

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AYTU BIOSCIENCE, INC

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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): September 26, 2019

AYTU BIOSCIENCE, INC.

(Exact Name of Registrant as Specified in 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, Colorado

(Address of Principal Executive Offices)

80112

(Zip Code)

Registrant's Telephone Number, Including Area Code: (720) 437-6580

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 (see General Instruction A.2. below):

- 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))

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.

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

Item 2.02 Results of Operations and Financial Condition.

On September 26, 2019, the Company issued a press release announcing that the Company will present its operational results for the fiscal fourth quarter and year ended June 30, 2019 on Thursday, September 26, 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 September 26, 2019

SIGNATURE

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.

Date: September 26, 2019

By: /s/ Joshua Disbrow

Name: Joshua Disbrow

Title: Chief Executive Officer

Aytu BioScience Reports 100% Revenue Growth to \$7.3 million in FY 2019

Results Do Not Include September 2019 Definitive Agreement to Acquire Innovus Pharmaceuticals: Combined LTM revenues of over \$31M, Diversifies product line by 10x to over 30 products

ENGLEWOOD, CO / ACCESSWIRE / September 26, 2019 / Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, today will provide an overview of its business, including the company's operational and financial results for its fiscal year 2019 that ended June 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.

FY 2019 and Recent Operational Highlights

- Fiscal Year ending June 30, 2019 revenue increased 100% to \$7.3 million; results do not include any contribution from September 2019 Definitive Agreement to acquire Innovus Pharmaceuticals: combined last twelve-month revenues of over \$31 million
 - Generated \$5.1 million in FY 2019 gross profit, a 218% increase over prior year
 - Grew product portfolio from Natesto® only, to three products – with the acquisition of ZolpiMist™ and Tuzistra® XR
 - Natesto Spermatogenesis Study results were accepted for presentation as a “Late-Breaking Abstract” by the American Society for Reproductive Medicine (ASRM). The study results will be presented at the 75th ASRM Scientific Congress & Expo in Philadelphia, PA October 16, 2019
 - Used \$2.1 million less cash than prior year despite cash used to purchase two new products, buy inventory and launch both quickly, within one-quarter of closing each transaction
 - Raised \$20.6 million new capital (debt, equity and warrant exercises)
 - Added multiple high-quality, healthcare focused fundamental institutional investors
 - Added two sell-side analysts covering AYTU
 - Expanded the board to include Steve Boyd, Founder and CIO of healthcare institutional investor Armistice Capital, and Ketan Mehta, Founder, President, and Chief Executive Officer of Tris Pharma
-

Subsequent to Fiscal Year Ending June 30, 2019

Announced Innovus Pharmaceuticals acquisition to form an integrated specialty pharmaceutical company:

- Combined trailing twelve-month revenues of over \$31 million
- Diversifies product line by 10x to over 30 products in both Rx and consumer segments
- Adds a robust, growing consumer health business to complement current growing prescription product portfolio
- Adds complementary, seasoned management team to continue the growth of the Innovus consumer health business
- Innovus operating near breakeven; near-term commercial, administrative, and operational synergies, resulting in acceleration of time to EBIDTA positive, are expected to be realized through the rapid integration of the two companies' operations.

Announced Natesto license re-negotiation with Acerus Pharmaceuticals to accelerate revenue growth and increase promotion to Low T specialists:

- Doubles Natesto sales representatives; augments current Aytu sales force with nationwide specialty sales team focused on urology and endocrinology
- Increases gross profit, eliminates milestone payments, removes regulatory fees and clinical trial expenses

Announced Tuzistra XR co-promotion with Poly Pharmaceuticals to accelerate Rx growth and increase physician coverage:

- Doubles the Tuzistra XR sales representative headcount; potential to double revenue in FY2020
- Expands primary care physician promotion by over 7,500 prescribers

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "FY 2019 and subsequent activities reflect that Aytu is entering a period of hypergrowth. Revenue in FY 2019 increased 100% year over year to \$7.3 million, as we grew the product portfolio 3x from one product to three. With our September 2019 definitive agreement to acquire Innovus Pharmaceuticals, combined trailing twelve-month revenue is more than \$31 million, and this grows and diversifies our product line by 10x to over 30 products in both Rx and consumer health segments. The synergies from the combination are expected to result in accelerating our time to EBITDA positive, which we expect will be a significant catalyst that further increases shareholder value."

FY19 Financial Results

- Net revenue for the year-ended June 30, 2019 was \$7.3 million, an increase of 100% over the prior year ended June 30, 2018.
- Cash, cash equivalents, and restricted cash was approximately \$11.3 million as of June 30, 2019
- Cash used in operations for the year ended June 30, 2019 decreased by \$2.1 million from the prior year ended June 30, 2018.
- Operating expenses excluding COGS for the year ended June 30, 2019 were \$22 million, which were comparable to the prior year ended June 30, 2018.
- The company retired all of its outstanding debt through an exchange with Armistice Capital in the fourth quarter of 2019, which increased its equity investment in the company. The \$5 million exchange was approved by a shareholder vote with 95% of votes cast supporting the exchange.

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 53674.

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 recently acquired exclusive U.S. 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. 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: 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:

James Carbonara
Hayden IR
(646)-755-7412

Aytu BioScience, Inc.

Consolidated Statements of Operations Information

	Year Ended June 30,	
	2019	2018
Revenues		
Product revenue, net	\$ 7,314,581	\$ 3,660,120
License revenue, net	5,776	—
Total product revenue	<u>7,320,357</u>	<u>3,660,120</u>
Operating expenses		
Cost of sales	2,202,041	2,050,544
Research and development	589,072	167,595
Selling, general and administrative	18,887,783	17,732,490
Selling, general and administrative - related party	351,843	—
Impairment of intangible assets	—	1,856,020
Amortization of intangible assets	2,136,255	1,553,705
Total operating expenses	<u>24,166,994</u>	<u>23,360,354</u>
Loss from operations	<u>(16,846,637)</u>	<u>(19,700,234)</u>
Other (expense) income		
Other (expense), net	(535,500)	(749,423)
(Loss) / gain from change in fair value of contingent consideration	(9,830,550)	6,277,873
Gain from warrant derivative liability	80,779	3,983,921
Total other (expense) income	<u>(10,285,271)</u>	<u>9,512,371</u>
Net loss	<u>\$ (27,131,908)</u>	<u>\$ (10,187,863)</u>
Weighted average number of common shares outstanding	<u>\$ 7,794,489</u>	<u>\$ 665,605</u>
Basic and diluted net loss per common share	\$ (3.48)	(15.31)

Aytu BioScience, Inc.
Consolidated Balance Sheet Information

	June 30,	
	2019	2018
Assets		
Current assets		
Cash and cash equivalents	\$ 11,044,227	\$ 7,012,527
Restricted cash	250,000	100,000
Accounts receivable, net	1,740,787	578,782
Inventory, net	1,440,069	1,338,973
Prepaid expenses and other	957,781	440,009
Total current assets	<u>15,432,864</u>	<u>9,470,291</u>
Fixed assets, net		
Fixed assets, net	203,733	218,684
Licensed assets, net	18,861,983	11,120,086
Patents, net	220,611	245,944
Deposits	2,200	5,088
Total long-term assets	<u>19,288,527</u>	<u>11,589,802</u>
Total assets	<u>\$ 34,721,391</u>	<u>\$ 21,060,093</u>
Liabilities		
Current liabilities		
Accounts payable and other	\$ 2,297,270	\$ 2,119,672
Accrued liabilities	1,147,740	185,882
Accrued compensation	849,498	540,674
Current deferred rent	-	1,450
Current contingent consideration	1,078,068	547,100
Total current liabilities	<u>5,372,576</u>	<u>3,394,778</u>
Long-term contingent consideration	22,247,796	4,146,829
Warrant derivative liability	13,201	93,981
Total liabilities	<u>27,633,573</u>	<u>7,635,588</u>
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, par value \$.0001; 50,000,000 shares authorized; shares issued and outstanding 3,594,981 and 0, respectively as of June 30, 2019 and 2018, respectively.	359	-
Common Stock, par value \$.0001; 100,000,000 shares authorized; shares issued and outstanding 17,538,071 and 1,794,762, respectively as of June 30, 2019 and 2018	1,754	179
Additional paid-in capital	113,475,205	92,681,918
Accumulated deficit	<u>(106,389,500)</u>	<u>(79,257,592)</u>
Total stockholders' equity	<u>7,087,818</u>	<u>13,424,505</u>
Total liabilities and stockholders' equity	<u>\$ 34,721,391</u>	<u>\$ 21,060,093</u>

Aytu BioScience, Inc.

Consolidated Statements of Cash Flows Information

	Year Ended June 30,	
	2019	2018
Operating Activities		
Net loss	\$ (27,131,908)	\$ (10,187,863)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	2,727,067	2,591,270
Impairment of intangible assets	-	1,856,020
Stock-based compensation expense	1,022,202	596,934
Loss / (gain) from change in fair value of contingent consideration	9,830,550	(6,277,873)
Warrants issuance and amendments	-	183,920
Issuance of common stock to employee	11,690	-
Derivative income	(80,779)	(3,983,921)
Changes in operating assets and liabilities:		
(Increase) in accounts receivable	(1,162,005)	(50,743)
(Increase) decrease in inventory	(101,096)	(26,752)
(Increase) in prepaid expenses and other	(517,772)	(129,249)
Increase / (decrease) in accounts payable and other	134,775	(109,707)
Increase / (decrease) in accrued liabilities	961,858	(596,654)
Increase in accrued compensation	308,824	200,970
Increase in interest payable - related party	166,667	-
(Decrease) in deferred rent	(1,450)	(6,674)
Net cash used in operating activities	<u>(13,831,377)</u>	<u>(15,940,322)</u>
Investing Activities		
Deposit	2,888	(2,200)
Purchases of fixed assets	(59,848)	(74,707)
Contingent consideration payment	(505,025)	(7,385)
Purchase of assets	(500,000)	(400,000)
Net cash used in investing activities	<u>(1,061,985)</u>	<u>(484,292)</u>
Financing Activities		
Issuance of preferred, common stock and warrants	15,180,000	11,839,995
Issuance costs related to preferred, common stock and warrants	(1,479,964)	(1,402,831)
Issuance of preferred, common stock and warrants	-	12,900,020
Issuance costs related to preferred, common stock and warrants	-	(1,294,235)
Warrant exercises	375,026	677,100
S-3 registered offering cost	-	(60,450)
Issuance of debt - related party	5,000,000	-
Net cash provided by financing activities	<u>19,075,062</u>	<u>22,659,599</u>
Net change in cash, restricted cash and cash equivalents	4,181,700	6,234,985
Cash, restricted cash and cash equivalents at beginning of period	7,112,527	877,542
Cash, restricted cash and cash equivalents at end of period	<u>\$ 11,294,227</u>	<u>\$ 7,112,527</u>