Aytu BioPharma Reports Fourth Quarter and Full-Year Fiscal 2021 Financial Results

Quarterly net revenue increased 74% sequentially to $23.5M; 138% year-over-year to $65.6M

Ended quarter with approximately $50M in cash, cash equivalents and restricted cash

Planned pivotal study for AR101 in Vascular Ehlers-Danlos Syndrome (VEDS) to begin in 1H22; scientific advisory board recently formed

Initiation of Healight randomized, sham-controlled study planned near-term; recently published positive and validating data for UV-A light technology platform

Future revenue growth expected from newly consolidated sales force and product portfolio supported by fully integrated and expanding RxConnect patient support program

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

ENGLEWOOD, CO / September 27, 2021 / Aytu BioPharma, Inc. (Nasdaq:AYTU), a specialty pharmaceutical company focused on commercializing novel therapeutics and consumer healthcare products, today reported financial results for the fiscal fourth quarter and full-year ended June 30, 2021.

“This was our first quarter operating as a fully integrated, pediatric-focused, specialty pharmaceutical company, having closed the merger with Neos Therapeutics in March and acquiring the global license to pediatric-onset rare disease pipeline asset AR101 in April. We moved quickly into our post-merger plan, integrating the Aytu and Neos sales forces and consolidating the RxConnect patient access program. We have already begun to realize significant synergies from that consolidation, which we expect to support the continued growth of our commercial business,” commented Josh Disbrow, Chief Executive Officer of Aytu BioPharma. “Going forward, we have many value creating milestones on the horizon. For AR101, we expect to begin our pivotal study in early 2022, are seeking Orphan Drug Designation from the FDA and EMA and will collaborate with our newly formed scientific advisory board. We are also seeking to maximize our Aytu-Neos merger synergy plan including removing redundant expenses, divesting and monetizing certain non-core products and outsourcing manufacturing of the Neos heritage products to significantly improve the financial performance of those brands. We expect fiscal 2022 to be a year of substantial progress as we begin to realize the economic benefits of this plan, grow our commercial prescription and consumer health product revenues and advance our late-stage development pipeline.”

Fourth Quarter and Full-Year Fiscal 2021 Financial Results:

- Net revenue for the fourth quarter of fiscal 2021 was $23.5 million, compared to $14.9 million in the same quarter in fiscal 2020, and was the highest net revenue posted by the Company. For the full fiscal year 2021, net revenue was $65.6 million, a 138% increase as compared to net revenue of $27.6 million the previous year.
    - Net revenue from the consumer health division in the fourth quarter of fiscal 2021 was $8.9 million, compared to $6.9 million in the same quarter last year, and was the highest net revenue from the consumer health division posted by the Company. Consumer health revenue growth was driven primarily by growth from the e-commerce and direct-to-consumer marketing channels and the introduction of new products.
    - Net revenue from the prescription division in the fourth quarter of fiscal 2021 was $14.6 million, compared to $7.9 million in the same quarter last year.
- Net loss for the fourth quarter of fiscal 2021 was $19.0 million, or $0.81 per share. Net loss for the year ended June 30, 2021, including deal expenses and costs related to the acquisitions of Neos Therapeutics and the assets of Rumpus Therapeutics, was $58.3 million, or $3.48 per share.
    - Gross margin was negatively impacted by a $2.1 million increase in cost of goods sold for the attention deficit hyperactivity disorder (ADHD) products resulting from the full absorption of increased inventory cost to fair value at the Neos Therapeutics acquisition date, resulting in zero margin for those products in the fourth quarter of fiscal 2021.
    - Costs of $2.9 million associated with the acquisition of the assets of Rumpus Therapeutics, including the licenses to AR101, were expensed to research and development in the quarter ended June 30, 2021.
    - Impairment expense of $8.5 million was recognized in the quarter ended June 30, 2021 due to the write-off of a licensed intangible asset as a result of the impact of COVID-19 and other factors negatively impacting product sales.
- Cash, cash equivalents and restricted cash totaled $49.9 million as of June 30, 2021.

Recent Corporate and Pipeline Highlights:

- **Expanded development pipeline with pivotal study-ready protein kinase C β isoform (PKCβ) inhibitor, AR101, for rare disease indications:** In April 2021, Aytu announced the acquisition of a global license to 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. Aytu is pursuing Orphan Drug Designation (ODD) from the FDA for AR101, with the goal of receiving this status in the first half of calendar year

2022. The Company also plans to launch a single pivotal study, 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 study is fatal or non-fatal arterial events, such as ruptures, dissections and pseudo-aneurisms. The Company expects to fully enroll the study by early calendar 2023.

- **Successfully integrated the Aytu and Neos sales forces and patient access programs, contributing significantly toward the Company's expected $15.0 million in merger synergies savings expected in fiscal year 2022:** This quarter, the Company completed the resizing and integration of Aytu and Neos' sales forces, now operating a single sales force with 40 CNS-aligned sales specialists promoting Adzenys XR-ODT, Cotempla XR-ODT and ZolpiMist, and 10 pediatric-aligned sales specialists promoting Poly-Vi-Flor, Tri-Vi-Flor and Karbinal ER. Additionally, Aytu BioPharma consolidated the Aytu and Neos patient access programs and launched the newly branded and expanded Aytu RxConnect. This integrated program combines the Aytu-heritage patient access initiatives with the Neos-developed RxConnect program to build commercial scale and enable seamless pharmacy cross-selling, with five core prescription brands and over 1,200 network pharmacies. This commercial integration has yielded a significant portion of the expected merger synergy savings and was completed in June 2021. The proprietary Aytu RxConnect program reduces prescriber hassles that physicians encounter when prescribing branded medications and offers prescribers and patients affordability, predictability and access to Aytu's brands for an improved patient experience.
- **Divested Natesto rights to Acerus Pharmaceuticals for $7.5 million:** In April 2021, the Company announced the divestment of Natesto rights to Acerus Pharmaceuticals to continue focusing internal commercial efforts on its core, pediatric-centric business. This transaction provides for cash of $7.5 million to the company in the form of $250,000 monthly payments over 30 months, which commenced in April 2021.
- **Established a 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, 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, the Head of the Department of Genetics at the Hospital Pompidou (HEGP) and the Director of the INSERM research team 3, U970, at the Paris Cardiovascular Research Centre, Peter Byers – Professor of Medicine, Pathology and Medical Genetics at the Genetic Medicine Clinic and Center on Human Development and Disability and Pathology Services at University of Washington Medical Center, 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. – Pediatric Cardiologist and Medical Director of Cardiovascular Genetics at Texas Children's Hospital and Associate Professor at Baylor College of Medicine. This SAB will support newly appointed Executive Vice Presidents Topher Brooke and Nate Massari in steering AR101 through clinical development.

- **Further validated the Healight platform with two data publications demonstrating UVA light reduces cellular cytokine release, decreases COVID-19 viral load, and improves COVID-19 clinical outcomes:** In July 2021, Aytu announced the publication of a manuscript titled "Ultraviolet-A light reduces cellular cytokine release from human endotracheal cells infected with Coronavirus" in the peer-reviewed journal *Photodiagnosis and Photodynamics Therapy*, with data demonstrating UVA light reduces cellular cytokine release from human endotracheal cells infected with Coronavirus. Additionally, in June 2021, the Company announced the publication of "Endotracheal application of ultraviolet A light in critically ill patients infected with severe acute respiratory syndrome coronavirus-2: A first-in-human study of internal ultraviolet A therapy" in the peer-reviewed journal *Advances in Therapy*, with clinical results from the Healight pilot study. These data demonstrated that UVA light catheter therapy is associated with a significant reduction in SARS-CoV-2 viral load and marked improvement in clinical outcomes for mechanically ventilated COVID-19 patients. Both publications point to potentially groundbreaking efficacy in Aytu's Healight UVA light platform and support advancing its clinical development.
- **Initiated manufacturing transfer from the former Neos Grand Prairie, TX production facility to a U.S.-based, global contract manufacturer:** In May 2021, the Company announced the planned closure of its Grand Prairie, TX manufacturing facility, with the goal of improving gross profit margins and reducing manufacturing expenses associated with the ADHD products. It is anticipated that this transition will occur over the next 18 months, and the transition to outsourced manufacturing of these products is expected to result in a 15-20% improvement in gross profit margins for the ADHD products and a significant reduction of cash expenses and investment in inventory. In conjunction with the manufacturing transition, the Company plans to consolidate additional operational and administrative positions to further reduce headcount redundancies and associated expenses. The manufacturing transition is expected to require aggregate, one-time capital expenditures of approximately $4.0 million over the course of the project.

Anticipated Upcoming Milestones and Events for Calendar Year 2021 and 2022:

Commercial

- Multiple new product launches in the consumer health segment in the first half of 2022

and organic product growth through the e-commerce and direct-to-consumer channels
- Grow prescription products with a focus on ADHD brands Adzenys XR-ODT and Cotempla XR-ODT and multi-vitamin brands Poly-Vi-Flor and Tri-Vi-Flor
- Expand Aytu RxConnect to maximize prescription portfolio pharmacy pull-through

Pipeline

- Obtain Orphan Drug Designation from the FDA for AR101 for VEDS
- Obtain Orphan Drug Designation from the European Medicines Agency (EMA) for AR101 in VEDS
- Submit an Investigational New Drug application to the FDA for AR101 in the second half of 2021 to start a pivotal global study in VEDS in the first half of 2022
- Initiate study evaluating Healight for the treatment of patients with SARS-CoV-2 in the second half of 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

Upcoming September Event:

- Presentation at the virtual Cantor Global Healthcare Conference on Thursday, September 30th at 4:40 p.m. ET.

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 1-844-602-0380 (toll-free) or 1-862-298-0970 (international).

The webcast will be accessible live and archived at the following link: https://www.webcaster4.com/Webcast/Page/2142/42555 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 1-877-481-4010 (toll-free) or 919-882-2331 (international) and using the replay access code 42555.

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), Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING), and Adzenys-ER® (amphetamine) extended-release oral suspension (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, and the anticipated future regulatory submissions, potential adverse changes to our financial position or our 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.

AYTU BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(In thousands, except share and per-share)

	Three Months Ended June 30,		Year Ended June 30,	
	2021	2020	2021	2020
Product revenue, net	$ 23,482	$ 14,861	$ 65,632	$ 27,632
Cost of sales	12,183	4,817	36,432	8,281
Gross profit	11,299	10,044	29,200	19,351
Operating expenses				
Research and development	4,764	1,499	5,623	1,722
Selling and marketing	12,180	5,198	30,308	11,403
General and administrative	8,552	6,852	25,500	19,657
Acquisition related costs	70	814	2,919	2,348
Restructuring costs	11	531	4,886	667
Impairment of intangible assets	8,539	195	12,825	195
Amortization of intangible assets	1,255	1,590	6,009	4,490
Total operating expenses	35,371	16,679	88,070	40,482
Loss from operations	(24,072)	(6,635)	(58,870)	(21,131)
Other (expense) income				
Other (expense), net	(495)	(1,425)	(2,050)	(2,606)
Gain / (Loss) from contingent consideration	7,139	5,231	4,459	10,430
Gain (Loss) on extinguishment of debt	(1,311)	(316)	(1,569)	(316)
Gain from warrant derivative liability	–	–	–	2
Total other (expense) income	5,333	3,490	840	7,510
Loss before income tax	(18,739)	(3,145)	(58,030)	(13,621)
Income tax benefit	259	–	259	–
Net loss	$ (18,998)	$ (3,145)	$ (58,289)	$ (13,621)
Weighted average number of common shares outstanding	23,519,870	11,335,425	16,746,679	4,519,201
Basic and diluted net loss per common share	$ (0.81)	$ (0.28)	$ (3.48)	$ (3.01)

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

	June 30,	
	2021	2020
Assets		
Current assets		
Cash and cash equivalents	$ 49,649	$ 48,082
Restricted cash	252	251
Accounts receivable, net	28,176	5,633
Inventory, net	16,339	9,999
Prepaid expenses	9,780	5,715
Other current assets	1,038	5,742
Total current assets	105,234	75,422
Property and equipment, net	5,140	259
Operating lease right-of-use asset	3,563	634
Intangible assets, net	85,464	48,855
Goodwill	65,802	28,090
Other long-term assets	465	33
Total long-term assets	160,434	77,871
Total assets	$ 265,668	$ 153,293
Liabilities		
Current liabilities		

Accounts payable and other	$ 19,255	$ 11,640
Accrued liabilities	51,295	8,831
Accrued compensation	5,939	3,117
Short-term line of credit	7,934	–
Current portion of debt	16,668	982
Current portion of operating lease liabilities	940	300
Current portion of fixed payment arrangements	3,134	2,340
Current portion of CVR liabilities	218	840
Current portion of contingent consideration	4,055	713
Total current liabilities	109,438	28,763
Long-term debt, net of current portion	180	–
Long-term operating lease liability, net of current portion	2,624	725
Long-term fixed payment arrangements, net of current portion	6,324	11,172
Long-term CVR liabilities, net of current portion	1,177	4,732
Long-term contingent consideration, net of current portion	8,002	12,875
Other long-term liabilities	355	11
Total liabilities	128,100	58,278
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding as of June 30, 2021 and 2020	–	–
Common Stock, par value $.0001; 200,000,000 shares authorized; shares issued and outstanding 27,490,412 and 12,583,736, respectively, as of June 30, 2021 and 2020	3	1
Additional paid-in capital	315,864	215,024
Accumulated deficit	(178,299)	(120,010)
Total stockholders' equity	137,568	95,015
Total liabilities and stockholders' equity	$ 265,668	$ 153,293

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/665689/Aytu-BioPharma-Reports-Fourth-Quarter-and-Full-Year-Fiscal-2021-Financial-Results