

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AYTU BIOSCIENCE, INC

Form: 8-K

Date Filed: 2019-11-14

Corporate Issuer CIK: 1385818

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**FORM 8-K CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **November 14, 2019**

AYTU BIOSCIENCE, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-38247
(Commission File Number)

47-0883144
(IRS Employer Identification No.)

**373 Inverness Parkway, Suite 206
Englewood, CO 80112**
(Address of principal executive offices, including Zip Code) Registrant's telephone number, including area code: **(720) 437-6580**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	AYTU	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On November 14, 2019, the Company issued a press release announcing that the Company will present its operational results for the fiscal first quarter ended September 30, 2019 on Thursday, November 14, 2019, at 4:30 p.m. ET. A copy of the press release is attached as Exhibit 99.1 and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in the press release attached as Exhibit 99.1 hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibit is being filed herewith:

Exhibit	Description
99.1	Press Release dated November 14, 2019

SIGNATURES

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

AYTU BIOSCIENCE, INC.

By: /s/ Joshua R. Disbrow

Joshua R. Disbrow
Chief Executive Officer

Date: November 14, 2019



Aytu Reports First Quarter 2020 Financial Results

ENGLEWOOD, CO / ACCESSWIRE / November 14, 2019 / Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty pharmaceutical company focused on global commercialization of novel products addressing significant medical needs, today will provide an overview of its business, including the company's operational and financial results for its fiscal first quarter 2020 that ended September 30, 2019. The company will host a live conference call and webcast today at 4:30 p.m. ET. Conference call details are provided at the end of this press release.

2020 First Quarter Financial and Corporate Highlights

- Reports revenue of \$1.44 million for the three months ended September 30, 2019.
- Ends the quarter with cash, cash equivalents and restricted cash of \$7.3 million, which does not include \$10 million raised in a private placement closed subsequent to quarter end.
- Announced a definitive agreement to acquire Innovus Pharmaceuticals, Inc, and purchased a portfolio of prescription products from Cerecor, Inc, resulting in Pro Forma revenue¹ of approximately \$10.6 million and \$42.7 million for the three and twelve months ended September 30, 2019.
- Raised \$10 million (approximately \$9.3 million after fees and expenses) through a private placement with healthcare institutional investors, resulting in Pro Forma net cash², cash equivalents and restricted cash of approximately \$16.6 million as of September 30, 2019.

Commenting on the first quarter of 2019, Josh Disbrow, Chief Executive Officer of Aytu BioScience, stated, "During and subsequent to the quarter ending September 30 we announced two transformative transactions that increase our scale and are expected to accelerate our path to profitability. Those two transactions were the definitive agreement to acquire Innovus Pharmaceuticals and the acquisition of the portfolio of prescription products from Cerecor, Inc. These transactions significantly bolster the company's product portfolio to now include nine prescription products and, upon the closing of the Innovus acquisition, over thirty consumer health products. The result of this combination with Innovus and the Cerecor commercial portfolio yields trailing twelve-month combined pro forma revenue for the period ending September 30 of approximately \$43 million."

Mr. Disbrow continued, "While boosting our top line run rate, we also expect these transactions to accelerate the company's path to profitability. Both Innovus and the Cerecor commercial business operate at or near breakeven from a cash standpoint, so we are adding increased revenue scale without a corresponding increase in cash burn. We feel we are well positioned to reach break-even more rapidly as a result of the cost saving synergies the two transactions provide, as well as expected growth in revenue from product cross selling and increased physician reach due to the increased scale across combined sales forces. Additionally, as context, Aytu grew by 100% from fiscal 2018 to 2019, and Innovus has grown over 300% from 2017 to 2019. Through the combination of Aytu and Innovus, coupled with the asset purchase from Cerecor, we expect the consolidated entity to continue on a significant growth path while realizing operational synergies across the new combined organization to potentially achieve profitability sooner than the company would have prior to the consummation of these combinations."

¹ Pro Forma revenue is a non-GAAP metric calculated by combining the reported net revenues for: (i) Aytu BioScience, Inc., (ii) the net revenues associated with the acquired pediatric pharmaceutical products from Cerecor, which closed November 1, 2019, and (iii) the net revenues associated with the pending acquisition of Innovus Pharmaceuticals, Inc.

² Pro Forma net cash is a non-GAAP metric calculated by combining the (i) cash, cash equivalents and restricted cash on hand as of September 30, 2019, and (ii) the net cash proceeds from the October 2019 private placement financing.

Additional Corporate Highlights

- The Company re-negotiated the Natesto® license agreement with Acerus Pharmaceuticals, Inc. to accelerate prescription growth and increase promotion to specialists:
 - Doubles the number of Natesto sales representatives; augments current Aytu sales force with nationwide specialty sales team focused on urology and endocrinology,
 - Increases gross profit, eliminates milestone payments, and removes regulatory fees and clinical trial expenses.
- The Company announced a Tuzistra® XR co-promotion with Poly Pharmaceuticals to accelerate Rx growth and increase physician coverage:
 - Doubles the number of Tuzistra XR sales representatives,
 - Expands primary care physician promotion by over 7,500 prescribers.
- The Company announced a co-promotion agreement with Validus Pharmaceuticals for ZolpiMist™ and launched into the \$163 million psychiatry market
 - Adds 8 specialty representatives selling ZolpiMist to psychiatrists.
- The Company announced positive clinical results from a Natesto Spermatogenesis Study, which demonstrated maintenance of semen parameters (sperm concentration, sperm motility, and total motile sperm count) in hypogonadal men treated with Natesto for six months.
- Natesto added to two national pharmacy benefit managers' (PBM) formularies: Natesto now covered on payer plans covering over 36 million U.S. lives.
- Tuzistra XR added to a leading national PBM's formulary, increasing patient insurance coverage rates nationwide.
- The Company joined the Russell Microcap® Index.

Conference Call Information

The company will host a live conference call at 4:30 p.m. ET today. The conference call can be accessed by dialing either:

1- 844-602-0380 (toll-free)

1- 862-298-0970 (international)

The webcast will be accessible live and archived on Aytu BioScience's website, within the Investors section under Events & Presentations, at aytubio.com, for 90 days.

A replay of the call will be available for fourteen days. Access the replay by calling 1-877-481-4010 (toll-free) and using the replay access code 56773.

About Aytu BioScience, Inc.

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant patient needs. The company currently markets Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"). Aytu also has exclusive U.S. and Canadian rights to ZolpiMist™, an FDA-approved, commercial-stage prescription sleep aid indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Aytu is the exclusive U.S. licensee with commercial rights to Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup. Tuzistra XR is a prescription antitussive consisting of codeine polistirex and chlorpheniramine polistirex in an extended-release oral suspension. Additionally, Aytu is developing MiOXSYS®, a novel, rapid semen analysis system with the potential to become a standard of care for the diagnosis and management of male infertility caused by oxidative stress. MiOXSYS is commercialized outside of the U.S. where it is a CE Marked, Health Canada cleared, Australian TGA approved, Mexican COFEPRAS approved product, and Aytu is planning U.S.-based clinical trials in pursuit of 510k de novo medical device clearance by the FDA. Aytu's strategy is to continue building its portfolio of revenue-generating products, leveraging its focused commercial team and expertise to build leading brands within large therapeutic markets. For more information visit aytubio.com.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this presentation, are forward-looking statements. Forward-looking statements are generally written in the future tense and/or are preceded by words such as "may," "will," "should," "forecast," "could," "expect," "suggest," "believe," "estimate," "continue," "anticipate," "intend," "plan," or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the effects of the business combination of Aytu and the Commercial Portfolio and the previously announced, but not yet consummated, merger ("Merger") with Innovus Pharmaceuticals, including the combined company's future financial condition, results of operations, strategy and plans, the ability of the combined company to realize anticipated synergies in the timeframe expected or at all, changes in capital markets and the ability of the combined company to finance operations in the manner expected, the diversion of management time on Merger-related issues and integration of the Commercial Portfolio, the ultimate timing, outcome and results of integrating the operations the Commercial Portfolio and Innovus with Aytu's existing operations, the failure to obtain the required votes of Innovus' shareholders or Aytu's shareholders to approve the Merger and related matters, the risk that a condition to closing of the Merger may not be satisfied, that either party may terminate the merger agreement or that the closing of the Merger might be delayed or not occur at all, the price per share utilized in the formula for the initial \$8 million merger consideration in the Merger may not be reflective of the current market price of Aytu's common stock on the closing date, potential adverse reactions or changes to business or employee relationships, including those resulting from the announcement or completion of the Merger, risks relating to gaining market acceptance of our products, obtaining or maintaining reimbursement by third-party payors, the potential future commercialization of our product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results, of our ongoing and future clinical trials, the anticipated designs of our future clinical trials, anticipated future regulatory submissions and events, our anticipated future cash position and future events under our current and potential future collaboration. We also refer you to the risks described in "Risk Factors" in Part I, Item 1A of the company's Annual Report on Form 10-K and in the other reports and documents we file with the Securities and Exchange Commission from time to time.

Contact for Investors:

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SOURCE: Aytu BioScience, Inc.

Aytu BioScience, Inc.
Condensed Consolidated Balance Sheet Information

	(Unaudited) September 30, 2019	June 30, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 7,014,307	\$ 11,044,227
Restricted cash	250,000	250,000
Accounts receivable, net	1,705,428	1,740,787
Inventory, net	1,380,729	1,440,069
Prepaid expenses and other	573,199	957,781
Note receivable	1,000,000	-
Other current assets	59,014	-
Total current assets	<u>11,982,677</u>	<u>15,432,864</u>
Fixed assets, net		
Licensed assets, net	137,900	203,733
Patents, net	18,293,199	18,861,983
Right-of-use asset	214,278	220,611
Deposits	393,820	-
Total long-term assets	<u>19,041,397</u>	<u>19,288,527</u>
Total assets	<u>\$ 31,024,074</u>	<u>\$ 34,721,391</u>
Liabilities		
Current liabilities		
Accounts payable and other	\$ 2,632,642	\$ 2,297,270
Accrued liabilities	1,151,181	1,147,740
Accrued compensation	1,002,409	849,498
Current lease liability	79,362	-
Current contingent consideration	1,236,625	1,078,068
Total current liabilities	<u>6,102,219</u>	<u>5,372,576</u>
Long-term contingent consideration	22,272,068	22,247,796
Long-term lease liability	314,457	-
Warrant derivative liability	11,371	13,201
Total liabilities	<u>28,700,115</u>	<u>27,633,573</u>
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, par value \$.0001; 50,000,000 shares authorized; shares issued and outstanding 3,151,148 and 3,594,981, respectively as of September 30, 2019 (unaudited) and June 30, 2019.	315	359
Common Stock, par value \$.0001; 100,000,000 shares authorized; shares issued and outstanding 17,981,094 and 17,538,071, respectively as of September 30, 2019 (unaudited) and June 30, 2019.	1,798	1,754
Additional paid-in capital	113,640,376	113,475,205
Accumulated deficit	(111,318,530)	(106,389,500)
Total stockholders' equity	<u>2,323,959</u>	<u>7,087,818</u>
Total liabilities and stockholders' equity	<u>\$ 31,024,074</u>	<u>\$ 34,721,391</u>

Aytu BioScience, Inc.,
Consolidated Statements of Operations Information
(Unaudited)

	Three Months Ended	
	September 30,	
	2019	2018
Revenues		
Product revenue, net	\$ 1,439,826	\$ 1,431,809
Operating expenses		
Cost of sales	375,720	410,959
Research and development	78,020	155,878
Selling, general and administrative	5,146,443	3,576,580
Selling, general and administrative - related party	-	253,709
Amortization of intangible assets	575,117	451,957
Total operating expenses	<u>6,175,300</u>	<u>4,849,083</u>
Loss from operations	<u>(4,735,474)</u>	<u>(3,417,274)</u>
Other (expense) income		
Other (expense), net	(195,386)	(76,561)
Gain from warrant derivative liability	1,830	47,352
Total other (expense) income	<u>(193,556)</u>	<u>(29,209)</u>
Net loss	<u>\$ (4,929,030)</u>	<u>\$ (3,446,483)</u>
Weighted average number of common shares outstanding	<u>15,325,921</u>	<u>1,759,824</u>
Basic and diluted net loss per common share	\$ (0.32)	\$ (1.96)

Aytu BioScience, Inc,
Condensed Consolidated Cash Flow Information
(Unaudited)

	Three Months End	
	September 30,	
	2019	2018
Operating Activities		
Net loss	\$ (4,929,030)	\$ (3,446,483)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	869,312	556,807
Stock-based compensation expense	165,171	152,114
Derivative income	(1,830)	(47,352)
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	35,359	(181,274)
Decrease in inventory	59,340	28,870
Decrease (increase) in prepaid expenses and other	384,582	(296,971)
Increase (decrease) in accounts payable and other	276,917	(7,889)
Increase in accrued liabilities	3,441	242,969
Increase in accrued compensation	152,911	256,174
(Decrease) in deferred rent	(3,990)	(1,450)
Net cash used in operating activities	<u>(2,987,817)</u>	<u>(2,744,485)</u>
Investing Activities		
Deposit	-	2,888
Purchases of fixed assets	-	(6,065)
Contingent consideration payment	(42,103)	-
Note receivable	(1,000,000)	-
Purchase of assets	-	(300,000)
Net cash used in investing activities	<u>(1,042,103)</u>	<u>(303,177)</u>
Financing Activities		
Net cash provided by financing activities	<u>-</u>	<u>-</u>
Net change in cash, restricted cash and cash equivalents	(4,029,920)	(3,047,662)
Cash, restricted cash and cash equivalents at beginning of period	11,294,227	7,112,527
Cash, restricted cash and cash equivalents at end of period	<u>\$ 7,264,307</u>	<u>\$ 4,064,865</u>

Aytu BioScience, Inc,
Condensed Consolidated Statement of Stockholders' Equity Information
(Unaudited)

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
BALANCE - June 30, 2019	3,594,981	\$ 359	17,538,071	\$ 1,754	\$13,475,205	\$106,389,500	\$ 7,087,818
Stock-based compensation	-	-	-	-	165,171	-	165,171
Preferred stock converted in common stock	(443,833)	(44)	443,833	44	-	-	-
Net loss	-	-	-	-	-	(4,929,030)	(4,929,030)
BALANCE - September 30, 2019	3,151,148	\$ 315	17,981,904	\$ 1,798	\$13,640,376	\$111,318,530	\$ 2,323,959
	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
BALANCE - June 30, 2018	-	\$ -	1,794,762	\$ 179	\$92,681,918	\$79,257,592	\$13,424,505
Stock-based compensation	-	-	-	-	152,114	-	152,114
Adjustment for rounding of shares due to stock split	-	-	6,649	1	(1)	-	-
Net loss	-	-	-	-	-	(3,446,483)	(3,446,483)
BALANCE - September 30, 2018	-	\$ -	1,801,411	\$ 180	\$92,834,031	\$82,704,075	\$10,130,136

Aytu BioScience, Inc,
Reconciliation of GAAP to Non-GAAP Pro Forma Financial Information
(Unaudited)

	Three Months Ended September 30, 2019	Twelve Months Ended September 30, 2019
Pro Forma Revenue		
Aytu product revenue, net	\$ 1.4	7.3
Acquired Cerecor Pediatric Therapeutic revenue, net	3.4	12.7
Innovus revenue, net	5.8	22.7
Total Pro-Forma Revenue	<u>\$ 10.6</u>	<u>\$ 42.7</u>
		As of September 30, 2019
Pro Forma Net Cash		
Cash, cash equivalents and restricted cash at September 30, 2019		\$ 7.3
Cash raised from an October private placement financing		9.3
Total Pro Forma Cash		<u>\$ 16.6</u>
