Aytu BioPharma Reports First Quarter 2022 Financial Results

Quarterly net revenue increased 62% to $21.9 million

Ended quarter with approximately $40.6 million in cash, cash equivalents and restricted cash

Fully integrated and expanding RxConnect patient support program and salesforce drove growth across prescription portfolio

Planned pivotal study for AR101 in Vascular Ehlers-Danlos Syndrome (VEDS) to begin in 1H22

Initiation of Healight randomized, sham-controlled study by year-end 2021

Management to host live conference call and webcast today at 4:30 p.m. ET

ENGLEWOOD, CO / November 15, 2021 / Aytu BioPharma, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel therapeutics and consumer healthcare products, today reported financial results for its fiscal first quarter 2022 ended September 30, 2021.

“We posted a very strong quarter with net revenues of $21.9 million and two of our commercial products, Poly-Vi-Flor and Adzenys XR-ODT, hitting all-time highs in prescription performance. We have begun delivering on our projection that fiscal 2022 will be a year of substantial progress, as we continued to realize the economic benefits of our merger synergy plan following the Neos Therapeutics acquisition, organically grew our commercial prescription and consumer health product revenues and advanced our late-stage development pipeline toward key milestones,” commented Josh Disbrow, chief executive officer of Aytu BioPharma. “Regarding AR101, we expect to begin our pivotal study in early 2022, are seeking Orphan Drug Designation from the FDA and EMA, and have already begun collaborating with our newly formed scientific advisory board. We are also nearing the start of our sham-controlled study of Healight at a leading academic center in Barcelona, Spain and expect to have data in the first half of calendar year 2022. With the establishment of key fundamentals across our business, we are excited about the future as we continue building a leading specialty pharmaceutical company.”

First Quarter Fiscal 2022 Financial Results:

- Net revenue for the first quarter of fiscal year 2022 was $21.9 million, compared to $13.5 million in the same quarter in fiscal year 2021, a 62% increase year-over-year.
    - Net revenue from the consumer health division in the first quarter of fiscal year 2022 was $8.0 million, compared to $7.8 million in the same quarter last year, a

growth of over 3% year-over-year.
    - Net revenue from the prescription division in the first quarter of fiscal 2022 was $13.9 million, compared to $5.8 million in the same quarter last year, a growth of over 140% year-over-year.
- Gross profit increased to $12.5 million in the first quarter of fiscal 2022, the highest quarterly gross profit posted by the company, compared to $9.5 million in the same quarter in fiscal year 2021.
- Net loss for the first quarter of fiscal year 2022 was $27.9 million, or $1.09 per share.
    - Net loss was impacted by impairment expense of $19.5 million due to the write-off of goodwill related to the company's Aytu BioPharma segment.
- Cash, cash equivalents and restricted cash totaled $40.6 million as of September 30, 2021.

Recent Corporate Highlights:

- **Significant progress made on the Aytu-Neos integration and realization of synergies and operational improvements** : The first quarter of fiscal year 2022 marked the second full quarter as a newly merged company and the first full quarter operating with an integrated sales force of 50 sales specialists and newly branded RxConnect patient access program. During the quarter, the company experienced significant growth of RxConnect, with Neos legacy products and Aytu legacy products now integrated into the program. The company also continued to progress the technology transfer of heritage Neos brands out of its Grand Prairie, Texas manufacturing facility to a global contract manufacturer and is on track to complete this transition in the first half of calendar year 2023. The company expects to improve gross profit margin, reduce operating expenses and significantly reduce cash exposure from inventory builds as a result of this transition.
- **ADHD prescription products grew 12% during the quarter:** During the first quarter of fiscal year 2022, Aytu experienced 12% growth in prescriptions for ADHD brands Adzenys XR-ODT and Cotempla XR-ODT compared to the same quarter last year. Adzenys XR-ODT prescriptions grew 15% during the three-months ended September 30, 2021 compared to the same period last year. Demand for these products continues to grow, exemplified by all-time high weekly prescription levels for Adzenys XR-ODT during the week ending October 15th , and Cotempla XR-ODT weekly prescriptions also approaching all-time high levels.
- **Strong pediatric prescription products performance:** During the first quarter of fiscal year 2022, the company reported 8% growth of prescription multi-vitamins compared to the same period last year, reaching all-time highs in prescriptions for Poly-Vi-Flor chewable tablets. In addition, Karbinal ER, the company's prescription antihistamine, grew 46% during the first quarter of fiscal year 2022 compared to the same period last year.

Recent Pipeline Highlights

- **Formed Scientific Advisory Board (SAB) with scientific and clinical experts to support the development of AR101 for VEDS:** In September 2021, Aytu announced the formation of a new SAB, consisting of leading experts in rare, genetic, pediatric diseases and chaired by Dr. Hal Dietz, M.D., Professor of Genetic Medicine at the Johns Hopkins University School of Medicine, who has conducted the groundbreaking research to date supporting AR101 in VEDS. Other initial members of the SAB include Xavier Jeunemaitre, M.D., Ph.D., Professor of Genetics at University Paris Descartes; Peter Byers, M.D., Professor of Medicine, Pathology and Medical Genetics at the University of Washington; Bart Loeys M.D., Ph.D., Professor of Medical Genetics and Cardiogenomics at the Center for Medical Genetics of the Antwerp University Hospital in Belgium and in the Department of Human Genetics in the Radboud University Medical Center in Nijmegen, The Netherlands; and Shaine A. Morris, M.D., M.P.H., Medical Director of the Cardiovascular Genetics Program at Texas Children's Hospital and Associate Professor at Baylor College of Medicine.
- **Pivotal study-enabling work and site initiations ongoing for AR101 clinical trial:** Investigational New Drug (IND) submission preparations and study site qualifications are underway for the planned pivotal clinical trial of AR101, a pivotal study-ready therapeutic candidate initially targeting the treatment of vascular Ehlers-Danlos Syndrome (VEDS). VEDS is a rare genetic disorder typically diagnosed in childhood and characterized by arterial aneurysm, dissection and rupture, bowel rupture and rupture of the gravid uterus. There are currently no U.S. Food and Drug Administration (FDA)-approved treatments for VEDS.
- **Announced the publication of Healight™ endotracheal catheter technology data that continue to build upon the body of scientific evidence supporting the potential of this UVA platform technology:** In July 2021, the company announced publication of data which demonstrated that ultraviolet-A light reduces cellular cytokine release from human endotracheal cells infected with coronavirus. These data provide additional proof of concept and proposed mechanism of action of the Healight technology, supporting the potential use in respiratory infections.

Key Anticipated Upcoming Milestones and Events:

- Aytu is pursuing Orphan Drug Designation (ODD) from the FDA and the European Medicines Agency (EMA) for AR101, with the goal of receiving ODD in the first half of calendar year 2022.
- The company plans to launch a single pivotal trial, the PREVEnt Trial, of AR101 in patients with VEDS in the first half of calendar 2022. The planned patient enrollment for this randomized, placebo-controlled study is 260, randomized 1:1. The primary endpoint of this trial is reduction in fatal or non-fatal arterial events, such as ruptures, dissections, and pseudo-aneurisms. The company expects to fully enroll the study by

early calendar year 2023.

- The company is on track to initiate a study evaluating Healight for the treatment of patients with SARS-CoV-2 in 2021. This randomized, sham-controlled study will evaluate the safety and treatment effects of Healight in patients with SARS-CoV-2 that have been newly intubated and on mechanical ventilation. This study will be conducted at a leading academic hospital in Barcelona, Spain and is expected to enroll 40 patients. The primary endpoint of this study is change in viral load in endotracheal tube aspirates between day zero and the last day of treatment between treated and untreated subjects. The company expects to report top-line data in the first half of 2022.

Conference Call Details

The company will host a live conference call at 4:30 p.m. ET today. The conference call can be accessed by dialing either 877-545-0320 (toll-free) or 973-528-0002 (international), participant access code 664921. The webcast will be accessible live and archived at the following link: https://www.webcaster4.com/Webcast/Page/2142/43552 and on Aytu BioPharma'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 877-481-4010 (toll-free) or 919-882-2331 (international), using the replay access code 43552.

About Aytu BioPharma, Inc.

Aytu BioPharma is a specialty pharmaceutical company with a growing commercial portfolio of prescription therapeutics and consumer health products. The company's primary prescription products treat attention deficit hyperactivity disorder (ADHD) and other common pediatric conditions. Aytu markets ADHD products Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) and Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING). The company also markets ZolpiMist, a short-term treatment for insomnia characterized by difficulties with sleep initiation (see Full Prescribing Information, including Boxed WARNING). The company's other pediatric products include Karbinal® ER (carbinoxamine maleate), an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency. The company's evolution has been driven by strategic in-licensing, acquisition-based transactions and organic product growth. Aytu is building a complimentary therapeutic development pipeline including a prospective treatment (AR101/enzastaurin) for vascular Ehlers-Danlos Syndrome (VEDS), a rare genetic disease resulting in high morbidity and a significantly shortened lifespan. VEDS is a devastating condition for which there are no currently approved treatments. AR101 is an

orally available investigational first-in-class small molecule, serine/threonine kinase inhibitor of the PKC beta, PI3K and AKT pathways. AR101 has been studied in more than 3,300 patients across a range of solid and hematological tumor types, and we are now planning a randomized, controlled, pivotal clinical study with AR101 in VEDS. To learn more, please 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 press release, 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. All statements other than statements of historical facts contained in this presentation, are forward-looking statements. 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 associated with: the company's plans relating to the clinical development and commercialization of AR101, the company's overall financial and operational performance, the anticipated start dates, durations and completion dates, as well as the potential future results of the company's ongoing and future clinical trials, the anticipated designs of the company's future clinical trials, the company's ability to transfer its technology and the anticipated benefits of that transfer, and the anticipated future regulatory submissions, potential adverse changes to our financial position or the company's business, the results of operations, strategy and plans, changes in capital markets and the ability of the company to finance operations in the manner expected, risks relating to gaining market acceptance of our products, risks related to the ongoing COVID-19 pandemic and its impact on our operations, our ability to effectively integrate operations and manage integration costs following our acquisitions, our partners performing their required activities, our anticipated future cash position, regulatory and compliance challenges and future events under current and potential future collaboration. We also refer you to (i) the risks described in 'Risk Factors' in Part I, Item 1A of Aytu's most recent Annual Report on Form 10-K and in the other reports and documents it files with the Securities and Exchange Commission and (ii) the Risk Factors set forth in Aytu's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC.

Financial Tables

AYTU BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(In thousands, except share and per-share)
(Unaudited)

	Three Months Ended September 30,	
	2021	2020
Product revenue, net	$ 21,897	$ 13,520
Cost of sales	9,441	4,063
Gross profit	12,456	9,457
Operating expenses		
Research and development	2,096	183
Selling and marketing	9,297	5,826
General and administrative	8,216	5,420
Impairment of goodwill	19,453	–
Amortization of intangible assets	1,093	1,585
Total operating expenses	40,155	13,014
Loss from operations	(27,699)	(3,557)
Other (expense) income		
Other (expense), net	(40)	(751)
Gain / (Loss) from contingent consideration	(219)	2
Total other (expense) income	(259)	(749)
Loss before income tax	(27,958)	(4,306)
Income tax expense (benefit)	(107)	–
Net loss	$ (27,851)	$ (4,306)
Weighted average number of common shares outstanding	25,597,319	12,158,594
Basic and diluted net loss per common share	$ (1.09)	$ (0.35)

AYTU BIOPHARMA, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except share and per-share)

	(Unaudited) September 30, 2021	June 30, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 40,308	$ 49,649
Restricted cash	252	252
Accounts receivable, net	21,626	28,176
Inventory, net	16,314	16,339
Prepaid expenses	9,343	9,780
Other current assets	1,195	1,038
Total current assets	89,038	105,234
Property and equipment, net	4,666	5,140
Operating lease right-of-use asset	3,826	3,563
Intangible assets, net	83,385	85,464
Goodwill	46,349	65,802
Other long-term assets	465	465
Total long-term assets	138,691	160,434
Total assets	$ 227,729	$ 265,668
Liabilities		
Current liabilities		
Accounts payable and other	$ 9,383	$ 19,255
Accrued liabilities	54,380	51,295
Accrued compensation	4,762	5,939
Short-term line of credit	4,520	7,934
Current portion of debt	16,508	16,668
Current portion of operating lease liabilities	1,084	940
Current portion of fixed payment arrangements	3,221	3,134
Current portion of CVR liabilities	1	218
Current portion of contingent consideration	4,138	4,055
Total current liabilities	97,997	109,438
Long-term debt, net of current portion	154	180
Long-term operating lease liability, net of current portion	2,758	2,624
Long-term fixed payment arrangements, net of current portion	5,485	6,324
Long-term CVR liabilities, net of current portion	1,347	1,177
Long-term contingent consideration, net of current portion	8,169	8,002
Other long-term liabilities	319	355
Total liabilities	116,229	128,100
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding as of September 30, 2021 and June 30, 2021	–	–
Common Stock, par value $.0001; 200,000,000 shares authorized; shares issued and outstanding 27,771,912 and 27,490,412, respectively, as of September 30, 2021 and June 30, 2021	3	3
Additional paid-in capital	317,647	315,864
Accumulated deficit	(206,150)	(178,299)
Total stockholders' equity	111,500	137,568
Total liabilities and stockholders' equity	$ 227,729	$ 265,668

Contact for Media and Investors:

Sarah McCabe
Stern Investor Relations, Inc.

Sarah.mccabe@sternir.com

SOURCE: Aytu BioPharma, Inc.

View source version on accesswire.com:
https://www.accesswire.com/672723/Aytu-BioPharma-Reports-First-Quarter-2022-Financial-Results