

## **Aytu BioPharma Reports Fiscal Third Quarter 2021 Financial Results and Recent Business Highlights**

- Closed merger with Neos Therapeutics creating a proforma combined \$100 million revenue specialty pharmaceutical company -**
- Added late-stage pediatric onset rare disease asset, protein kinase C  $\beta$  isoform (PKC $\beta$ ) inhibitor, AR101 (enzastaurin) to development pipeline -**
- Record quarter for consumer health division with revenue reaching \$8.4 million and Rx division revenue up 9% over same quarter last year -**
- Grew leadership team with three executives including CFO, Rich Eisenstadt -**
- Management to host live conference call and webcast today at 4:30 p.m. ET -**

**ENGLEWOOD, CO / May 17, 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 third quarter ended March 31, 2021 and provided recent business highlights.

“This quarter we accomplished several key milestones that further solidified our position as a leading specialty pharmaceutical company. We continued to grow our commercial portfolio of prescription therapeutics and consumer health products, notably through the close of our merger with Neos Therapeutics. Additionally, subsequent to the quarter end, we expanded our development pipeline by acquiring a late-stage pediatric-onset rare disease pipeline asset from Rumpus Therapeutics, which we now call AR101. We expect the AR101 enzastaurin pivotal program to get underway soon following the finalization of the pivotal study protocol and submission of an IND application to the FDA,” commented Josh Disbrow, chief executive officer of Aytu BioPharma. “During the quarter we continued our year-over-year growth in both business segments and grew our leadership team, including the recent appointment of Rich Eisenstadt as chief financial officer. Q3 was a pivotal quarter for the company, and we have already begun the integration of the Neos business while beginning to leverage the operational and financial synergies we expect to realize over the coming quarters.”

### **Third Quarter Fiscal 2021 Financials:**

- Net revenue was \$13.5 million, compared to \$8.2 million in the same quarter last year. The company continues to increase sales through both organic product growth and through the realization of the recently-completed Neos transaction.
  - Net revenue from the consumer health division was \$8.4 million, an increase over the \$3.5 million in the same quarter last year. Consumer health growth was driven

- primarily by multiple product launches and growth of the e-commerce channel.
- Net revenue from the Rx division was \$5.1 million, an increase over the \$4.7 million in the same quarter last year and includes the product revenue contributed from Neos only for the period following the close of the merger on March 19, 2021.
  - Net loss was \$25.5 million, or \$1.41 per share. Net loss increased primarily as a result of Neos merger-related and other deal expenses of \$10.6 million and the write off of \$7.1 million in slow-moving inventory in the quarter.
  - Cash, cash equivalents and restricted cash totaled \$46.8 million as of March 31, 2021, after making a principal payment of \$15.0 million toward the Deerfield Note held by Neos.

### **Recent Corporate and Pipeline Highlights:**

- **Expanded development pipeline with pivotal study-ready protein kinase C  $\beta$  isoform (PKC $\beta$ ) inhibitor, AR101 (enzastaurin), for rare disease indications:** In April 2021, Aytu announced the acquisition of a global license to AR101 (enzastaurin), a pivotal study-ready therapeutic candidate initially targeting the treatment of vascular Ehlers-Danlos Syndrome (vEDS) from Rumpus Therapeutics, a privately-held biopharmaceutical company focused on the treatment of pediatric onset rare and orphan diseases. 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.
- **Closed merger with Neos Therapeutics:** In March 2021, Aytu announced the close of its merger with Neos Therapeutics, putting it in a strong position to enhance its footprint in pediatrics and expand its presence in adjacent specialty care segments. The company expects to begin realizing estimated annualized cost synergies of \$15.0 million in fiscal year 2022. As part of the go forward plan for the newly combined company to best serve its patients, management evaluated the operations cost structure and concluded that moving to a production outsourcing strategy for the company's ADHD products is expected to result in a more efficient supply and lower conversion cost of these ADHD products. As such, the company plans to close its Grand Prairie, Texas manufacturing operations over the next eighteen months as it completes the technology transfer of the production process.
- **Published *in vitro* data demonstrating ultraviolet-A light increases mitochondrial anti-viral signaling protein within cells:** In May 2021, Aytu announced the publication of *in vitro* data related to the ultraviolet A (UVA) light used in the Healight™ UVA endotracheal catheter technology in bioRxiv. The manuscript titled "*Ultraviolet-A light increases mitochondrial anti-viral signaling protein via cell-cell communication*" concluded that UVA light increases the expression of mitochondrial antiviral-signaling (MAVS) protein within cells, and the results suggest that this

transmission of an increase in intracellular MAVS involves cell-to-cell communication. These findings confirm that an increase of MAVS in response to UVA light can be transmitted from cells directly exposed to UVA light to neighboring cells that have not been directly exposed to UVA light.

- **Reported positive clinical results from pilot study of Healight™ UVA light catheter technology in SARS-CoV-2 patients:** In March 2021, the company reported data from a first in-human, open label, clinical trial in SARS-CoV-2 patients. The data show that endotracheal UVA light treatment was associated with a significant reduction of SARS-CoV-2 viral load and improvement in WHO clinical severity scores. Additionally, the endotracheal UVA light treatment did not result in any serious adverse device effects and was well tolerated. The data was published in MedRxiv, and a manuscript has been submitted for peer review.
- **Sold rights to Natesto to Acerus Pharmaceuticals Corporation for \$7.5 million:** In April, the company announced that it signed an agreement with Acerus whereby Acerus would acquire all remaining rights to Natesto in the United States from Aytu. In consideration, Aytu will received \$7.5 million in cash from Acerus, which is payable in equal monthly payments of \$250,000 over 30 months. Additionally, Acerus has assumed all product responsibilities associated with Natesto as of April 1, 2021.
- **Appointed Richard Eisenstadt as chief financial officer:** In April 2021, the company appointed Richard Eisenstadt as chief financial officer. Mr. Eisenstadt is an accomplished pharmaceutical industry executive with more than 20 years of experience in leading finance and accounting operations, supporting clinical development and commercialization, and raising capital within the life sciences sector. He was most recently CFO of Neos Therapeutics.
- **Substantially expanded management team:** In April 2021, the company added Rumpus Therapeutics co-founders and principal executive officers, Topher Brooke and Nate Massari as executive vice presidents and will be responsible for the AR101 program and the development of the company's pediatric onset rare disease pipeline.

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

- Continue discussions with the FDA and other regulatory agencies regarding the advancement of its Healight™ UVA light catheter technology.
- Initiate Phase 2 trial of Healight in COVID-19 in second half of 2021.
- Announce multiple new product launches for the consumer health segment in the second half of 2021.
- Integrate sales forces and Neos RxConnect, to be rebranded as Aytu RxConnect, in the second half of 2021.
- Submit an Investigational New Drug application to the FDA for AR101 in the second half of 2021 and start a pivotal study in vEDS in the first half of 2022.

- Participate in Jefferies Virtual Healthcare Conference on Tuesday, June 1<sup>st</sup> and the Raymond James Human Health Innovation Conference on Wednesday, June 23<sup>rd</sup>.

### **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 877-407-9124 (toll-free) 201-689-8584 (international). The webcast will be accessible live and archived at the following link

<https://www.webcaster4.com/Webcast/Page/2142/40724> and on Aytu BioPharma's website, within the Investors section under Events & Presentations, at [aytubio.com](http://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 40724.

### **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), Cotelma 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. As Aytu continues this trajectory, the company is building a complimentary therapeutic development pipeline that will address significant unmet needs. For more information, please visit [aytubio.com](http://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, including but not limited to any statements regarding the financial results and statements presented in this press release and during the business update call following its release. 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: 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 combined 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 restructure or refinance our current indebtedness on favorable terms, obtaining reimbursement by third-party payors, the potential future commercialization of the company's product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results of our ongoing and future clinical trials, anticipated future regulatory submissions and events, our ability to effectively integrate operations and manage integration costs following our acquisitions, our partners performing their required activities, our ability to effectively transfer the manufacturing process for the Neos products, our anticipated future cash position 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 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 Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC.

**AYTU BIOPHARMA, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Operations**  
**(unaudited)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>March 31,</b>		<b>March 31,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
<b>Revenues</b>				
Product revenue, net	\$ 13,482,282	\$ 8,156,173	\$ 42,149,561	\$ 12,771,235
<b>Operating expenses</b>				
Cost of sales	13,682,297	1,998,659	23,499,842	2,980,425
Research and development	389,262	78,502	858,698	223,197
Selling, general and administrative	12,851,087	9,190,386	35,825,175	19,494,368
Acquisition related costs	1,536,800	311,083	2,849,037	1,533,723
Restructuring costs	4,818,064	???	4,874,723	135,981
Amortization and impairment of intangible assets	5,870,436	1,370,986	9,039,597	2,899,553
Total operating expenses	39,147,946	12,949,616	76,947,072	27,267,247
Loss from operations	(25,665,664)	(4,793,443)	(34,797,511)	(14,496,012)
<b>Other (expense) income</b>				
Other (expense), net	(425,425)	(538,862)	(1,555,924)	(1,181,206)
Gain / (Loss) from change in fair value of contingent consideration	631,298	-	(2,680,022)	-
Gain from derecognition of contingent consideration	-	-	-	5,199,806

Gain from warrant derivative liability	-	-	-	1,830
Loss on debt exchange	-	-	(257,559)	-
Total other (expense) income	205,873	(538,862)	(4,493,505)	4,020,430
<b>Net loss</b>	\$ (25,459,791)	\$ (5,332,305)	\$ (39,291,016)	\$ (10,475,582)
Weighted average number of common shares outstanding	18,092,465	3,527,530	14,490,219	2,261,697
Basic and diluted net loss per common share	\$ (1.41)	\$ (1.51)	\$ (2.71)	\$ (4.63)

**AYTU BIOPHARMA, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets**

	<b>March 31, 2021 (Unaudited)</b>	<b>June 30, 2020</b>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 46,537,958	\$ 48,081,715
Restricted cash	251,995	251,592
Accounts receivable, net	28,228,434	5,632,717
Inventory	16,575,757	9,999,441
Prepaid expenses	6,803,583	5,715,089
Other current assets	1,615,024	5,742,011
Total current assets	100,012,751	75,422,565
Fixed assets, net	5,557,727	258,516
Operating lease right-of-use asset	3,781,737	634,093
Intangible assets, net	96,236,796	48,854,561
Goodwill	65,802,636	28,090,407
Other long-term assets	164,954	32,981
Total long-term assets	171,543,850	77,870,558
Total assets	\$ 271,556,601	\$ 153,293,123

**AYTU BIOPHARMA, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Balance Sheets, cont'd**

	<b>March 31, 2021 (Unaudited)</b>	<b>June 30, 2020</b>
<b>Liabilities</b>		
Current liabilities		
Accounts payable and other	\$ 16,528,646	\$ 11,824,560
Accrued liabilities	43,181,920	8,645,984
Accrued compensation	10,510,228	3,117,177
Notes payable	-	982,076
Short-term line of credit	4,738,825	-
Current portion of debt	725,357	-
Current portion of operating lease liabilities	910,885	300,426
Current portion of fixed payment arrangements	1,998,012	2,340,166
Current portion of CVR liabilities	911,826	839,734
Current portion of contingent consideration	4,177,282	713,251
Total current liabilities	83,682,981	28,763,374
Long-term debt, net of current portion	16,930,682	-

Long-term operating lease liability, net of current portion	2,871,845	725,374
Long-term fixed payment arrangements, net of current portion	9,422,768	11,171,491
Long-term CVR liabilities, net of current portion	4,679,227	4,731,866
Long-term contingent consideration, net of current portion	10,726,691	12,874,351
Other long-term liabilities	92,894	11,371
Total liabilities	128,407,088	58,277,827

**Commitments and contingencies (Note 10)**

**Stockholders' equity**

Preferred Stock, par value \$.0001; 50,000,000 shares authorized; shares issued and outstanding 0 and 0, respectively as of March 31, 2021 and June 30, 2020, respectively.	-	-
Common Stock, par value \$.0001; 200,000,000 shares authorized; shares issued and outstanding 23,457,887 and 12,583,736, respectively as of March 31, 2021 and June 30, 2020.	2,346	1,259
Additional paid-in capital	302,448,362	215,024,216
Accumulated deficit	(159,301,195)	(120,010,179)
Total stockholders' equity	143,149,513	95,015,296
Total liabilities and stockholders' equity	\$ 271,556,601	\$ 153,293,123

**Contact for Media and Investors:**

Sarah McCabe  
Stern Investor Relations, Inc.  
sarah.mccabe@sternir.com

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