Aytu BioPharma Reports Third Quarter 2022 Financial Results and Outlines Key Strategic Priorities

Quarterly Net Revenue Increased 79% Year-Over-Year to $24.2 Million, the Highest Revenue in Company History

Strategic Priorities Focused on Driving Revenue Growth, Increasing Financial Efficiencies and Performance and Preparing Pipeline for Long-term Value Creation

ENGLEWOOD, CO / May 16, 2022 / Aytu BioPharma, Inc. (NASDAQ:AYTU), a pharmaceutical company focused on developing and commercializing novel therapeutics, today reported financial results for its fiscal 2022 third quarter, ended March 31, 2022 and outlined its key strategic priorities.

"In our fiscal third quarter and throughout 2022, we continued to make solid progress in growing our commercial businesses and developing our product candidate pipeline, and the operational improvements we've implemented following the Neos acquisition are being realized," said Josh Disbrow, chief executive officer of Aytu BioPharma. "We've identified three key areas of strategic focus for our organization in the near-term – executing and growing our base business, enhancing our operational efficiencies, and preparing to advance a pipeline that addresses significant areas of medical need – all of which we believe will drive Aytu's long-term growth and success. To date, we've demonstrated growth of the prescription portfolio with an integrated, streamlined sales force, and our consumer division posted its highest revenue quarter in company history. With our ongoing plan to gain manufacturing efficiencies, we expect to see increased gross margins on our commercial-stage ADHD products, and, following that, we'll be well positioned to improve profitability across our commercial business to help fund our pipeline advancements. We've continued to advance our AR101 and Healight™ programs, which are aimed at treating life-threatening conditions for which there are no or very few available treatment options. To execute against these objectives, we are dedicated to building a strong, value-driven organization comprised of high-performing, talented individuals who are committed to serving patients and caregivers who are in need of new therapeutic solutions for rare and complex conditions."

Key Strategic Operational Priorities

- **Drive revenue growth with the company's Rx product franchise and consumer health products**
    - Aytu is commercializing two novel Attention Deficit Hyperactivity Disorder (ADHD) products, Adzenys XR-ODT and Cotempla XR-ODT, and pediatric products Poly-Vi-Flor, Tri-Vi-Flor, and Karbinal ER. Through its 50-person sales force and expansion of RxConnect, the company's innovative patient support program, Aytu has grown its ADHD prescriptions 11% year-over-year YTD and its pediatric prescriptions 18%

year-over-year YTD. Further, the company generated 21,281 Adzenys XR-ODT prescriptions in March 2022, representing the highest prescription month since 2019.
    - In parallel, Aytu is growing its consumer health products, with an increasing focus on driving sales through its e-commerce consumer channels, a more profitable and efficient channel than traditional direct-to-consumer marketing. The company's e-commerce health revenue grew 63% in year-over-year YTD, with continued growth expected through portfolio expansion and increased sales of its established consumer brands.
- **Enhance its financial performance through operational and manufacturing efficiencies and portfolio prioritization**
    - Aytu expects to improve gross margins for its ADHD product franchise through transfer of manufacturing to a well-established, global commercial manufacturing organization, a transition that is expected to occur in mid calendar 2023.
    - In addition, the company has undertaken an effort to further prioritize its portfolio and operations, which include the divestiture or discontinuation of non-core, unprofitable products, including Cefaclor, Flexichamber, Tuzistra XR, generic Tussionex, and Zolpimist. These products produced negative contribution margin, consumed internal resources and incurred expenses, and will be removed from the portfolio.
- **Advance and expand a pipeline focused on rare and complex disorders**
    - Aytu is advancing a pipeline comprised of multiple programs, including AR101 (enzastaurin), a well-characterized PKCβ inhibitor that has been evaluated in over 50 clinical trials and in more than 3,300 patients. The company is advancing AR101 toward a registrational clinical trial for the treatment of Vascular Ehlers-Danlos Syndrome (VEDS), a life-threatening inherited connective tissue disorder for which there are no treatments approved today.
    - In parallel, Aytu is advancing Healight, its novel ultraviolet A (UVA) light therapy for a range of complex diseases, including ventilator-associated pneumonia (VAP) and SARS-CoV-2. Aytu is preparing to initiate a sham-controlled study of Healight for use in patients with SARS-CoV-2 and is collaborating with leading researchers at Hospital Clinic de Barcelona on a large, proof-of-concept pre-clinical study for VAP. In clinical testing to date, Healight treatment has been associated with a significant reduction of SARS-CoV-2 viral load and improvement in WHO clinical severity scores and has been well-tolerated with no serious adverse effects observed.

Pipeline Progress

- **AR101 pivotal trial readiness underway with key regulatory designations granted:** Aytu has executed its global regulatory strategy, with orphan drug and fast track designation granted to AR101 for the treatment of Ehlers-Danlos Syndrome,

including VEDS, by the U.S. Food and Drug Administration, and orphan drug designation granted to AR101 for the treatment of VEDS by the European Commission. These designations support the company's global clinical development plan for AR101. Aytu is underway with preparation activities for its PREVEnt Trial, a randomized, double-blind, placebo-controlled clinical study evaluating once daily enzastaurin in the treatment of VEDS. The PREVEnt Trial is designed to enroll approximately 260 patients with COL3A1-positive VEDS in order to assess time to arterial events leading to intervention among patients treated with AR101 compared to patients treated with standard-of-care. The trial is expected to begin enrolling patients by early 2023.

- **Proof-of-Concept Established for Healight in Ventilator-Associated Pneumonia:** In collaboration with researchers at Hospital Clinic de Barcelona, Aytu reported pre-clinical proof-of-concept results from a porcine model demonstrating efficacy with Healight as a potential treatment for VAP. In a well-characterized porcine model, the administration of Healight delayed the time to development of VAP by 46% compared to controls. In addition, UVA light administered through the Healight endotracheal catheter demonstrated a reduction in multidrug-resistant *Pseudomonas aeruginosa* (PA C1-17) following two separate 20-minute treatments. Based on these positive study findings, Aytu has initiated a larger porcine VAP study at Hospital Clinic de Barcelona and plans to report findings in the second half of calendar 2022.

Business Progress

- **Advanced manufacturing transfer of ADHD products.** Aytu's operational team made significant progress with the technology transfer of Adzenys XR-ODT and Cotempla XR-ODT to a global contract manufacturer. The manufacturing transfer is on-track to occur by mid-calendar 2023 and, once complete, is expected to improve gross margins on our ADHD products by 15% or more.
- **First U.S. patent issued for Healight:** The United States Patent and Trademark Office (USPTO) issued U.S. Patent Number 11,179,575, titled "Internal Ultraviolet Therapy," the first issued patent protecting Healight, which provides patent protection to August 2040. The patent covers methods of treating a patient for an infectious condition inside the patient's body through the insertion of a UV-light-emitting delivery tube inside a respiratory cavity of the patient at specific UV-A light wavelengths.

Fiscal Third Quarter 2022 Financial Results

- Net revenue for the third quarter of fiscal year 2022 was $24.2 million, compared to $13.5 million for the third quarter of fiscal year 2021, a 79% increase year-over-year.
    - Net revenue from prescription sales was $13.9 million, compared to $5.1 million in the same quarter last year, growth of over 170% year-over-year.
        - ADHD brands Adzenys XR-ODT and Cotempla XR-ODT experienced 5% growth in prescriptions compared to the quarter ended March 31, 2021.

        - Prescription pediatric portfolio comprised of Poly-Vi-Flor, Tri-Vi-Flor, and Karbinal ER experienced 9% growth in prescriptions compared to the quarter ended March 31, 2021.
    - Net revenue for the third quarter of fiscal year 2022 from the consumer health franchise was $10.3 million, compared to $8.4 million in the same quarter last year, representing a growth of over 23% year-over-year.
- Gross profit increased to $12.7 million in the third quarter of fiscal 2022, compared to $(0.5) million in the same quarter in fiscal year 2021.
- Net loss for the third quarter of fiscal 2022 was $53.1 million, or $1.79 per share, compared to $25.5 million, or $1.41 per share for the same quarter last year.
    - Net loss was impacted by impairment of $45.2 million due to the $37.7 million impairment of goodwill associated with its 2021 Neos acquisition, primarily driven by the decline in Aytu's market capitalization, and $7.5 million impairment due to the discontinuation of five non-core, negative margin commercial assets.
- Adjusted EBITDA[1] for the third quarter of fiscal year 2022 was $(2.9) million compared to $(3.5) million in the second quarter of fiscal year 2022.
- Cash and cash equivalents totaled $27.6 million as of March 31, 2022.

Annual Shareholder Meeting

Mr. Disbrow and Mark Oki, chief financial officer of Aytu, will present a corporate update at its Virtual Annual Meeting of Shareholders, scheduled for May 18, 2022 at 10:00 AM Mountain Time. The meeting will be accessible at www.virtualshareholdermeeting.com/AYTU2022AM .

About Aytu BioPharma, Inc.

Aytu BioPharma is a pharmaceutical company with a portfolio of commercial prescription therapeutics and consumer health products, and a growing therapeutics pipeline focused on treating rare, pediatric-onset disorders. The company's prescription products include 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) for the treatment of attention deficit hyperactivity disorder (ADHD), as well as Karbinal® ER (carbinoxamine maleate), an extended-release antihistamine suspension containing carbinoxamine indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines in various formulations for infants and children with fluoride deficiency. Aytu is also building a therapeutic pipeline, which includes AR101 (enzastaurin), a PKCβ inhibitor in development for the treatment of Vascular Ehlers-Danlos Syndrome (VEDS). VEDS is a rare genetic disease typically diagnosed in childhood resulting in high morbidity and a significantly shortened lifespan, and for which there are no currently approved treatments. AR101 has received Orphan Drug designation and Fast Track designation from the U.S. Food and Drug

Administration and has received Orphan Drug designation from the European Commission. Aytu is also researching and advancing the development of the Healight ultraviolet light A (UVA) endotracheal catheter, a patented, investigational medical device with potential application in the treatment of severe, difficult-to-treat respiratory infections. 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. Forward-looking statements, including but not limited to any statements regarding the financial results and statements presented in this press 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: the ability to attract and retain key management team members, the future growth potential of our commercial portfolio, the anticipated start dates, durations and completion dates and the potential safety and efficacy of our product candidates AR101 and Healight. We also refer you to the risks described in ‘Risk Factors’ in Aytu’s Annual and Quarterly Reports on Form 10-K and 10-Q and in the other reports and documents it files with the Securities and Exchange Commission.

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2022	2021	2022	2021
Product revenue, net	$ 24,199	$ 13,483	$ 69,221	$ 42,150
Cost of sales	11,513	13,935	31,780	24,249
Gross profit	12,686	(452)	37,441	17,901
Operating expenses				
Research and development	3,726	390	10,742	859
Selling and marketing	9,743	6,597	28,700	18,128
General and administrative	7,615	6,001	23,784	16,948
Acquisition related costs	–	1,537	–	2,849
Restructuring costs	–	4,818	–	4,875

Impairment expense	45,196	4,286	64,649	4,286
Amortization of intangible assets	1,061	1,585	3,214	4,754
Total operating expenses	67,341	25,214	131,089	52,699
Loss from operations	(54,655)	(25,666)	(93,648)	(34,798)
Other income (expense)				
Other income/(expense), net	(55)	(425)	(75)	(1,555)
Gain (loss) from contingent consideration	1,257	631	761	(2,680)
Gain (loss) on extinguishment of debt	169	–	169	(258)
Gain on derivative warrant liability	211	–	211	–
Total other expense	1,582	206	1,066	(4,493)
Loss before income tax	(53,073)	(25,460)	(92,582)	(39,291)
Income tax benefit	–	–	(110)	–
Net loss	$ (53,073)	$ (25,460)	$ (92,472)	$ (39,291)
Weighted average number of common shares outstanding	29,689,856	18,092,465	27,211,708	14,490,219
Basic and diluted net loss per common share	$ (1.79)	$ (1.41)	$ (3.40)	$ (2.71)

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

	(Unaudited) March 31, 2022	June 30, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 27,613	$ 49,649
Restricted cash	–	252
Accounts receivable, net	27,613	28,176
Inventory, net	13,891	16,339
Prepaid expenses	7,942	9,780
Other current assets	888	1,038
Total current assets	77,947	105,234
Property and equipment, net	3,479	5,140
Operating lease right-of-use asset	3,561	3,563
Intangible assets, net	74,428	85,464
Goodwill	8,637	65,802
Other non-current assets	774	465
Total non-current assets	90,879	160,434
Total assets	$ 168,826	$ 265,668
Liabilities		
Current liabilities		
Accounts payable and other	$ 11,130	$ 19,255
Accrued liabilities	53,470	51,295
Accrued compensation	5,258	5,939
Short-term line of credit	3,385	7,934
Current portion of debt	100	16,668
Current portion of operating lease liabilities	1,203	940
Current portion of fixed payment arrangements	2,903	3,134
Current portion of CVR liabilities	156	218
Current portion of contingent consideration	–	4,055
Other current liabilities	2,755	–
Total current liabilities	80,360	109,438
Debt, net of current portion	14,167	180
Operating lease liabilities, net of current portion	2,406	2,624
Fixed payment arrangements, net of current portion	4,237	6,324
CVR liabilities, net of current portion	564	1,177
Contingent consideration, net of current portion	371	8,002
Other non-current liabilities	5,577	355
Total liabilities	107,682	128,100
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding as of March 31, 2022 and June 30, 2021	–	–
Common Stock, par value $.0001; 200,000,000 shares authorized; shares issued and outstanding 33,355,935 and 27,490,412, respectively, as of March 31, 2022 and June 30, 2021	3	3
Additional paid-in capital	331,912	315,864
Accumulated deficit	(270,771)	(178,299)
Total stockholders' equity	61,144	137,568
Total liabilities and stockholders' equity	$ 168,826	$ 265,668

AYTU BIOPHARMA, INC.
Reconciliation of GAAP to Non-GAAP Financial Information
(In thousands)

	Three Months Ended March 31, 2022
Reconciliation of net loss to Adjusted EBITDA:	
Net loss	$ (53,073)
Addback:	
Research and development – AR101 & Healight	2,943
Depreciation and Amortization	2,447

Impairment expense	45,196
Stock based compensation	1,201
Interest expense	831
Other income	(776)
Gain from contingent considerations	(1,257)
Gain on derivative warrant liability	(211)
Gain on extinguishment of debt	(169)
Adjusted EBITDA	$ (2,868)

[1] Aytu uses the term EBITDA (Earnings Before Interest, Income Taxes, Depreciation and Amortization), which is a term not defined under United States Generally Accepted Accounting Principles. The Company uses this term because it is a widely accepted financial indicator utilized to analyze and compare companies on the basis of operating performance. The Company believes that presenting EBITDA adjusted to exclude expenses related to development of its AR101 and Healight development programs and impairment expenses and non-cash adjustments (Adjusted EBITDA) provides information to evaluate the Company's ongoing commercial activities. See reconciliation of Adjusted EBITDA to net income in table set forth below. The Company's method of computation of EBITDA may or may not be comparable to other similarly titled measures used by other companies.

SOURCE: Aytu BioPharma, Inc.

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https://www.accesswire.com/701243/Aytu-BioPharma-Reports-Third-Quarter-2022-Financial-Results-and-Outlines-Key-Strategic-Priorities