

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AYTU BIOSCIENCE, INC

Form: 8-K

Date Filed: 2020-10-06

Corporate Issuer CIK: 1385818

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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):

October 6, 2020

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 October 6, 2020, the Company issued a press release announcing the Company's financial results for the three- and twelve months ended June 30, 2020. 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) Exhibits

Exhibit	Description
99.1	Press release dated October 6, 2020

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.

Date: October 6, 2020

By: /s/ Joshua R. Disbrow
Joshua R. Disbrow
Chief Executive Officer

Aytu BioScience Announces Fiscal Q4 2020 Net Revenue of \$14.9 Million, an Increase of 82% Sequentially, and 766% Year-Over-Year**Company's highest revenue quarter to date is more than 2X its entire fiscal 2019 revenue**

ENGLEWOOD, CO / ACCESSWIRE / October 6, 2020 / Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty pharmaceutical company (the "Company") focused on commercializing novel products that address significant patient needs today reported financial results for its fiscal fourth quarter 2020, for the three month period ending June 30, 2020.

Fourth Quarter Fiscal 2020 Financial Highlights

- Q4 Net Revenue increased 82% sequentially, and 766% year-over-year to \$14.9 million
- Highest revenue quarter to date is more than 2X entire fiscal 2019 revenue
- Q4 Consumer Health Net Revenue was \$6.9 million, compared to \$3.5 in Q3
- Q4 Rx Net Revenue was \$7.9 million, compared to \$4.7 in Q3
- Q4 net loss of (\$3.1) million and Q4 Adjusted EBITDA of (\$1.7) million
- Cash, cash equivalents and restricted cash of \$48.3 million on June 30, 2020, after fully extinguishing the \$15 million Deerfield balloon payment obligation.

Commenting on the fourth quarter of fiscal 2020, Josh Disbrow, Chief Executive Officer of Aytu BioScience, stated "Revenue increased exponentially in Q4 2020, to \$14.9 million, compared to \$1.7 million for Q4 2019. It is important to note that this was the first full quarter of revenue from the combined Aytu and Innovus businesses, along with the Cerecor assets. Turning to the bottom line, adjusted EBITDA loss was reduced to just \$1.7 million for Q4 2020, compared to a \$3.7 million adjusted EBITDA loss for Q4 2019. On the balance sheet, with approximately \$48.3 million in cash, cash equivalents and restricted cash after paying \$15 million to fully extinguish the Deerfield balloon payment previously due January 2021, we have less than \$1 million of debt, and at current spending levels, we believe we have sufficient runway to reach profitability."

Mr. Disbrow continued, "Taking a closer look at the top line, both of our revenue streams, from the Consumer Health and Rx segments, performed well. On the Consumer Health side, we generated \$6.9 million in revenue, an increase compared to Q3. Contributing to those results was organic growth within our core Consumer Health product lines of diabetes care, sexual wellness and bladder health. Additionally, we strengthened our e-commerce business for Consumer Health. Furthermore, our newly launched Consumer Health product, Regoxidine®, an over-the-counter foam formulation of minoxidil for hair regrowth, is on track to contribute revenue in excess of seven figures in its first 12-months from launch."

Mr. Disbrow added, "On the Rx side, revenue was \$7.9 million, a significant increase compared to Q3. Contributing to Rx revenue was solid contribution from the pediatric franchise. Additional value was created with Natesto® gaining preferred status on Express Scripts' national formulary and the Natesto spermatogenesis study results published in the *Journal of Urology*, both of which we expect to drive prescription growth in the coming quarters. Organic Rx growth was fueled by a relatively balanced contribution across our key products and improved sales execution. Despite the impact COVID has had on physician office access, Q4 represented a record revenue quarter for our Rx business and significant growth over the previous quarters. This is a strong statement about our field execution and clinical value of our products, and I'm pleased to see our call levels now picking back up to near normal in the current quarter to further drive prescription growth."

Mr. Disbrow concluded, "At \$14.9 million in record quarterly revenue, with a narrowed Adjusted EBITDA loss, \$48.3 million of cash, cash equivalents and restricted cash on the balance sheet, the addition of the Healight opportunity for COVID-19 and future potential non-COVID-19 applications, and our addition to the Russell 2000, we have strong momentum to grow shareholder value in fiscal 2021 and onward."

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:

877-407-9124 (toll-free)
201-689-8584 (international)

The webcast will be accessible live at <https://www.webcaster4.com/Webcast/Page/2142/37506> 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) or 919-882-2331 (international) and using the replay access code 37506

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 a portfolio of prescription products addressing large primary care and pediatric markets. The primary care portfolio includes (i) Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"), (ii) ZolpiMist®, the only FDA-approved oral spray prescription sleep aid, and (iii) Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup. The recently acquired Pediatric Portfolio includes (i) Cefaclor, a second-generation cephalosporin antibiotic suspension; (ii) Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions; and (iii) Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various forms for infants and children with fluoride deficiency. Aytu also distributes a COVID-19 IgG/IgM rapid test. This antibody test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. Aytu has also licensed the Healight™ Platform Technology. Healight is a pre-clinical investigational device being studied as a potential treatment for COVID-19 in severely ill, intubated patients and potentially other respiratory illnesses.

Aytu also operates a consumer health subsidiary, Innovus Pharmaceuticals, Inc. ("Innovus"), a specialty pharmaceutical company licensing, developing, and commercializing safe and effective consumer healthcare products designed to improve health and vitality. Innovus commercializes over twenty consumer health products competing in large healthcare categories including diabetes, men's health, sexual wellness and respiratory health. The Innovus product portfolio is commercialized through direct-to-consumer marketing channels utilizing the company's proprietary Beyond Human® marketing and sales platform.

Aytu's strategy is to continue building its portfolio of revenue-generating Rx and consumer health products, leveraging its focused commercial team and expertise to build leading brands within large therapeutic markets. For more information visit aytubio.com and visit innovuspharma.com to learn about the company's consumer healthcare products.

Forward-Looking Statement

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: market and other conditions, our ability to successfully commercialize Healight Platform Technology, our ability to obtain FDA approval for the Healight Platform Technology, the effectiveness of the Healight Platform Technology in treating patients with COVID-19 or other illnesses, our ability to adequately protect the intellectual property associated with the Healight Platform Technology, regulatory delays, the reliability of the Healight Platform Technology in killing viruses and bacteria, market acceptance of UV based medical devices, the regulatory and commercial risks associated with introducing the COVID-19 rapid tests, any delays in shipment that may impact our ability to distribute the COVID-19 rapid tests, any reputational harm we may incur if there are delays in receiving the shipment of the COVID-19 rapid tests, our ability to enforce the exclusivity provisions of the distribution agreements, the reliability of serological testing in detecting COVID-19, shipping delays and their impact on our ability to introduce the COVID-19 rapid tests, the ability of the COVID-19 rapid tests to accurately and reliably test for COVID-19, the manufacturers of the COVID-19 rapid tests' ability to manufacture such testing kits on a high volume scale, manufacturing problems or delays related to the COVID-19 rapid tests, our ability to satisfy any labelling conditions or other FDA or other regulatory conditions to sell the COVID-19 rapid test kits, the demand or lack thereof for the COVID-19 rapid test kits, our ability to obtain additional COVID-19 rapid tests to meet demand, our ability to secure additional tests if the manufacturers of the COVID-19 rapid tests are unable to meet demand, the effects of the business combination of Aytu and the Pediatric Portfolio and the recently completed 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 Pediatric Portfolio, the ultimate timing, outcome and results of integrating the operations the Pediatric Portfolio and Innovus with Aytu's existing operations, risks relating to gaining market acceptance of our products, obtaining or maintaining reimbursement by third-party payors for our prescription products, the potential future commercialization.

Contact for Media and Investors:

James Carbonara
Hayden IR
(646) 755-7412
james@haydenir.com

Non-GAAP Financial Information

This press release contains a financial measure that does not comply with U.S. generally accepted accounting principles (GAAP), Non-GAAP Adjusted EBITDA. Non-GAAP Adjusted EBITDA excludes (i) amortization, (ii) depreciation, (iii) stock-based compensation, (iv) other expenses comprising net interest expense, (v) non-cash gains and/or losses recognized in the quarter or year due to changes in the fair value of certain of Aytu's financial liabilities, such as contingent consideration, derivative warrant liability, or certain exchanges of debt, (vi) bad debt expense, (vii) impairment of certain long-lived assets; (viii) one-time transaction costs and (ix) costs associated with the Company's Healight technology. Management believes these measures are useful to supplement its GAAP financial statements with this non-GAAP information because management uses such information internally for its operating, budgeting and financial planning purposes. In addition, Aytu believes these non-GAAP financial measures are useful to investors because they allow for greater transparency into the indicators used by management as a basis for its financial and operational decision making. Non-GAAP information is not prepared under a comprehensive set of accounting rules and therefore, should only be read in conjunction with financial information reported under U.S. GAAP when understanding Aytu's operating performance. A reconciliation between GAAP and non-GAAP financial information is provided in the financial statement tables below.

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

	(Unaudited)			
	Three Months Ended June 30,		Year Ended June 30,	
	2020	2019	2020	2019
Revenues				
Product revenue, net	\$ 14,860,845	\$ 1,715,745	\$ 27,632,080	\$ 7,314,581
License revenue, net	-	-	-	5,776
Total product revenue	<u>14,860,845</u>	<u>1,715,745</u>	<u>27,632,080</u>	<u>7,320,357</u>
Operating expenses				
Cost of sales	4,572,606	649,091	7,553,031	2,202,041
Research and development	1,498,222	175,264	1,721,419	589,072
Selling, general and administrative	13,638,360	4,896,267	34,802,432	18,887,783
Selling, general and administrative - related party	-	-	-	351,843
Impairment of intangible assets	195,278	-	195,278	-
Amortization of intangible assets	1,590,913	575,118	4,490,466	2,136,255
Total operating expenses	<u>21,495,379</u>	<u>6,295,740</u>	<u>48,762,626</u>	<u>24,166,994</u>
Loss from operations	<u>(6,634,534)</u>	<u>(4,579,995)</u>	<u>(21,130,546)</u>	<u>(16,846,637)</u>
Other (expense) income				
Other (expense), net	(1,425,281)	(136,667)	(2,606,487)	(535,500)
(Loss) / gain from change in fair value of contingent consideration	5,230,446	(9,830,550)	10,430,252	(9,830,550)
(Loss) on extinguishment of debt	(315,728)	-	(315,728)	-
Gain from warrant derivative liability	-	15,311	1,830	80,779
Total other (expense) income	<u>3,489,437</u>	<u>(9,951,906)</u>	<u>7,509,867</u>	<u>(10,285,271)</u>
Net loss	<u>\$ (3,145,097)</u>	<u>\$ (14,531,901)</u>	<u>\$ (13,620,679)</u>	<u>\$ (27,131,908)</u>
Weighted average number of shares outstanding of common shares outstanding	<u>113,354,250</u>	<u>13,908,932</u>	<u>45,192,010</u>	<u>7,794,489</u>
Basic and diluted net loss per common share	\$ (0.03)	\$ (1.04)	\$ (0.30)	\$ (3.48)

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

	June 30,	
	2020	2019
Assets		
Current assets		
Cash and cash equivalents	\$ 48,081,715	\$ 11,044,227
Restricted cash	251,592	250,000
Accounts receivable, net	5,175,924	1,740,787
Inventory, net	9,999,441	1,440,069
Prepaid expenses and other	5,715,089	957,781
Other current assets	5,742,011	-
Total current assets	74,965,772	15,432,864
Fixed assets, net	258,516	203,733
Right-of-use asset	634,093	-
Licensed assets, net	16,586,847	18,861,983
Patents and tradenames, net	11,081,048	220,611
Product technology rights, net	21,186,666	-
Deposits	32,981	2,200
Goodwill	28,090,407	-
Total long-term assets	77,870,558	19,288,527
Total assets	\$ 152,836,330	\$ 34,721,391

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Consolidated Balance Sheets, Cont'd

Liabilities

	June 30,	
	2020	2019
Current liabilities		
Accounts payable and other	\$ 11,824,560	\$ 2,133,522
Accrued liabilities	7,849,855	1,311,488
Accrued compensation	3,117,177	849,498
Debt	982,076	-
Contract liability	339,336	-
Current lease liability	300,426	-
Current portion of fixed payment arrangements	2,340,166	-
Current portion of CVR liabilities	839,734	-
Current portion of contingent consideration	713,251	1,078,068
Total current liabilities	28,306,581	5,372,576
Long-term contingent consideration, net of current portion	12,874,351	22,247,796
Long-term lease liability, net of current portion	725,374	-
Long-term fixed payment arrangements, net of current portion	11,171,491	-
Long-term CVR liabilities, net of current portion	4,731,866	-
Warrant derivative liability	11,371	13,201
Total liabilities	57,821,034	27,633,573

Commitments and contingencies

Stockholders' equity

Preferred Stock, par value \$.0001; 50,000,000 shares authorized; shares issued and outstanding 3,594,981, respectively as of June 30, 2020 and 2019	—	359
Common Stock, par value \$.0001; 200,000,000 shares authorized; shares issued and outstanding 125,837,357 and 17,538,071, respectively as of June 30, 2020 and 2019	12,584	1,754
Additional paid-in capital	215,012,891	113,475,205
Accumulated deficit	(120,010,179)	(106,389,500)
Total stockholders' equity	95,015,296	7,087,818
Total liabilities and stockholders' equity	\$ 152,836,330	\$ 34,721,391

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows

	<u>Year Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>
Operating Activities		
Net loss	\$ (13,620,679)	\$ (27,131,908)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	6,245,827	2,727,067
Impairment of intangible assets	195,278	-
Stock-based compensation expense	1,079,311	1,022,202
Loss / (gain) from change in fair value of contingent consideration	(5,291,629)	9,830,550
Derecognition of contingent consideration	(5,199,806)	-
Gain on the change in fair value of CVR payout	(267,130)	-
Changes in allowance for bad debt	404,549	-
Loss / (gain) from change in fair value of CVR	352,782	-
Loss / (gain) from note conversion	315,728	-
Loss / (gain) from settlement payment	(24,469)	-
Issuance of common stock to employee	48,083	11,690
Derivative income	(1,830)	(80,779)
Changes in operating assets and liabilities:		
(Increase) in accounts receivable	(3,560,860)	(1,162,005)
(Increase) in inventory	(6,950,624)	(101,096)
(Increase) in prepaid expenses and other	(2,315,881)	(517,772)
(Increase) in other current assets	(3,749,846)	-
(Decrease) / increase in accounts payable and other	(1,376,521)	134,775
Increase in accrued liabilities	4,330,856	961,858
Increase in accrued compensation	1,124,624	308,824
(Decrease) in contract liabilities	(111,650)	-
Increase in interest payable - related party	-	166,667
(Decrease) in deferred rent	-	(1,450)
Net cash used in operating activities	<u>(28,373,887)</u>	<u>(13,831,377)</u>
Investing Activities		
Deposit	6,000	2,888
Purchases of fixed assets	-	(59,848)
Contingent consideration payment	(202,688)	(505,025)
Cash received from acquisition	390,916	-
Purchase of assets	(5,850,000)	(500,000)
Net cash used in investing activities	<u>\$ (5,655,772)</u>	<u>\$ (1,061,985)</u>

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows, Cont'd

	Year Ended June 30,	
	2020	2019
Financing Activities		
Issuance of preferred, common stock and warrants	\$ 65,729,900	\$ 15,180,000
Issuance costs related to preferred, common stock and warrants	(5,404,151)	(1,479,964)
Warrant exercises	26,991,841	375,026
Payments made to borrowings	(19,436,779)	-
Proceeds from borrowings	2,547,928	-
Issuance of note payable	640,000	-
Issuance of debt - related party	-	5,000,000
Net cash provided by financing activities	<u>71,068,739</u>	<u>19,075,062</u>
Net change in cash, restricted cash and cash equivalents	37,039,080	4,181,700
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>\$ 48,333,307</u>	<u>\$ 11,294,227</u>

Supplemental disclosures of cash and non-cash investing and financing transactions

Warrants issued to investors and underwriters	\$ -	\$ 1,888,652
Contingent consideration included in accounts payable	16,014	42,821
Contingent consideration related to product acquisition	-	8,833,219
Issuance of preferred stock related to purchase of assets	-	519,600
Conversion of debt to equity	-	5,166,667
Cash paid for interest	1,040,276	-
Fair value of right-to-use asset and related lease liability	334,895	-
Issuance of Series G preferred stock due to acquisition of the Pediatric Portfolio of therapeutics	5,559,941	-
Issuance of Series H preferred stock due to acquisition of the Innovus	12,805,263	-
Fixed payment arrangements included in accounts payable	894,900	-
Exchange of convertible preferred stock into common stock	2,540	-
Reclass of par from APIC to Common Stock for issuance of stock for equity classified instruments	1,488	-
Issuance cost related to S-3	1,531,190	-
Issuance of common stock for settlement	125,531	-
Issuance of common stock for note conversion	2,578,864	-
Issuance of common stock to consultants	231,000	-
CVR payout for calendar year 2019	\$ 2,000,000	\$ -

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Reconciliation of GAAP to Non-GAAP Financial Information
(Unaudited)

	Three Months Ended June 30, 2020		Year Ended June 30,	
	2020	2019	2020	2019
Adjusted EBITDA Reconciliation				
Net Loss	\$ (3,145,097)	\$ (14,531,901)	\$ (13,620,679)	\$ (27,131,908)
Amortization expense	1,590,913	575,118	4,490,466	2,136,255
Depreciation expense	33,529	15,443	89,824	74,798
Other expense, net	1,425,281	136,667	2,606,487	535,500
Stock-based compensation	536,567	299,360	1,127,394	1,022,200
(Gain)/Loss on change in fair value of contingent consideration	(5,230,446)	9,830,550	(10,430,252)	9,830,550
Gain/loss on extinguishment of debt	315,728	-	315,728	-
(Gain)/Loss on change in fair value of derivative warrant liability	-	(15,311)	(1,830)	(80,779)
Bad debt expense	408,365	-	408,457	-
Impairment of intangible assets	195,278	-	245,278	-
Healight development costs	1,309,080	-	1,309,080	-
Acquisition transaction costs	814,033	-	2,333,174	-
Adjusted EBITDA	<u>\$ (1,746,769)</u>	<u>\$ (3,690,074)</u>	<u>\$ (11,126,873)</u>	<u>\$ (13,613,384)</u>