Aytu BioScience Reports Third Quarter Fiscal 2020 Financial Results

Company Reports Revenue for the Three Months Ended March 31, 2020 of $8.2M, Up 243% Year-over-Year

$62.5 Million in Cash and Cash Equivalents as of March 31, 2020

Management to Host Conference Call at 4:30 PM ET

ENGLEWOOD, CO / May 14, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company (the "Company") focused on commercializing novel products that address significant medical needs, today reported financial results for the three months ended March 31, 2020 and provided a corporate update.

Third Quarter Fiscal 2020 and Other Recent Corporate Developments:

COVID-19 Update

- The Company secured an exclusive U.S. distribution agreement for a COVID-19 IgG/IgM rapid test from Hong Kong-based L.B. Resources.
- The Company announced a second distribution agreement for a COVID-19 IgG/IgM rapid test with Singapore-based Biolidics Limited.
- The Company received an initial shipment of 100,000 COVID-19 IgG/IgM rapid tests and began shipping to U.S. customers.
- The Company announced positive results from an independently conducted clinical study of the Zhejiang Orient Gene Biotech COVID-19 IgG/IgM rapid test demonstrating test accuracy of 98.0% and 94.1% for IgG and IgM, respectively, when using PCR-positive cases as true positives.
- The Company signed an exclusive worldwide license from Cedars-Sinai to develop and commercialize the Healight Platform Technology ("Healight"). This ultraviolet light-based medical device technology platform, developed by scientists at Cedars-Sinai, is being studied as a potential treatment for coronavirus and other severe respiratory infections.
- The Company signed an agreement with Sterling Medical Devices to finalize the development of Healight.

Rx Business Update

The Company announced the acceptance and publication of the Natesto® Spermatogenesis Study results in the *Journal of Urology.* The study concluded that Natesto was effective in

returning hypogonadal men to back to normal testosterone levels, significantly improve erectile function and quality of life, preserve gonadotropin hormones, and most importantly preserve semen parameters through 6 months of treatment.

Consumer Health Business Update

The Company completed the acquisition of Innovus Pharmaceuticals to expand the Company's portfolio to include an approximately $25 million annual consumer health portfolio.

Company's newly acquired Innovus consumer health subsidiary launched its first post-acquisition product Regoxidine®, an over-the-counter foam formulation of minoxidil for hair regrowth available for use by both men and women, targeting over 11 Million U.S. consumers who purchased hair regrowth products in 2019.

Financial Results and Financing Update

Revenue: The Company recorded revenue of $8.2 million for the three months ended March 31, 2020, an increase of approximately 243% compared to the three months ended March 31, 2019, and an increase of approximately 157% compared to the three months ended December 31, 2019.

The Company's third quarter revenue results represent partial revenue contribution from the acquisition of Innovus Pharmaceuticals, which closed on February 14, 2020, and zero revenue contribution from COVID-19 IgG/IgM rapid tests first received at the start of the fiscal fourth quarter on April 1, 2020.

Cash and cash equivalents: As of March 31, 2020, the Company had cash, cash equivalents and restricted cash of $62.5 million, compared to $5.5 million as of December 31, 2019.

Shares Outstanding: At March 31, 2020, the Company had 100,610,380 shares of common stock outstanding. There are currently no outstanding preferred shares.

Financings: The Company completed three registered direct offerings priced at-the-market and announced the exercise of 17.1 million warrants.

Commenting on the third quarter of fiscal 2020, Josh Disbrow, Chief Executive Officer of Aytu BioScience, stated, "We had a transformative third quarter and have had exceptional performance in the period year to date. Starting with revenue, in Q3 we reported our highest ever revenue quarter with $8.2 million in top line, up 243% year over year. Additionally, through our recent equity offerings and warrant exercises we strengthened our balance sheet and have $62.5 million in cash, restricted cash, and cash equivalents as of March 31st.

Further, by signing two distribution agreements for COVID-19 rapid tests and securing an exclusive worldwide licensing agreement with Cedars-Sinai for the Healight technology platform, the Company is well positioned to continue to take the fight to COVID-19. With a large number of tests having just arrived at our warehouse this week, we can now help even more providers screen patients for COVID-19 IgG and IgM antibodies as we collectively work to reopen the country."

Mr. Disbrow continued, "Looking at our growth drivers beyond fiscal Q3, the Company has three strategic areas from which we expect to make progress going forward: growth of our organic Rx and consumer health business segments, continuing the distribution of the two COVID-19 antibody test kits for which we've secured distribution rights, and progressing the development of the Healight platform technology as a prospective treatment for COVID-19 and other severe infections. Organically in Q4, we will have our first full quarter of revenue contribution from the newly acquired Innovus consumer health segment. Importantly, the consumer business has already launched Regoxidine, for hair regrowth, and more near-term consumer health product launches are planned. With respect to the prescription business, we reported recently published Phase IV data for Natesto and demonstrated that a testosterone replacement therapy can increase serum testosterone levels while maintaining sperm concentration, motility, and total motile sperm count. We believe this clinical development enables Natesto to stand apart from other testosterone replacement therapies in offering a treatment solution for hypogonadal men wishing to maintain fertility. In terms of COVID-19 testing revenue, we began shipping product in April, so we expect a significant increase in revenue in Q4 now that those test sales are under way. Additionally, we signed an exclusive global license with Cedars-Sinai for Healight, which represents a novel opportunity as a potential treatment for COVID-19 and other serious infections for hospitalized patients."

Mr. Disbrow concluded, "When considering our organic growth, a $62.5 million cash balance, our expected revenue from the COVID-19 antibody test kits, the addition of the Healight opportunity, and a cleaned-up capital structure, I have never been more optimistic about the future of Aytu BioScience."

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 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 34718.

About Aytu BioScience, Inc.

Aytu BioScience, Inc. 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 pediatric portfolio includes (i) AcipHex® Sprinkle™, a granule formulation of rabeprazole sodium, a commonly prescribed proton pump inhibitor; (ii) Cefaclor, a second-generation cephalosporin antibiotic suspension; (iii) Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions; and (iv) Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various for infants and children with fluoride deficiency. Aytu recently acquired exclusive U.S. distribution rights to two COVID-19 IgG/IgM rapid tests. These coronavirus tests are solid phase immunochromatographic assays 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. The Company also recently signed an exclusive worldwide licensing agreement with Cedars-Sinai to develop the Healight™ technology platform, which is being studied as a potential treatment for COVID-19 and other severe respiratory infections.

Aytu recently acquired Innovus Pharmaceuticals, a specialty pharmaceutical company commercializing, licensing and developing safe and effective consumer healthcare products designed to improve men's and women's health and vitality. Innovus commercializes over thirty-five 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 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 Commercial 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 Commercial Portfolio, the ultimate timing, outcome and results of integrating the operations the Commercial 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.

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2020	2019	2020	2019
Revenues				
Product revenue, net	$ 8,156,173	$ 2,372,016	$ 12,771,235	$ 5,598,836
License revenue	–	5,776	–	5,776
Total revenue	8,156,173	2,377,792	12,771,235	5,604,612
Operating expenses				
Cost of sales	1,998,659	616,853	2,980,425	1,552,950
Research and development	78,502	108,901	223,197	413,808
Selling, general and administrative	9,501,469	5,368,762	21,164,072	13,991,516
Selling, general and administrative – related party	–	6,797	–	351,843
Amortization of intangible assets	1,370,986	575,117	2,899,553	1,561,137
Total operating expenses	12,949,616	6,676,430	27,267,247	17,871,254
Loss from operations	(4,793,443)	(4,298,638)	(14,496,012)	(12,266,642)
Other (expense) income				
Other (expense), net	(538,862)	(194,703)	(1,181,206)	(398,833)
Gain from derecognition of contingent consideration	–	–	5,199,806	–
Gain from warrant derivative liability	–	(2,521)	1,830	65,468
Total other (expense) income	(538,862)	(197,224)	4,020,430	(333,365)
Net loss	$ (5,332,305)	$ (4,495,862)	$ (10,475,582)	$ (12,600,007)
Weighted average number of common shares outstanding	35,275,296	9,061,023	22,616,962	5,785,669
Basic and diluted net loss per common share	$ (0.15)	$ (0.50)	$ (0.46)	$ (2.18)

Aytu BioScience, Inc.
Consolidated Balance Sheet Information

	March 31, 2020 (Unaudited)	June 30, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 62,264,676	$ 11,044,227
Restricted cash	251,407	250,000
Accounts receivable, net	10,203,423	1,740,787
Inventory, net	3,854,685	1,440,069

Prepaid expenses and other	4,830,881	957,781
Other current assets	1,849,598	–
Total current assets	83,254,670	15,432,864
Fixed assets, net	288,415	203,733
Right-of-use asset	675,980	–
Licensed assets, net	17,155,632	18,861,983
Patents and tradenames, net	11,724,626	220,611
Product technology rights, net	21,754,166	–
Deposits	38,981	2,200
Goodwill	24,061,333	–
Total long-term assets	75,699,133	19,288,527
Total assets	$ 158,953,803	$ 34,721,391
Liabilities		
Current liabilities		
Accounts payable and other	$ 6,956,091	$ 2,133,522
Accrued liabilities	9,830,373	1,311,488
Accrued compensation	2,210,288	849,498
Current lease liability	289,238	–
Current contingent consideration	947,449	1,078,068
Current portion of fixed payment arrangements	17,395,219	–
Current portion of CVR liabilities	786,564	–
Notes payable, net	3,617,680	–
Total current liabilities	42,032,902	5,372,576
Long-term contingent consideration, net of current portion	17,806,573	22,247,796
Long-term lease liability, net of current portion	804,393	–
Long-term fixed payment arrangements, net of current portion	8,162,494	–
Long-term CVR liabilities, net of current portion	4,432,254	–
Warrant derivative liability	11,371	13,201
Total liabilities	73,249,987	27,633,573
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; shares issued and outstanding 9,805,845 and 3,594,981, respectively as of March 31, 2020 (unaudited) and June 30, 2019.	981	359
Common Stock, par value $.0001; 200,000,000 shares authorized; shares issued and outstanding 100,610,380 and 17,538,071, respectively as of March 31, 2020 (unaudited) and June 30, 2019.	10,061	1,754
Additional paid-in capital	202,557,856	113,475,205
Accumulated deficit	(116,865,082)	(106,389,500)
Total stockholders' equity	85,703,816	7,087,818
Total liabilities and stockholders' equity	$ 158,953,803	$ 34,721,391

Aytu BioScience, Inc.
Condensed Consolidated Cash Flow Information

(Unaudited)

	Nine Months Ended March 31,	
	2020	**2019**
Operating Activities		
Net loss	$ (10,475,582)	$ (12,600,007)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	3,780,310	1,974,213
Stock-based compensation expense	590,826	722,842
Derecognition of contingent consideration	(5,199,806)	–
Gain on the change in fair value of CVR payout	(267,130)	–
Issuance of common stock to employee	–	11,690
Derivative income	(1,830)	(65,468)
Changes in operating assets and liabilities:		
(Increase) in accounts receivable	(8,183,810)	(797,576)
(Increase) in inventory	(345,452)	(191,110)
(Increase) in prepaid expenses and other	(1,611,681)	(364,831)
(Increase) in other current assets	(358,022)	–
(Decrease) in accounts payable and other	(4,912,245)	(191,331)
Increase in accrued liabilities	6,761,319	758,370
Increase in accrued compensation	271,560	250,912
(Decrease) in fixed payment arrangements	(657,655)	–
Increase in interest payable	–	134,795
Net cash used in operating activities	(20,609,198)	(10,357,501)
Investing Activities		
Deposit	–	2,888
Purchases of fixed assets	–	(59,848)
Contingent consideration payment	(151,648)	(408,917)
Cash received from acquisition	390,916	–
Purchase of assets	(5,850,000)	(500,000)
Net cash used in investing activities	(5,610,732)	(965,877)
Financing Activities		
Issuance of preferred, common stock and warrants	58,999,666	15,180,000
Issuance costs related to preferred, common stock and warrants	(5,280,426)	(1,479,963)
Warrant exercises	22,989,666	258,512
Preferred stock converted in common stock	92,880	–
Issuance of note payable	640,000	5,000,000
Net cash provided by financing activities	77,441,786	18,958,549
Net change in cash, restricted cash and cash equivalents	51,221,856	7,635,171
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	$ 62,516,083	$ 14,747,698

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

Cash paid for interest	$ 392,641	$ –
Fair value of right-to-use asset and related lease liability	354,929	–
Issuance of Series G preferred stock due to acquisition of the Cerecor portfolio of pediatrics therapeutics	5,559,914	–
Issuance of Series H preferred stock due to acquisition of the Innovus	12,805,263	–
Inventory payment included in accounts payable	460,416	–
Contingent consideration included in accounts payable	27,571	29,348
Fixed payment arrangements included in accounts payable	501,766	–
Exchange of convertible preferred stock into common stock	1,559	–
Return deductions received by Cerecor	2,000,000	–
Issuance of restricted stock	107	–
Cashless warrant exercises	792	–
Fair value of warrants issued to investors and underwriters	–	1,888,652
Issuance of preferred stock related to purchase of asset	–	519,600
Contingent consideration related to purchase of asset	$ –	$ 8,833,219

SOURCE: Aytu BioScience, Inc.

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