and all marketing and sales assets and materials related solely to Primisol (together, the Primisol Business ), and assumed certain of the Seller s liabilities, including those related to the sale and marketing of Primisol arising after the closing.

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Aytu paid \$500,000 at closing for the Primsol Business and Aytu also agreed to pay an additional \$142,000 payable within five days after transfer of the Primsol-related product inventory. Aytu also agreed to pay an additional (a) \$500,000 payable no later than March 31, 2016, (b) \$500,000 payable no later than June 30, 2016, and (c) \$250,000 payable no later than September 30, 2016 (together, the **Installment Payments** ).

On October 8, 2015, Aytu entered into a Master Services Agreement with Biovest International, Inc. ( **Biovest** ). The agreement provides that Aytu may engage Biovest from time to time to provide services in accordance with mutually agreed upon project addendums and purchase orders. Aytu expects to use the agreement from time to time for manufacturing services, including without limitation, the manufacturing, processing, quality control testing, release or storage of its products.

The agreement provides customary terms and conditions, including those for performance of services by Biovest in compliance with project addendums, industry standards, regulatory standards and all applicable laws. Biovest will be responsible for obtaining and maintaining all governmental approvals, at our expense, during the term of the agreement.

The agreement has a term of four years, provided that either party may terminate the agreement or any project addendum under the agreement on 30 days written notice of a material breach under the agreement. In addition, Aytu may terminate the agreement or any project addendum under the agreement upon 180 days written notice for any reason.

In conjunction with entering into the agreement, Aytu submitted a work order to Biovest to provide us with active pharmaceutical ingredient for ProstaScint over a four-year period at a total cost of \$5,000,000, of which Aytu paid \$1,000,000 upon submission of the work order and anticipate paying the remaining balance as follows:

2015	\$ 500,000
2016	1,500,000
2017	1,000,000
2018	500,000
2019	500,000
	\$ 4,000,000

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

*This discussion should be read in conjunction with our historical consolidated financial statements. The following discussion and analysis contain forward-looking statements that involve risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. For additional information regarding these risks and uncertainties, please see Part II, Item 1A of this Form 10-Q, **Risk Factors**, and the risk factors included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 24, 2015.*

**Overview**

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

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

## **MERGER/SUBSIDIARY**

### **Aytu BioScience, Inc.**

On April 16, 2015, Luoxis and Vyrrix, each previously a subsidiary of ours, entered into an Agreement and Plan of Merger, or the Merger Agreement, by and among Rosewind Corporation, a Colorado corporation and public company, or Rosewind, Luoxis, Vyrrix, two major stockholders of Rosewind and two subsidiaries of Rosewind created solely for the purposes of the Merger (as defined below), and which did not survive the Merger.

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In the first stage of the transaction, each of Luoxis and Vyrix merged with and into one of Rosewind's merger subsidiaries. Luoxis and Vyrix survived these mergers. The outstanding shares of stock of Luoxis and the outstanding shares of stock of Vyrix were converted into the right to receive shares of common stock in Rosewind. The Luoxis stock and the Vyrix stock were each converted at an exchange factor. The exchange factor for each of them was determined upon the basis of a relative value opinion obtained by Ampio prior to the Merger. The outstanding shares of Rosewind's merger subsidiary that merged with Luoxis were converted into shares of Luoxis as the surviving corporation. The outstanding shares of Rosewind's merger subsidiary that merged with Vyrix were converted into shares of Vyrix as the surviving corporation. After completion of the first stage of the transaction, Luoxis and Vyrix were wholly-owned subsidiaries of Rosewind.

In the second stage of the transaction, which occurred on the same day as the first stage of the transaction, each of Luoxis and Vyrix was merged with and into Rosewind, with Rosewind surviving. The first and second stage mergers are referred to collectively as the Merger. Following the consummation of the Merger, we became the holder of 81.5% of the common stock of Rosewind.

Pursuant to the Merger, Rosewind changed its fiscal year end from August 31 to June 30.

On June 1, 2015, the Rosewind shareholders voted to change the state of incorporation from Colorado to Delaware and to change the Rosewind's name to Aytu BioScience, Inc., which was effective June 8, 2015. Along with the reincorporation, Aytu now has 300 million authorized shares of common stock with a par value of \$0.0001 per share and 50 million authorized shares of preferred stock with a par value of \$0.0001 per share. The Aytu shareholders also approved the 2015 Stock Option and Incentive Plan, which provides for the award of stock options, stock appreciation rights, restricted stock and other equity awards for up to an aggregate of 10 million shares of common stock. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by Aytu prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2015 Plan will be added back to the shares of common stock available for issuance under the 2015 Plan. At the time of this filing, one grant has been made under the 2015 Plan.

On June 1, 2015, the Rosewind shareholders voted and approved a reverse stock split that was in effect on June 8, 2015. The reverse stock split was at a ratio of one new share for every 12.174 shares outstanding.

In May 2015, Aytu entered into and closed on an asset purchase agreement with Jazz Pharmaceuticals, Inc., pursuant to which Aytu purchased assets related to Jazz Pharmaceuticals' product known as ProstaScint® (capromab pendetide), including certain intellectual property and contracts, and the product approvals, inventory and work in progress (together, the ProstaScint Business), and assumed certain of Jazz Pharmaceuticals' liabilities, including those related to product approvals and the sale and marketing of ProstaScint. The purchase price consists of the upfront payment of \$1.0 million. Aytu also agreed to pay an additional \$500,000 payable within five days after transfer for the ProstaScint-related product inventory and \$227,000 payable on September 30, 2015 (which represents a portion of certain FDA fees). Aytu also will pay 8% on its net sales made after October 31, 2017, payable up to a maximum aggregate payment of an additional \$2.5 million.

During July and August 2015, Aytu issued in a private placement unsecured convertible promissory notes (Notes) with an aggregate principal amount of \$5.2 million. Aytu also is obligated to issue to the placement agents in the private placement, warrants which will convert into 8% of the gross number of shares of Aytu stock issuable upon conversion of the Notes issued to investors introduced to Aytu by the private placement agents pursuant to the private placement. The placement agent warrants have a term of five years, will have an exercise price equal to the lowest conversion price per share at which the Notes are converted into Aytu common stock.



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In October 2015, Aytu entered into and closed on an Asset Purchase Agreement with FSC Laboratories, Inc. (the Seller ). Pursuant to the agreement, Aytu purchased assets related to the Seller's product known as Primisol® (trimethoprim solution), including certain intellectual property and contracts, inventory, work in progress and all marketing and sales assets and materials related solely to Primisol (together, the Primisol Business ), and assumed certain of the Seller's liabilities, including those related to the sale and marketing of Primisol arising after the closing. Aytu paid \$500,000 at closing for the Primisol Business and Aytu agreed to pay an additional \$142,000 payable within five days after transfer of the Primisol-related product inventory. Aytu also agreed to pay an additional (a) \$500,000 payable no later than March 31, 2016, (b) \$500,000 payable no later than June 30, 2016, and (c) \$250,000 payable no later than September 30, 2016 (together, the Installment Payments ). The accounting for this business combination is not yet complete and the amount assigned to the assets acquired is provisional because the final appraisal report has not been received at the time of this filing.

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### **Product Update**

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

#### **AMPION**

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

We have completed multiple clinical trials in the development of Ampion. Clinical trial development began in 2011 with a Phase I/II study. In 2013, we announced the results of the single injection Phase III Spring study, which met its primary endpoint, and was deemed by the FDA as one of the two pivotal trials required to support a Biologics License Application, or BLA. Results of the Spring study have been published. Multiple injections were evaluated in the first and second quarter of 2015. The multiple injection Phase II Strut study demonstrated a 64% reduction in pain over baseline at 20 weeks. The multiple injection Stride Study did not reach its primary endpoint, though it did demonstrate a significant reduction in pain over baseline at 20 weeks. In July 2015, we held an investor call and announced our meeting with the FDA where a single injection clinical trial and a Special Protocol Assessment, or SPA, were recommended by the FDA as the second, and final, pivotal trial for the BLA. An SPA is a process by which the FDA provides written agreement on the design and size of a clinical protocol for the purpose of BLA filing. An SPA can significantly de-risk the path to market due to insufficient data or unexpected safety concerns. On September 22, 2015 Ampio announced the FDA awarded Ampio an SPA and the second Phase III pivotal trial of Ampion had begun. The clinical trial is currently underway.

#### **OPTINA**

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

In 2012, we announced results for a Phase II study. In November 2014, we announced the completion of the OptimEyes study and the beginning of statistical analysis. In May 2015, we announced initial results for the OptimEyes study and released additional analysis in July 2015, which showed Optina is effective when given at the correct dose for body mass index (BMI) in a subset of patients. Additionally, analysis demonstrated a synergistic effect of Optina with common kidney-induced high blood pressure medications (angiotensin receptor blocker and angiotensin converting enzyme inhibitor). On October 14, 2015, following a meeting with the FDA, Ampio announced updates on the regulatory path for FDA approval of Optina. The guidance from the FDA was that: Ampio perform a confirmatory study on patients with Diabetic Macular Edema 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 will have approximately 80 patients randomized 1:1 between placebo and Optina, which is significantly fewer patients than in the previous OptimEyes study; Optina will be compared to placebo, not to anti-vascular endothelial growth factor (VEGF) drugs; the FDA will consider improved vision as measured by Best Corrected Visual Acuity (BCVA), which is statistically significant and clinically meaningful as determined by experts in the field; the duration of the study will be a maximum of 12 months.

## **Future Development**

We also intend to study Ampion<sup>®</sup> for therapeutic applications outside of osteoarthritis of the knee. We expect to engage development partners to study Ampion<sup>®</sup> in various conditions including: (i) acute and chronic inflammatory conditions; (ii) degenerative bone diseases; and (iii) respiratory and allergic disorders. Based on the continuing evaluation, we are also studying Ampion<sup>®</sup>'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<sup>®</sup> clinical portfolio, and will enable clinical applications in large therapeutic markets where there are significant unmet needs. We expect that initial investigations into strategically attractive indications will be conducted on an investigator-sponsored basis.

## **Aytu Products:**

### **PROSTASCINT**

In May 2015, Aytu acquired ProstaScint from Jazz Pharmaceuticals. ProstaScint is the only commercially available diagnostic imaging agent approved by the U.S. Food and Drug Administration or the FDA that specifically targets prostate cancer cells that have spread to tissue outside of the prostate gland. ProstaScint was approved by the FDA in October 1996 and was initially commercialized by Cytogen which was acquired by EUSA Pharma. Jazz Pharmaceuticals acquired EUSA Pharma and its product portfolio including ProstaScint in 2012.



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### **PRIMSOL**

In October 2015, Aytu acquired Primsol (trimethoprim hydrochloride) from FSC Laboratories, Inc. Primsol is the only FDA-approved trimethoprim-only oral solution and is standard therapy for urinary tract infections. Primsol is a sulfa-free, pleasant tasting liquid that is appropriate for patients that are sulfa allergic and individuals that have difficulty swallowing pills. Primsol was approved by the FDA in 2000 and was originally marketed by Ascent Pediatrics. FSC Laboratories acquired Primsol from Taro Pharmaceutical.

### **REDOXSYS**

RedoxSYS is a novel, diagnostic platform comprised of a first-in-class, point-of-care device and disposable testing strips that together measure the presence of oxidative stress and antioxidant reserves. We believe this device could also be used as a key indicator in male reproductive health as a stand-alone application. Currently, the device is being studied in over 60 research collaborations that will continue through 2015. To date, the revenue related to the device and the test strips is not material.

### **MIOXSYS**

Aytu intends to leverage our RedoxSYS research tool to develop a clinical application known as MiOXSYS to assess oxidative stress levels in infertile males. Proof of concept studies in male infertility have been conducted with a leading center in the United States and determined that oxidation-reduction potential effectively measures oxidative stress levels in semen and seminal fluid. Semen analysis studies are routinely conducted to assess causes of infertility, so we expect clinicians and oxidative stress researchers to readily integrate MiOXSYS into routine use. Additional studies are now underway that will determine the MiOXSYS system's performance in semen analysis as it relates to infertility.

### **ZERTANE**

Zertane is an oral drug subject to an open Investigational New Drug Application for a Phase III clinical trial for the treatment of premature ejaculation, or PE. The FDA has accepted our Investigational New Drug application and a Phase III clinical study may now begin in the United States although we not have yet determined when this study will start.

### **AMPION MANUFACTURING FACILITY**

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

During July 2014, we moved into our new headquarters, manufacturing and research facility. Our new manufacturing facility will initially provide registration batches of Ampion supporting the BLA. We have completed validation on the facility, utilities, analytical laboratories and manufacturing equipment. We have also successfully completed FDA requirements for aseptic process simulation and manufacture product for use in clinical investigation. Once the manufacturing operation is approved by the FDA for commercial production, the facility is expected to have an annual production capacity of approximately ten million doses of Ampion. The raw material, HSA, required to manufacture Ampion has already been secured through a long-term, non-exclusive, supply agreement. We expect the facility will be fully placed in service in 2016. The total cost of the facility was approximately \$10.4 million. We have manufactured the Ampion drug and placebo (Saline) for the second Phase III Ampion trial which started during the

third quarter 2015.

## **KNOWN TRENDS OR FUTURE EVENTS**

We have not generated any significant revenues and have therefore incurred significant net losses totaling \$123.9 million since our inception in December 2008. The assets we purchased from BioSciences in April 2009 generated minimal revenues prior to their acquisition. We expect to generate operating losses for the foreseeable future, but intend to try to limit the extent of these losses by entering into co-development or collaboration agreements with one or more strategic partners. Although we have raised capital in the past with net proceeds of \$63.4 million, \$28.9 million and \$15.4 million through the sale of common stock in 2014, 2013 and 2012, respectively, we cannot assure you that we will be able to secure such additional financing, if needed, or that it will be adequate to execute our business strategy. Even if we obtain additional financing, it may be costly and may require us to agree to covenants or other provisions that will favor new investors over existing shareholders.

Our primary focus is advancing the clinical development of our core assets: Ampion and Optina.

## **ACCOUNTING POLICIES**

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

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of the consolidated financial statements requires management to make estimates and

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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, stock compensation, valuation of derivative instruments, allowances and contingencies. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The methods, estimates, and judgments used by us in applying these most critical accounting policies have a significant impact on the results we report in our financial statements. Our significant accounting policies and estimates are included in our 2014 Annual Report reported on Form 10-K, filed with the SEC on February 24, 2015.

Ampio accounts for financial instruments (convertible debt with embedded derivative features conversion options and conversion provisions) and related warrants by recording the fair value of each instrument in its entirety and recording the fair value of the warrant derivative liability. The fair value of the financial instruments and related warrants was calculated using a Monte Carlo based valuation model. Ampio recorded a derivative expense at the inception of the instrument reflecting the difference between the fair value and cash received. Changes in the fair value in subsequent periods will be recorded as unrealized gain or loss on fair value of debt instruments for the financial instruments and to derivative income or expense for the warrants.

**Newly Issued Accounting Pronouncements**

In September 2015, the FASB issued Accounting Standards Update ( ASU ) 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments, which require that an acquirer recognize adjustments to estimated amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the estimated amounts, calculated as if the accounting had been completed at the acquisition date. The amendments also require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the estimated amounts had been recognized as of the acquisition date. The amendment is effective for financial statements issued for fiscal years beginning after December 15, 2015 and early adoption is permitted. As of September 30, 2015, we early adopted this standard.

In July 2015, the FASB issued ASU 2015-12, Plan Accounting: Defined Benefits Pension Plans (Topic 960), Defined Contribution Pension Plans (Topic 962) and Health and Welfare Benefit Plans (Topic 965): I. Fully Benefit-Responsive Investment Contracts; II. Plan Investment Disclosures; and III. Measurement Date Practical Expedient. This three-part ASU simplifies current benefit plan accounting and requires (i) fully benefit-responsive investment contracts to be measured, presented, and disclosed only at contract value and accordingly removes the requirement to reconcile their contract value to fair value; (ii) benefit plans to disaggregate their investments measured using fair value by general type, either on the face of the financial statements or in the notes to the financial statements; (iii) the net appreciation or depreciation in investments for the period to be presented in the aggregate rather than by general type, and removes certain disclosure requirements relevant to individual investments that represent five percent or more of net assets available for benefits. Further, the amendments in this ASU eliminate the requirement to disclose the investment strategy for certain investments that are measured using Net Asset Value ( NAV ) per share using the practical expedient in the FASB ASC Topic 820. Part III of the ASU provides a practical expedient to permit employee benefit plans to measure investments and investment-related accounts as of the month-end that is closest to the plan's fiscal year-end, when the fiscal period does not coincide with a month-end, while requiring certain additional disclosures. The amendments in Parts I and II of this standard are effective

retrospectively for fiscal years beginning after December 15, 2015 and early adoption is permitted. The amendments in Part III of this standard are effective prospectively for fiscal years beginning after December 15, 2015 and early adoption is permitted. We are currently evaluating the impact of this standard on our financial statements.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*. ASU 2015-11 clarifies that inventory should be held at the lower of cost or net realizable value. Net realizable value is defined as the estimated selling price, less the estimated costs to complete, dispose and transport such inventory. ASU 2015-11 will be effective for fiscal years and interim periods beginning after December 15, 2016. ASU 2015-11 is required to be applied prospectively and early adoption is permitted. The adoption of ASU 2015-11 is not expected to have a material impact on our financial position or results of operations.

In June 2015, the FASB issued ASU 2015-10, *Technical Corrections and Improvements*. The amendments represent changes to clarify the codification, correct unintended application of guidance, or make minor improvements to the codification that are not expected to have a significant effect on current accounting practice or create a significant administrative cost. In addition, some of the amendments will make the codification easier to understand and easier to apply by eliminating inconsistencies, providing needed clarifications, and improving the presentation of guidance in the codification. The amendments that require transition guidance are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. All other amendments will be effective upon issuance. We are evaluating the impact of ASU 2015-10 on our financial statements.

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In April 2015, the FASB issued ASU 2015-03, *Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* to simplify the presentation of debt issuance costs. The amendments in the update require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct reduction of the carrying amount of the debt. Recognition and measurement of debt issuance costs were not affected by this amendment. In August 2015, FASB issued ASU 2015-15, *Presentation and Subsequent Measurement of Debt Issuance Costs Associated With Line-of-Credit Arrangements Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting* which clarified that the SEC would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement. The amendments are effective for financial statements issued for fiscal years beginning after December 15, 2015. This standard does not have an impact on our financial statements. As of September 30, 2015, we early adopted this standard and recorded debt issuance costs as a debt discount. There was no impact related to this adoption as we did not have any debt issuance costs previously.

In January 2015, the FASB issued ASU 2015-01, *Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*. The purpose of this amendment is to eliminate the concept of extraordinary items. As a result, an entity will no longer be required to separately classify, present and disclose extraordinary events and transactions. The amendment is effective for annual reporting periods beginning after December 15, 2015 and subsequent interim periods with early application permitted. We are evaluating the impact the adoption of ASU 2015-01 will have on our financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. The amendments in this ASU are effective for reporting periods beginning after December 15, 2016, with early adoption permitted. We are evaluating the impact the adoption of ASU 2014-15 will have on our financial statements.

In May 2014, the FASB issued ASU 2014-09 regarding ASC Topic 606, *Revenue from Contracts with Customers*. The standard provides principles for recognizing revenue for the transfer of promised goods or services to customers with the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers: Deferral of the Effective Date*, which deferred the effective date of the new revenue standard for periods beginning after December 15, 2016 to December 15, 2017, with early adoption permitted but not earlier than the original effective date. We are currently evaluating the effect that the updated standard will have on our financial statements.

**SEGMENT REPORTING****Ampio Segment**

The Ampio segment consists of our core biopharmaceuticals compounds, Ampion and Optina, and the clinical trials associated with them. To date, this business segment has not generated revenue and has incurred losses each year since its inception.

**Aytu Segment**

The Ayту segment contains our men's health platform which consists of its diagnostic device platform, a prostate cancer screening drug and sexual dysfunction portfolio. To date, this business segment has not generated significant revenue and has incurred losses each year since its inception.

## **RESULTS OF OPERATIONS**

### **Results of Operations September 30, 2015 Compared to September 30, 2014**

Results of operations for the three months ended September 30, 2015, and the three months ended September 30, 2014, reflected net losses of approximately \$7.8 million and \$9.5 million, respectively. These losses include in part non-cash charges related to stock-based compensation, depreciation, amortization and accretion and amortization of prepaid research and development related party, collectively in the amount of \$1.4 million in the 2015 quarter and \$2.7 million in the 2014 quarter. The non-cash charges decreased in the 2015 quarter primarily due to the decrease in stock-based compensation.

Results of operations for nine months ended September 30, 2015 or the 2015 period, and the nine months ended September 30, 2014 or the 2014 period, reflected net losses of approximately \$23.1 million and \$28.9 million, respectively. These losses include in part non-cash charges related to stock-based compensation, depreciation, amortization and accretion and amortization of prepaid

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and development related party and common stock issued for services, collectively in the amount of \$5.1 million in the 2015 nine month period and \$5.5 million in the 2014 nine month period. The non-cash charges decreased in the nine month period of 2015 primarily due to the decrease in stock-based compensation, offset by the increase in depreciation and amortization of our new manufacturing facility.

**Revenue**

We have not generated significant license revenue in our operating history. The \$21,000 license revenue recognized in the 2015 quarter and 2014 quarter, respectively, and the \$64,000 and \$55,000 license revenue recognized in the 2015 period and 2014 period, respectively, represents the amortization of the upfront payments received on Aytu's license agreements. The initial payment of \$500,000 from the license agreement of Zertane with a Korean pharmaceutical company was deferred and is being recognized over ten years. The initial payment of \$250,000 from the license agreement of Zertane with a Canadian-based supplier was deferred and is being recognized over seven years.

The \$466,000 and \$629,000 product and service revenue recognized in the 2015 quarter and nine month period, respectively, represents sales from our Aytu segment which includes the ProstaScint product and the RedoxSYS System. We did not generate any product and service revenue in the corresponding 2014 quarter and period.

**Operating Expenses***Cost of Sales*

The cost of sales of \$37,000 and \$125,000 recognized in the September 30, 2015 quarter and nine month period is related to the ProstaScint product and the RedoxSYS System.

*Research and Development*

Research and development costs are summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Clinical trials and sponsored research	\$ 2,927,000	\$ 3,533,000	\$ 7,591,000	\$ 14,696,000
Labor	848,000	518,000	2,514,000	1,397,000
Stock-based compensation	513,000	1,815,000	1,727,000	2,993,000
Consultants and other	339,000	288,000	1,099,000	476,000
Sponsored research related party	84,000	66,000	252,000	144,000
	\$ 4,711,000	\$ 6,220,000	\$ 13,183,000	\$ 19,706,000

Research and development costs consist of clinical trials and sponsored research, labor and stock-based compensation. Costs of research and development decreased \$1.5 million, or 24.3%, for the quarter ended September 30, 2015 compared to the same quarter in 2014 and \$6.5 million, or 33.1% for the nine month period ended September 30, 2015 compared to the same period in 2014. The decrease is primarily due to a decrease in clinical trials and sponsored research expenses due to the completion of our prior trials. During 2015, we expect that our clinical trial expense will be less than our 2014 expense as we are not expecting to do any additional Optina trials during the second half of this

year. The increase in labor and consultants and other is due to the additional costs related to preparing our facility to become operational and the additional professional staffing.



**Table of Contents***Selling, General and Administrative*

Selling, general and administrative costs are summarized as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Stock-based compensation	\$ 427,000	\$ 683,000	\$ 2,391,000	\$ 2,161,000
Labor	1,097,000	524,000	2,717,000	1,692,000
Professional fees	418,000	598,000	1,706,000	1,416,000
Occupancy, travel and other	859,000	877,000	2,057,000	1,976,000
Patent costs	551,000	555,000	1,313,000	1,827,000
Directors fees	59,000	62,000	195,000	190,000
	\$ 3,411,000	\$ 3,299,000	\$ 10,379,000	\$ 9,262,000

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Selling, general and administrative costs increased \$112,000, or 3.4%, for the quarter ended September 30, 2015 compared to the same quarter in 2014. The increase is due to the increase in labor offset by the decrease in stock-based compensation and professional fees. For the nine month period ended September 30, 2015, general and administrative costs increased \$1.1 million, or 12.1%, compared to the same period in 2014 primarily as a result of increased stock-based compensation, labor and professional fees which was offset by a decrease in patent costs. We expect that our selling, general and administrative expense will remain approximately flat in the last quarter of 2015 compared to the first three quarters of 2015.

### *Loss from Operations*

The loss from operations during the nine months ended September 30, 2015 of \$23.1 million is less than the loss from operations of \$28.9 million for the same period in 2014. The loss from operations for the quarter ended September 30, 2015 of \$7.8 million is less than the loss from operations of \$9.5 million for the same quarter in 2014. The decreases in the losses are primarily caused by the reduction in our clinical trial expenses. This trend is expected to continue into the last quarter of 2015.

### *Net Cash Used in Operating Activities*

During the nine month period ended September 30, 2015, our operating activities used approximately \$18.7 million in cash which was less than the net loss of \$23.1 million primarily as a result of the non-cash stock-based compensation and increase in accrued compensation offset by a decrease in accounts payable and increase in prepaid expenses and other.

In the 2014 period, the use of cash was \$25.0 million which was less than the net loss of \$28.9 million principally as a result of non-cash stock-based compensation and an increase in deferred rent offset by an increase in prepaid expenses and other and prepaid research and development related party.

### *Net Cash Used in Investing Activities*

During the nine month period ended September 30, 2015, \$1.0 million of cash was used to acquire the ProstaScint asset. Purchase of fixed assets decreased to \$112,000 compared to \$7.9 million for the same period in 2014. This reflects the near completion of our manufacturing facility in the first three quarters of 2015.

### *Net Cash from Financing Activities*

Net cash provided by financing activities during the nine month period ended September 30, 2015 of \$4.9 million was primarily related to the Aytu convertible promissory notes which reflects gross proceeds of \$5.2 million offset by the cash portion of the debt issuance costs related to the Notes of \$298,000.

Net cash provided by financing activities during the 2014 period of \$63.4 million reflects gross proceeds from the public offering of \$68.4 million offset by costs related to the offering of \$5.0 million.

### *Liquidity and Capital Resources*

As a biopharmaceutical company, we have not generated significant revenue as our primary activities are focused on research and development, advancing our primary product candidates, and raising capital. As of September 30, 2015, we had cash and cash equivalents totaling \$35.4 million. At that same date, we had \$2.3 million in accounts payable. Based upon our current expectations, we believe our capital resources at September 30, 2015 will be sufficient to fund

our currently planned operations through fiscal 2016 and into early fiscal 2017. This estimate is based on a number of assumptions that may prove to be wrong, and we could exhaust our available cash and cash equivalents earlier than presently anticipated. We may be required or choose to seek additional capital to expand our clinical development activities for developing our products. This could be necessary either assuming positive results of our ongoing clinical trials or if we face challenges or delays in connection with those trials. Additional funding will be required if we choose to do a commercial launch of Ampion ourselves. We may also choose to seek additional capital to maintain minimum cash balances that we deem reasonable and prudent. We intend to evaluate the capital markets from time to time to determine whether to raise additional capital in the form of equity, convertible debt or otherwise, depending on market conditions relative to our need for funds at such time, and we may seek to raise additional capital should we conclude that such capital is available on terms that we consider to be in our best interests and the best interest of our shareholders.

Our current forecast for 2015 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 \$1.1 million per month excluding our clinical trial costs.

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As additional funding is required, it will be necessary to raise additional capital and/or enter into licensing or collaboration agreements. At this time, we expect to satisfy our future cash needs through private or public sales of our securities or debt financings. We cannot be certain that financing will be available to us on acceptable terms, or at all. In recent years, volatility in the financial markets has adversely affected the market capitalizations of many pharmaceutical companies and generally made equity and debt financing more difficult to obtain. This volatility, coupled with other factors, may limit our access to additional financing.

If we cannot raise adequate additional capital in the future when we require it, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. This may lead to impairment or other charges, which could materially affect our balance sheet and operating results.

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

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

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

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

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

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

### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal controls over financial reporting that occurred during the period covered by this report that 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 May 8, 2015 and May 14, 2015, purported stockholders of the Company brought two putative class action lawsuits in the United States District Court in the Central District of California, Napoli v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03474-TJH and Stein v. Ampio Pharmaceuticals, Inc., et al., Case No. 2:15-cv-03640-TJH (the Securities Class Actions ), alleging that Ampio and certain of its current and former officers violated federal securities laws by misrepresenting and/or omitting information regarding the STEP study. The lawsuits seek unspecified damages, pre-judgment and post-judgment interest, and attorneys' fees and costs.

On August 6, 2015 and September 25, 2015, purported stockholders of the Company brought derivative actions in the United States District Court in the Central District of California, Oglina v. Macaluso et al., Case No. 2:15-cv-05970-TJH-PJW ( Oglina action ) and the Colorado state court in Denver, Loyd v. Giles et al., Case No. 2015CV33429 ( Loyd action ), alleging primarily that the directors and officers of Ampio breached their fiduciary duties because of their alleged misstatements and/or omissions regarding the STEP study. The United States District Court in the Central District of California has stayed the proceedings in the Oglina action because it is related to the pending Securities Class Actions. Counsel are also seeking a stay in the Loyd action for the same reason.

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

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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 below in this Quarterly Report on Form 10-Q and in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission, which could materially affect our business, financial condition or future results. During the quarterly period covered by this Quarterly Report on Form 10-Q, there were no material changes to the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, except to update for the acquisition by Aytu of ProstaScint from Jazz Pharmaceuticals and of Primisol from FSC Laboratories.

**Our acquisitions expose us to risks that could adversely affect our business, and we may not achieve the anticipated benefits of acquisitions of businesses or technologies.**

Any acquisition involves numerous risks and operational, financial, and managerial challenges, including underperformance of any acquired technologies or products relative to our expectations and the price we paid. In May 2015 Aytu acquired certain assets from Jazz Pharmaceuticals, Inc. related to its product known as ProstaScint, including certain intellectual property and contracts, and the product approvals, inventory and work in progress (collectively, the ProstaScint Business). In October 2015 Aytu acquired certain assets from FSC Laboratories, Inc., including certain intellectual property and contracts, inventory, work in progress and all marketing and sales assets and materials related solely to Primisol (collectively, the Primisol Business). We may not be able to successfully commercialize the ProstaScint Business or the Primisol Business, which could adversely affect our business, financial condition, or results of operations.

***Future sales and issuances of Aytu's common stock or rights to purchase common stock at Aytu, including pursuant to Aytu's equity incentive plan or otherwise, could cause Aytu's stock price to fall.***

We expect that Aytu will require significant additional capital in the future to continue planned operations. To raise capital, Aytu may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner Aytu's management may determine from time to time. If Aytu sells common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted by subsequent sales. Additionally, any such sales may result in material dilution to Aytu's existing stockholders, including us, and new investors could gain rights, preferences and privileges senior to those of holders of Aytu common stock. Further, any future sales of our common stock by Aytu or resales of our common stock by Aytu's existing stockholders could cause the market price of Aytu's common stock to decline. Any future grants of options, warrants or other securities exercisable or convertible into Aytu's common stock (and the amount and pricing of such securities), or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of Aytu's common stock as well.

In addition, there is not now, nor has there been since our inception, any substantial trading activity in Aytu's common stock or a market for shares of Aytus's common stock, and an active trading market for Aytu's shares may never develop or be sustained. Given the illiquid nature of Aytu's common stock, the value of Aytu's common stock cannot necessarily be based on the price of Aytu's common stock as quoted on the OTCQB. Investors in future financings may be able to negotiate a price for Aytu's common stock or derivatives that is significantly less than the price quoted on the OTCQB. Such an event could have an adverse effect on the market price of Aytu's common stock.

**Item 2. Unregistered Sales of Securities and Use of Proceeds.**

As previously reported by Aytu in timely filed Current Reports on Form 8-K, on July 22, August 11 and September 1, 2015, Aytu closed on note purchase agreements with institutional and high net worth individual investors for the purchase and sale of convertible promissory notes with an aggregate principal amount of \$5.2 million. Newbridge Securities Corporation, through LifeTech Capital, acted as sole placement agent for the institutional portion of the offering. Aytu paid the placement agent 8% of the gross proceeds of notes sold by the placement agent and a warrant to purchase shares of Aytu's common stock equal to 8% of the gross proceeds of the notes sold by the placement agent divided by the price per share at which equity securities are sold in Aytu's next equity financing. The placement agent warrant has a term of five years, will have an exercise price equal to 100% of the price per share at which equity securities are sold in Aytu's next equity financing, and provides for cashless exercise.

The notes are convertible at any time in a noteholder's discretion into that number of shares of Aytu common stock equal to 120% of the number of shares of common stock calculated by dividing the then outstanding principal and accrued interest by \$4.63. A holder of notes will be obligated to convert on the terms of Aytu's next public offering of its stock resulting in gross proceeds to it of at least \$5,000,000 (excluding indebtedness converted in such financing) prior to the maturity date of the notes (a "Qualified Financing"). The principal and accrued interest under the notes will automatically convert into a number of shares of such equity securities of Aytu sold in such financing equal to 120% of the principal and accrued interest under such note divided by the lesser of (i) the lowest price paid by an investor in such financing or (ii) \$4.63. In the event that Aytu sells equity securities to investors at any time while the notes are outstanding in a financing transaction that is not a Qualified Financing, then the noteholders will have the option to convert in whole the outstanding principal and accrued interest as of the closing of such financing into a number of shares of Aytu capital stock in an amount equal to 120% of the number of such shares calculated by dividing the outstanding principal and accrued interest by the lesser of (i) the lowest cash price per share paid by purchasers of shares in such financing, or (ii) \$4.63.

The notes and the placement agent warrant were sold in a transaction exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(2) thereof and Regulation D promulgated thereunder as transactions by an issuer not involving any public offering.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

**Exhibit**

**Description**

**Number**

- 10.1 Amendment to Employment Agreement between the Company and David Bar-Or, M.D., dated August 3, 2015 (1).
- 10.2 Amendment to Employment Agreement between the Company and Vaughan Clift, M.D., dated July 31, 2015 (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, 2015 formatted in XBRL: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Stockholders' Equity (Deficit), (iv) the Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements.

\* The certification attached as Exhibit 32.1 accompanying this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, shall not be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

(1) Incorporated by reference from the Company's Current Report on Form 8-K filed on August 6, 2015.



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**SIGNATURES**

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

AMPIO PHARMACEUTICALS, INC.

By: /s/ Michael Macaluso  
**Michael Macaluso**  
**Chairman and Chief Executive Officer**  
**Date: November 6, 2015**

By: /s/ Gregory A. Gould  
**Gregory A. Gould**  
**Chief Financial Officer, Treasurer and**  
**Secretary**  
**Date: November 6, 2015**