

Ampio Pharmaceuticals, Inc.
Form 10-Q
August 07, 2015
Table of Contents

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

Table of Contents

**AMPIO PHARMACEUTICALS, INC.
AND SUBSIDIARIES
FOR THE QUARTER ENDED JUNE 30, 2015
INDEX**

	Page
PART I FINANCIAL INFORMATION	
Item 1. <u>Consolidated Financial Statements</u>	4
<u>Consolidated Balance Sheets as of June 30, 2015 (unaudited) and December 31, 2014</u>	4
<u>Consolidated Statements of Operations for the three and six months ended June 30, 2015 (unaudited) and the three and six months ended June 30, 2014 (unaudited)</u>	5
<u>Consolidated Statements of Stockholders' Equity (Deficit) (unaudited)</u>	6
<u>Consolidated Statements of Cash Flows for the six months ended June 30, 2015 (unaudited) and the six months ended June 30, 2014 (unaudited)</u>	7
<u>Notes to Consolidated Financial Statements (unaudited)</u>	8
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	22
PART II OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	22
Item 1A. <u>Risk Factors</u>	23
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
Item 3. <u>Defaults Upon Senior Securities</u>	23
Item 4. <u>Mine Safety Disclosures</u>	23
Item 5. <u>Other Information</u>	23
Item 6. <u>Exhibits</u>	23
<u>SIGNATURES</u>	24

Table of Contents

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, Vyrix, 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**

	June 30, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	\$ 36,783,380	\$ 50,320,656
Prepaid expenses and other	1,344,328	672,716
Prepaid research and development related party (Note 7)	265,785	265,785
Total current assets	38,393,493	51,259,157
Fixed assets, net (Note 2)	9,628,560	9,945,428
In-process research and development	7,500,000	7,500,000
ProstaScint asset	1,000,000	
Patents, net	628,776	664,169
Long-term portion of prepaid research and development related party (Note 7)	730,908	863,802
Deposits	38,742	35,854
	19,526,986	19,009,253
Total assets	\$ 57,920,479	\$ 70,268,410
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	\$ 2,466,920	\$ 3,299,025
Accrued compensation	923,087	235,665
Deferred rent	59,526	59,579
Deferred revenue	85,714	85,714
Total current liabilities	3,535,247	3,679,983
Long-term deferred rent	646,976	661,160
Long-term deferred revenue	425,893	468,749
Total liabilities	4,608,116	4,809,892
Commitments and contingencies (Note 4)		

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

Stockholders' equity

Preferred Stock, par value \$.0001; 10,000,000 shares authorized; none issued		
Common Stock, par value \$.0001; 100,000,000 shares authorized; shares issued and outstanding 51,998,306 in 2015 and 51,972,266 in 2014	5,200	5,197
Additional paid-in capital	167,975,967	168,108,278
Advances to stockholders	(90,640)	(90,640)
Accumulated deficit	(116,543,580)	(101,904,570)
Total Ampio stockholders' equity	51,346,947	66,118,265
Non-controlling interests	1,965,416	(659,747)
Total equity	53,312,363	65,458,518
Total liabilities and equity	\$ 57,920,479	\$ 70,268,410

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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue				
License revenue	\$ 21,427	\$ 21,429	\$ 42,856	\$ 33,929
Product and service revenue	163,008		163,008	
Total revenue	184,435	21,429	205,864	33,929
Operating Expenses				
Cost of sales	87,884		87,884	
Research and development	3,727,414	5,567,559	8,303,682	13,361,967
Research and development related party (Note 7)	83,948	66,446	167,897	77,521
General and administrative	4,007,195	3,327,625	6,968,253	6,009,899
Loss from operations	(7,722,006)	(8,940,201)	(15,321,852)	(19,415,458)
Other income				
Interest income	8,328	7,505	16,753	11,000
Total other income	8,328	7,505	16,753	11,000
Net loss	(7,713,678)	(8,932,696)	(15,305,099)	(19,404,458)
Net loss applicable to non-controlling interests	358,252	241,176	666,089	470,755
Net loss applicable to Ampio	\$ (7,355,426)	\$ (8,691,520)	\$ (14,639,010)	\$ (18,933,703)
Weighted average number of Ampio common shares outstanding	51,989,986	51,917,528	51,985,687	48,453,144
Basic and diluted Ampio net loss per common share	\$ (0.14)	\$ (0.17)	\$ (0.28)	\$ (0.39)

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)**

	Series A Preferred Stock	Common Stock		Additional	Advances	Accumulated	Non-controlling	Total
	Shares	Shares	Amount	Paid-in	to	Deficit	Interests	Stockholders
	Amount			Capital	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)				3,147,684				3,147,684
Liabilities paid pursuant to merger (unaudited)				(20,014)				(20,014)
Luoxis options paid pursuant to merger (unaudited)				(27,476)				(27,476)
Non-controlling interests on contributed assets (unaudited)				(3,291,252)			3,291,252	
Net loss (unaudited)						(14,639,010)	(666,089)	(15,305,099)
Balance June 30, 2015 (unaudited)	\$	51,998,306	\$ 5,200	\$ 167,975,967	\$ (90,640)	\$ (116,543,580)	\$ 1,965,416	\$ 53,312,363

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)**

	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Cash flows from operating activities:		
Net loss	\$ (15,305,099)	\$ (19,404,458)
Stock-based compensation expense	3,147,684	2,626,905
Depreciation and amortization	461,572	83,075
Amortization of prepaid research and development related party (Note 7)	132,894	77,521
Common stock issued for services	30,000	30,000
Adjustments to reconcile net loss to net cash used in operating activities:		
(Increase) decrease in prepaid expenses and other	(671,612)	(1,020,948)
(Increase) in prepaid research and development related party (Note 7)		(890,000)
(Decrease) increase in accounts payable	(856,964)	198,671
(Decrease) increase in deferred rent	(14,237)	350,073
(Decrease) increase in deferred revenue	(42,856)	216,071
Increase (decrease) in accrued compensation	687,422	(485,002)
Net cash used in operating activities	(12,431,196)	(18,218,092)
Cash flows used in investing activities:		
Purchase of fixed assets	(84,451)	(5,898,866)
ProstaScint asset purchase	(1,000,000)	
Deposits	(2,888)	
Net cash used in investing activities	(1,087,339)	(5,898,866)
Cash flows from financing activities:		
Proceeds from sale of common stock		68,442,553
Costs related to sale of common stock		(4,999,777)
Proceeds from option exercise	28,749	
Liability payout pursuant to merger	(20,014)	
Luoxis option payout pursuant to merger	(27,476)	
Net cash (used in) provided by financing activities	(18,741)	63,442,776
Net change in cash and cash equivalents	(13,537,276)	39,325,818
Cash and cash equivalents at beginning of period	50,320,656	26,309,449
Cash and cash equivalents at end of period	\$ 36,783,380	\$ 65,635,267
Non-cash transactions:		
Fixed asset purchases included in accounts payable	\$ 24,860	\$ 1,537,903
	\$	\$ 450,000

Related party research and development liability included in prepaid
research and development related party

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

Table of Contents

AMPIO PHARMACEUTICALS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(unaudited)

Note 1 Basis of Presentation, Merger and Business

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), a 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. 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 June 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 June 30, 2015 is unaudited. Ampio's activities, being primarily research and development and raising capital, have not generated significant revenue to date.

New 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 10,000,000 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, no options under the Aytu 2015 Stock Option and Incentive Plan had been granted.

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.

Asset Acquisition 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.

Table of Contents

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. 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.

Newly Issued Accounting Pronouncements

In June 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 consolidated 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. The update requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. We are evaluating the impact of ASU 2015-03 on our consolidated financial statements.

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. Management is currently assessing 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. Management is currently assessing 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. The guidance will be effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted but not prior to the original public organization effective date of December 15, 2016. We are currently evaluating the

accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

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 June 30, 2015	As of December 31, 2014
Manufacturing Facility/Clean Room-in progress	8	\$ 2,734,000	\$ 2,684,000
Leasehold improvements	10	6,075,000	6,064,000
Office furniture and equipment	3-10	556,000	556,000
Lab equipment	5	1,109,000	1,060,000
Less accumulated depreciation		(845,000)	(419,000)
Fixed assets, net		\$ 9,629,000	\$ 9,945,000

Note 3 License Agreement/Revenue Recognition

Ampio has not generated significant revenue in its operating history. The \$21,000 license revenue recognized in the 2015 quarter and 2014 quarter, respectively, and the \$43,000 and \$34,000 license revenue recognized in the 2015 period and 2014 period, respectively, represents the amortization of the upfront payments received on 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.

The \$163,000 product and service revenue recognized in the 2015 quarter and six month period represents sales from Ampio's Aytu segment which includes the ProstaScint product and the RedoxSYS System.

Note 4 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	\$ 5,696,000	\$ 596,000	\$	\$ 2,550,000	\$ 2,550,000	\$	\$
Clinical research and trial obligations	5,516,000	4,520,000	996,000				
Facility lease	3,227,000	211,000	332,000	342,000	337,000	326,000	1,679,000
Sponsored research agreement with	1,534,000	198,000	395,000	395,000	395,000	151,000	

related party							
ProstaScint							
inventory							
transfer fee	500,000	500,000					
ProstaScint							
FDA fees	227,000	227,000					
Aytu							
manufacturing							
and commercial							
development	133,000	133,000					
	\$ 16,833,000	\$ 6,385,000	\$ 1,723,000	\$ 3,287,000	\$ 3,282,000	\$ 477,000	\$ 1,679,000

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 \$5,696,000. Per an amendment to the original agreement, Ampio is not committed to take its full allocation in 2015 and no purchases in 2016.

Clinical Research and Trial Obligations

In connection with upcoming clinical trials, as of June 30, 2015, Ampio has a remaining commitment of \$5,037,000 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 \$329,000.

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

Table of Contents

the term of the lease of approximately \$3.3 million and includes rent abatements and leasehold incentives. The Company recognizes rental expense of the facility on a straight-line basis over the term of the lease. Differences between the straight-line net expenses on rent payments are classified as liabilities between current deferred rent and long-term deferred rent. Rent expense for the respective periods is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Rent expense	\$ 71,000	\$ 92,000	\$ 138,000	\$ 122,000

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 7 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.

ProstaScint Inventory Transfer Fee

Aytu is obligated to pay \$500,000 for the ProstaScint-related product inventory upon the inventory transfer in July 2015.

ProstaScint FDA Fees

Aytu is obligated to pay \$227,000 for the ProstaScint-related FDA fees on September 30, 2015.

Aytu Manufacturing and Commercial Development

Aytu entered into agreements with manufacturing companies to build its RedoxSYS System. The current remaining commitment is \$133,000.

Note 5 Common Stock***Capital Stock***

At June 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.

Table of Contents***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 six months ended June 30, 2015 and 2014, respectively.

Note 6 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.

In April 2015, the Company modified options held by a former executive which accelerated vesting of 111,160 options and extended the exercise period from 90 days after termination to April 15, 2020. All of the \$692,000 expense related to this modification was recognized in the period ended June 30, 2015.

In May 2015, the Company modified options held by a former executive which extended the exercise period from August 15, 2015 to August 15, 2016. All of the \$126,000 expense related to this modification was recognized in the period ended June 30, 2015.

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 our 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 six months ended June 30, 2015, Ampio granted 30,000 options at a price of \$3.46 to employees which represented the fair market value on date of the grants and 33,000 options at a price of \$2.47 to employees which represented the fair market value on date of grant. Ampio has computed the fair value of all options granted during the six months ended June 30, 2015 using the following assumptions:

Expected volatility	104% - 113%
Risk free interest rate	1.50%
Expected term (years)	5.0 - 6.0
Dividend yield	0%

Ampio stock option activity is as follows:

Number of Options	Weighted Average	Weighted Average Remaining	Aggregate Fair
----------------------	---------------------	-------------------------------	-------------------

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

		Exercise Price	Contractual Life	Value
Outstanding December 31, 2014	6,568,248	\$ 3.82	7.66	\$ 17,090,000
Granted	63,000	\$ 2.94		
Exercised	(10,416)	\$ 2.76		
Forfeited/Cancelled	(60,000)	\$ 3.53		
Outstanding June 30, 2015	6,560,832	\$ 3.82	6.90	\$ 17,063,000
Exercisable at June 30, 2015	5,632,074	\$ 3.56	6.56	\$ 13,310,000
Available for grant at June 30, 2015	3,744,773			

Table of Contents

Stock options outstanding and exercisable at June 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 Contractual Lives
\$1.03 - \$4.00	4,385,832	\$ 2.32	6.33
\$4.01 - \$7.00	1,240,000	\$ 6.17	8.34
\$7.01 - \$8.93	935,000	\$ 7.73	7.67
	6,560,832	\$ 3.82	6.90

The outstanding options in the Luoxis and Vyrix 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 unrecognized compensation of \$1.3 million related to the Luoxis and Vyrix options that had not vested as of the Merger date will not be recognized.

At the time of this filing, no options under the Aytu 2015 Stock Option and Incentive Plan had been granted.

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 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 six months ended June 30, 2015 and 2014:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Research and development expenses				
Stock options				
Ampio	\$ 449,000	\$ 399,000	\$ 1,057,000	\$ 1,038,000
Aytu	42,000	60,000	157,000	141,000
General and administrative expenses				
Common stock issued for services			30,000	30,000
Stock options				
Ampio	1,192,000	1,092,000	1,729,000	1,391,000
Aytu	48,000	54,000	205,000	57,000
	\$ 1,731,000	\$ 1,605,000	\$ 3,178,000	\$ 2,657,000
Unrecognized expense at June 30, 2015				

Ampio \$ 1,638,740

Weighted average remaining years to vest

Ampio 0.86

Warrants

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

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Outstanding December 31, 2014	516,329	\$ 3.26	1.44
Warrants exercised Private/Registered Direct Placements	(17,253)	\$ 3.94	
Outstanding June 30, 2015	499,076	\$ 3.24	0.91

Table of Contents

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.

Note 7 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 a sum of \$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 Oxidation Reduction Potential platform. In March 2014, Aytu also agreed to pay a sum of \$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 June 30, 2015 and December 31, 2014, advances of \$91,000 to stockholders remained outstanding.

Note 8 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue:				
Ampio	\$	\$	\$	\$
Aytu	184,000	21,000	206,000	34,000
Consolidated revenue	\$ 184,000	\$ 21,000	\$ 206,000	\$ 34,000
Consolidated net loss:				
Ampio	\$ (5,765,000)	\$ (6,942,000)	\$ (11,516,000)	\$ (15,411,000)

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

Aytu	(1,949,000)	(1,991,000)	(3,789,000)	(3,994,000)
Consolidated net loss	(7,714,000)	(8,933,000)	(15,305,000)	(19,405,000)
Reconciliation of consolidated net loss attributable to Ampio:				
Net loss applicable to non-controlling interests	358,000	241,000	666,000	471,000
Net loss attributable to Ampio	\$ (7,356,000)	\$ (8,692,000)	\$ (14,639,000)	\$ (18,934,000)

	June 30, 2015	December 31, 2014
Total assets		
Ampio	\$ 40,381,000	\$ 61,326,000
Aytu	17,540,000	8,942,000
Total assets	\$ 57,921,000	\$ 70,268,000

Table of Contents

Note 9 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, 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. 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 10 Subsequent Events

On July 22, 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 \$2.0 million. The sale of the notes is part of a private placement that Aytu expects to continue to undertake to raise up to a maximum of \$6.0 million although there can be no assurance that Aytu will be able to raise any more capital from the sale of notes. Aytu intends to use the net proceeds of the offering to conduct clinical studies for both Zertane® and RedoxSYS and for working capital to begin commercializing FDA-approved ProstaScint®, as well as general corporate purposes.

The notes are Aytu's unsecured obligation. Unless earlier converted, the notes will mature on January 22, 2017, with an option to extend up to six months at our 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 our company 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 our sole discretion.

The notes are convertible at any time in a noteholder's discretion into that number of shares of our 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 our next public offering of our stock resulting in proceeds to us of at least \$5,000,000 in gross proceeds (excluding indebtedness converted in such financing) prior to the maturity date of the notes, referred to as a Qualified Financing. The principal and accrued interest under the notes will automatically convert into a number of shares of such equity securities of our company 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 our 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.

Newbridge Securities Corporation, Member FINRA/SIPC, through LifeTech Capital, acted as sole placement agent for the institutional portion of the offering. 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 a warrant to purchase shares of our 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 our next equity financing, 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 100% of the price per share at which equity securities are sold in our next equity financing, and provides for cashless exercise.

On July 30, 2015, Ampio extended the Employment Agreements of Dr. David Bar-Or, Chief Scientific Officer, and Dr. Vaughan Clift, Chief Regulatory Affairs Officer, for one additional year, expiring July 31, 2016. Dr. Bar-Or agreed to his amendment on August 3, 2015 and Dr. Clift agreed to his amendment on July 31, 2015. In connection with these Amendments, Dr. Bar-Or and Dr. Clift were awarded 300,000 and 170,000 options, respectively, for Ampio common stock at an exercise price of \$2.60 and \$2.68, respectively with vesting upon successful meeting of certain endpoints in the Ampion clinical trials determined by Ampio's Board of Directors.

On July 30, 2015, Gregory A. Gould, Chief Financial Officer, was awarded 100,000 options for Ampio common stock with an exercise price of \$2.60 with vesting of one-third on grant date; one-third on July 30, 2016 and one-third on July 30, 2017.

Table of Contents

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. Information on or linked to the Company website is not incorporated by reference into this Quarterly Report on Form 10-Q. Filings with the SEC can also be obtained at the SEC's website, www.sec.gov.

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

NEW MERGER/SUBSIDIARY

Aytu BioScience, Inc.

On April 16, 2015, Luoxis and Vyrix, 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, 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, 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 10,000,000 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, no options under the Aytu 2015 Stock Option and Incentive Plan had been granted.

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

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. Per FDA guidance, we have submitted the clinical trial protocol to the FDA and we are awaiting for the FDA's written feedback. The next clinical trial is anticipated to begin following the FDA's guidance in the second half of 2015.

OPTINA

Optina is a low-dose formulation of danazol, an approved therapeutic from 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 the Phase II study. At the end of 2014 we announced the primary completion of the Phase II study the open label portion of which the Phase II study concluded in the first quarter of 2015. In July 2015, we announced additional analysis of the Optina data, which showed Optina is effective when given at the correct dose for body mass index (BMI). Additionally, analysis demonstrated a synergistic effect of Optina with common kidney-induced high blood pressure medications (angiotensin receptor blockers and angiotensin converting enzyme). We expect to meet with the FDA in the second half of fiscal 2015 to discuss the next step in our approval process.

PROTASCINT

A key part of the Aytu strategy is to identify, acquire, license, or otherwise promote marketed, complementary urology assets in order to establish a commercial footprint and generate revenues for already-approved or near-term medical products. To that end, Aytu acquired ProstaScint from Jazz Pharmaceuticals in May of 2015.

ProstaScint (capromab pendetide) is a radio-labeled monoclonal antibody, which is a biologic product that targets a specific antigen. ProstaScint targets Prostate Specific Membrane Antigen (PSMA), a protein uniquely expressed by

prostate tissue. Indium (In 111) is attached to the proprietary, mouse-derived antibody. The radiolabeled antibody is infused into the patient and is taken up by prostate cancer cells which can be detected and visualized with single-photon emission tomography (SPECT). ProstaScint has been shown to be clinically effective in determining the course of treatment for a patient who has had a prostatectomy and/or has suspected metastasis (spread of the cancer cells beyond the prostate). Further, ProstaScint is approved and has demonstrated efficacy in newly diagnosed patients classified as high-risk or with recurrent prostate cancer.

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 can be used as a key indicator in male reproductive health and is being studied at a leading US center in male infertility.

Table of Contents

We are actively developing the global market for the RedoxSYS System across a range of applications. Specifically, we have begun commercializing the RedoxSYS System for research use through direct selling, distribution partners, and academic collaborators. Over the past 18 months, we have engaged in over 60 trials around the world whereby prominent researchers are implementing oxidation-reduction potential as a marker in both chronic and acute illnesses and disorders in both clinical research as well as basic science research.

ZERTANE

Zertane is an oral drug in late stage development as treatment for premature ejaculation, or PE. The FDA agreed to review a draft study protocol in advance of us submitting our Investigational New Drug application, or IND. We are planning to start the first U.S. Phase III, Zertane trial in late 2015 and the second trial should occur in 2016. Upon completion of the two trials, if successful, we plan to submit a New Drug Application, or NDA, and subsequently start to market Zertane in the United States, if approved during the second half of 2017.

Future Development

We also intend to study Ampion[®] for therapeutic applications outside of osteoarthritis of the knee. We expect to engage development partners to study Ampion[®] 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[®]'s effects on cellular behavior to indicate potential effects on disease modification across multiple conditions. If successful, we believe these additional formulations and potential therapeutic indications will supplement the Ampion[®] clinical portfolio, and will enable clinical applications in large therapeutic markets where there are significant unmet needs. We expect that initial investigations into strategically attractive indications will be conducted on an investigator-sponsored basis.

AMPION MANUFACTURING FACILITY

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 Ampion trial which is expected to start in the second half of 2015 in our new facility.

KNOWN TRENDS OR FUTURE EVENTS

We have not generated any significant revenues and have therefore incurred significant net losses totaling \$116.5 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. 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.

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 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, 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.

Table of Contents

Newly Issued Accounting Pronouncements

In June 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 consolidated 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. The update requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. We are evaluating the impact of ASU 2015-03 on our consolidated financial statements.

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. Management is currently assessing 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. Management is currently assessing 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. The guidance will be effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted but not prior to the original public organization effective date of December 15, 2016. We are currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

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

Table of Contents

RESULTS OF OPERATIONS

Results of Operations June 30, 2015 Compared to June 30, 2014

Results of operations for the three months ended June 30, 2015, or the 2015 quarter, and the three months ended June 30, 2014 or the 2014 quarter, reflected net losses of approximately \$7.7 million and \$8.9 million, respectively. These losses include in part non-cash charges related to stock-based compensation, depreciation and amortization and amortization of prepaid research and development related party, collectively in the amount of \$2.0 million in the 2015 quarter and \$1.7 million in the 2014 quarter. The non-cash charges increased in the 2015 quarter primarily due to the increase in depreciation and amortization of our new manufacturing facility and the increase in stock-based compensation.

Results of operations for six months ended June 30, 2015 or the 2015 period, and the six months ended June 30, 2014 or the 2014 period, reflected net losses of approximately \$15.3 million and \$19.4 million, respectively. These losses include in part non-cash charges related to stock-based compensation, depreciation and amortization, amortization of prepaid research and development related party and common stock issued for services, collectively in the amount of \$3.8 million in the 2015 six month period and \$2.8 million in the 2014 six month period. The non-cash charges increased in the 2015 quarter primarily due to the increase in stock-based compensation, the increase in depreciation and amortization of our new manufacturing facility and the increase in amortization of prepaid research and development related party.

Revenue

We have not generated significant revenue in our operating history. The \$21,000 license revenue recognized in each of the June 30, 2015 quarter and 2014 quarter, and the \$43,000 and \$34,000 license revenue recognized in the six month period June 30, 2015 and 2014 period, respectively, represents the amortization of the upfront payments received on our 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 \$163,000 product and service revenue recognized in the June 30, 2015 quarter and six month period, represents sales from our Aytu segment which includes the ProstaScint product and the RedoxSYS System.

Operating Expenses

Cost of Sales

The cost of sales of \$88,000 recognized in the June 30, 2015 quarter and six 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Clinical trials and sponsored research	\$ 2,051,000	\$ 4,550,000	\$ 4,664,000	\$ 11,162,000
Labor	836,000	480,000	1,666,000	879,000
Stock-based compensation	491,000	459,000	1,214,000	1,178,000
Consultants and other	349,000	79,000	760,000	142,000
Sponsored research related party	84,000	66,000	168,000	78,000
	\$ 3,811,000	\$ 5,634,000	\$ 8,472,000	\$ 13,439,000

Research and development costs consist of clinical trials and sponsored research, labor and stock-based compensation. Costs of research and development decreased \$1.8 million, or 32.4%, for the quarter ended June 30, 2015 compared to the same quarter in 2014 and \$5.0 million, or 37.0% for the six month period ended June 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*General and Administrative*

General and administrative costs are summarized as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Stock-based compensation	\$ 1,240,000	\$ 1,146,000	\$ 1,964,000	\$ 1,478,000
Labor	878,000	461,000	1,620,000	1,168,000
Professional fees	720,000	372,000	1,288,000	818,000
Occupancy, travel and other	712,000	624,000	1,198,000	1,145,000
Patent costs	384,000	663,000	762,000	1,272,000
Directors fees	73,000	62,000	136,000	129,000
	\$ 4,007,000	\$ 3,328,000	\$ 6,968,000	\$ 6,010,000

General and administrative costs increased \$679,000, or 20.4%, for the quarter ended June 30, 2015 compared to the same quarter in 2014. The increase is due to the increase in labor and professional fees which was offset by the decrease in patent cost. For the six month period ended June 30, 2015, general and administrative costs increase \$958,000, or 15.9%, 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 general and administrative expense will remain flat or even slightly decrease in the second half of 2015 compared to the first half of 2015.

Loss from Operations

The loss from operations of during the six months ended June 30, 2015 of \$15.3 million is less than the loss from operations of \$19.4 million for the same period in 2014. The loss from operations for the quarter ended June 30, 2015 of \$7.7 million is less than the loss from operations of \$8.9 million for the same quarter in 2014. These losses are primarily caused by the reduction in our clinical trials. This trend is expected to continue into the second half of 2015.

Net Cash Used in Operating Activities

During the six month period ended June 30, 2015, our operating activities used approximately \$12.4 million in cash which was less than the net loss of \$15.3 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 \$18.2 million which was less than the net loss of \$19.4 million principally as a result of non-cash stock-based compensation offset by an increase in prepaid expenses and other and prepaid research and development related party.

Net Cash Used in Investing Activities

During the six month period ended June 30, 2015, \$1.0 million of cash was used to acquire the ProstaScint asset. Purchase of fixed assets decreased to \$84,000 compared to \$5.9 million for the same period in 2014. This reflects the near completion of our manufacturing facility in the first half of 2015.

Net Cash from Financing Activities

We had no significant financing activity in the first six months of 2015.

Net cash provided by financing activities in the 2014 period 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 June 30, 2015, we had cash and cash equivalents totaling \$36.8 million. At that same date, we had \$2.5 million in accounts payable. Based upon our current expectations, we believe our capital resources at June 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

Table of Contents

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.

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 engages 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 the 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 furnishes 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, 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. 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.

Table of Contents

Item 1A. Risk Factors.

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors 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, to update for the acquisition by Aytu of ProstaScint from Jazz Pharmaceuticals.

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). We may not be able to successfully commercialize the ProstaScint Business, which could adversely affect our business, financial condition, or results of operations.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits

Exhibit

Number

Description

- 10.1 Voting Agreement between Rosewind Corporation and the Company, dated April 21, 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 June 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 April 22, 2015.

Table of Contents

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: August 7, 2015

By: /s/ Gregory A. Gould
Gregory A. Gould
Chief Financial Officer, Treasurer and
Secretary
Date: August 7, 2015