Aytu BioPharma Reports Fiscal 2025 First Quarter Operational and Financial Results

Net income of $1.5 million

Adjusted EBITDA[1] of $1.9 million

ADHD Portfolio net revenue up 1% to $15.3 million

Pediatric Portfolio net revenue up 54% sequentially

$20.1 million cash balance at September 30, 2024

Organizational changes and operating optimization plan implemented to further streamline operations, reduce expenses, and accelerate path to consistent cash flow

Ryan Selhorn promoted to Chief Financial Officer

Company to host conference call and webcast today, November 13, 2024, at 4:30 p.m. Eastern time

DENVER, CO / November 13, 2024 / Aytu BioPharma, Inc. (the "Company" or "Aytu") (Nasdaq:AYTU), a pharmaceutical company focused on commercializing novel therapeutics, today announced operational and financial results for the fiscal 2025 first quarter.

Q1 2025 Highlights

- ADHD Portfolio (Adzenys XR-ODT® and Cotempla XR-ODT®) net revenue increased 1% to $15.3 million versus $15.1 million in Q1 fiscal 2024.
- Pediatric Portfolio (Karbinal® ER, Poly-Vi-Flor® and Tri-Vi-Flor®) net revenue increased 54% sequentially to $1.3 million, reflecting positive effects from recently implemented return-to-growth plan for the pediatric product line.
- Net revenue was $16.6 million versus $17.8 million in the prior year period with the decrease primarily related to a change in payor coverage last year, which impacted the Pediatric Portfolio.
- Gross profit percentage was 72% in Q1 fiscal 2025 compared to 73% in Q1 fiscal 2024.
- Net income for Q1 fiscal 2025 was $1.5 million, or $0.24 net income per share basic and $0.15 net loss per share diluted, compared to a net loss of $8.1 million, or $1.48 net loss per share for both basic and diluted in Q1 fiscal 2024.
- Adjusted EBITDA was $1.9 million in Q1 fiscal 2025 compared to $2.4 million in Q1 fiscal 2024.
- Cash and cash equivalents were $20.1 million at September 30, 2024, compared to $20.0 million at June 30, 2024.

Management Discussion

“The initiatives we undertook two years ago to reposition Aytu as a growing specialty pharmaceutical company focused on commercializing novel prescription therapeutics were done with an aim towards driving consistent operating cash flow. The results of the first quarter continue to showcase the positive impact from these initiatives as we reported our sixth consecutive quarter of positive adjusted EBITDA and posted positive net income for the first time in the Company’s history,” commented Josh Disbrow, Chief Executive Officer of Aytu. “Looking forward, we expect to further accelerate our profitability goals through continued revenue growth across our product portfolio by leveraging the unique capabilities of our commercial platform, including Aytu RxConnect, as well as through continued optimization of our organizational processes with an expectation of reducing our operating expenses by at least $2.0 million annually. We remain steadfast in our pursuit to drive stockholder value in Aytu.”

“During the first quarter, we experienced continued year-over-year and sequential net revenue growth of our ADHD Portfolio primarily due to an improvement in our gross-to-nets. The ADHD market returned to a more normalized status following the competitor stimulant shortages over the past 18 months, which helped to temporarily bolster Adzenys and Cotempla scripts. I am pleased that we exited this period with our prescriptions well above the historical trends. During the first quarter of fiscal 2025, there were approximately 99,000 ADHD prescriptions written compared to 91,000 in Q1 2022 and 90,000 in Q1 2023. We have successfully reset the baseline as prescribers and patients have recognized the benefits that both our products and dynamic RxConnect program provide.”

“Pediatric Portfolio net revenue increased 54% quarter over quarter. This is the first sequential revenue growth we have reported in the last five quarters and is directly attributable to the initiatives we put in place to counteract the payor changes experienced last year. These programs included improving coverage, increasing promotional emphasis and repositioning our products in the marketplace. I am pleased with the momentum we continue to see in both our ADHD and pediatric portfolios.”

Organizational Changes and Operating Optimization Plan

Aytu successfully repositioned itself as a growing specialty pharmaceutical company focused on commercializing novel prescription therapeutics. During the past year, the Company wound down and sold its Consumer Health business. Prior to that, the Company announced the indefinite suspension of all pipeline clinical development programs. The Company also spent over two years working on manufacturing, operational, and regulatory initiatives to outsource the contract manufacturing of its ADHD products with the Grand Prairie, Texas facility set to be returned to the landlord at the end of calendar 2024. Recently, the Company implemented a new series of organizational changes focused on optimizing operations and

driving near-term cash flow. These new optimization efforts are expected to further reduce operating expenses by at least $2.0 million annually.

Key optimization efforts include:

- The promotion of Ryan Selhorn, current Executive Vice President of Finance and Business Optimization, to the role of Chief Financial Officer, replacing Mark Oki, who will depart the Company;
- The elimination of the role of Senior Vice President of Research and Development; current Senior Vice President of Research and Development, Russ McMahen, will leave the company and is expected to transition to a consulting role; and
- Elimination of several general and administrative positions primarily within accounting and other corporate functions.

Mr. Disbrow commented, “By virtue of implementing these optimization strategies, we say goodbye to two highly experienced executives to whom we are very grateful, Mark Oki and Russ McMahen, along with additional members of our team. Mark led the accounting and finance functions through an important time of growth, consolidation and process improvement, and has positioned us well as we move into this next phase of growth. Mark was instrumental in leading multiple key aspects of the Company’s transformation over the last two-plus years, and we wish him well in his future endeavors and thank him for his steadfast leadership at Aytu.”

“Russ has been an instrumental member of the Aytu management team since the Neos Therapeutics acquisition in 2021 and was a pivotal member of the team responsible for bringing Adzenys and Cotempla through the development process and to market. Russ has been the consummate professional through this time of transition, and now that we have fully transitioned out of the Texas facility, wish him well and thank him for continuing to assist the Company in his planned consulting role going forward.”

“Aytu is in great hands with Ryan leading the accounting and finance functions for the team going forward. Ryan joined Aytu in 2020 and has over 21 years of experience across finance, accounting, business development, business integrations and operations and has served as a public company Chief Financial Officer at numerous life sciences companies. I look forward to his leadership moving forward,” Mr. Disbrow concluded.

Prior to Ryan’s appointment as Chief Financial Officer, he served as Aytu’s Executive Vice President, Finance and Business Optimization since November 2022. Prior to this, Ryan was Aytu’s Senior Vice President, Finance and Operations, Consumer Healthcare Division from February 2022 to November 2022 and as Vice President, Finance, Consumer Healthcare Division from February 2020 to February 2022. Ryan served as Vice President and Chief Financial Officer from April 2018 at Innovus Pharmaceuticals, Inc., a publicly held consumer healthcare company, until Aytu’s acquisition of Innovus in February 2020. From August 2013 to April 2018, Ryan served as Chief Financial Officer and Chief Accounting Officer of Signature

Analytics, a privately held fractional Chief Financial Officer and accounting firm, where he also served as Chief Financial Officer of Medicinova, Inc., a publicly held biotechnology company. Ryan worked at Grant Thornton LLP, a public accounting firm, from October 2003 to July 2013, most recently in the role of Senior Manager, Transaction Advisory Services. Ryan received his B.S./B.A., Accounting and Finance from Georgetown University and is a Certified Public Accountant (inactive).

Consumer Health – Discontinued Operations

In June 2023, the Company announced that it had instituted a strategic mandate focusing its business solely on its Rx business. Following the successful completion of the wind down and divestiture of the Consumer Health business in the first quarter of fiscal 2025, this marked the completion of the Company's restructuring efforts, which also included the suspension of all pipeline clinical development programs and the transfer of the manufacturing of certain of the Company's products to a United States-based third-party manufacturer and the related closure of its manufacturing facility in Grand Prairie, Texas. The Company expects the savings realized from these strategic shifts to significantly enhance its operating results and drive stockholder value.

The accounting requirements for reporting the Consumer Health business divestiture as a discontinued operation were met when the wind down and divestiture was completed on July 31, 2024. Accordingly, the Company's unaudited consolidated financial statements for all periods presented reflect the Consumer Health business as a discontinued operation. In addition, the Company's fiscal 2024 quarterly results classify the Consumer Health business as a discontinued operation.

Net Revenue by Portfolio

	Three Months Ended September 30,	
	2024	2023
	(in thousands)	
ADHD Portfolio	$ 15,264	$ 15,128
Pediatric Portfolio	1,293	2,565
Other*	17	124
Total net revenue	$ 16,574	$ 17,817

*Other includes discontinued or deprioritized products.

Q1 2025 Financial Results

Net revenue for the first quarter of fiscal 2025 was $16.6 million, compared to $17.8 million for the prior year period. The decrease was primarily due to a decrease in net revenue from the Pediatric Portfolio driven by payer changes that negatively affected prescription coverage. In the first quarter of 2025, we reduced an accrued rebate liability related to the ADHD Portfolio by $3.3 million resulting in an increase in net revenue of $3.3 million.

The ADHD Portfolio (Adzenys XR-ODT® and Cotempla XR-ODT®) experienced a 1% increase in net revenue to $15.3 million in the first quarter of fiscal 2025, compared to the prior year period. The Pediatric Portfolio (Karbinal® ER, Poly-Vi-Flor® and Tri-Vi-Flor®) net revenue decreased to $1.3 million primarily related to a change in payor coverage last year that impacted prescriptions. Pediatric Portfolio revenue increased 54% sequentially.

Gross profit was $12.0 million, or 72% of net revenue, in the first quarter of fiscal 2025, compared to $13.0 million, or 73% of net revenue, in the same quarter last year.

Operating expenses, excluding amortization of intangible assets and restructurings costs, were $11.2 million in the first quarter of fiscal 2025 compared to $13.0 million in the prior year period. The decrease was a result of continued cost reduction efforts and improved operational efficiencies.

Loss from operations was $0.9 million for both the first quarter of fiscal 2025 and the prior year period.

Net income during the first quarter of fiscal 2025 was $1.5 million, or $0.24 net income per share basic and $0.15 net loss per share diluted, compared to a $8.1 million net loss, or $1.48 net loss per share for both basic and diluted, in the prior year period. The fiscal 2025 first quarter results were impacted by $2.9 million of derivative warrant liabilities gain due primarily to the decrease in the Company’s stock price and $0.4 million of income tax expense.

Adjusted EBITDA was $1.9 million in the first quarter of fiscal 2025, compared to $2.4 million in the prior year period, a $0.5 million decrease resulting largely from the decrease in the Pediatric Portfolio net revenue, partially offset by decreased operating costs as a result of reduced spending and improved operational efficiencies.

Cash and cash equivalents at September 30, 2024, were $20.1 million compared to $20.0 million at June 30, 2024.

Conference Call Details

Date and Time: Wednesday, November 13, 2024, at 4:30 p.m. Eastern time.

Call-in Information: Interested parties can access the conference call by dialing (877) 545-0320 for United States callers or +1 (973) 528-0002 for international callers and using the participant access code 428941.

Webcast Information: The webcast will be accessible live and archived at https://www.webcaster4.com/Webcast/Page/2142/51583, and accessible on the Investors section of the Company’s website at https://investors.aytubio.com/ under Events & Presentations.

Replay: A teleconference replay of the call will be available until Wednesday, November 27, 2024, at (877) 481-4010 for United States callers or +1 (919) 882-2331 for international callers and using replay access code 51583.

About Aytu BioPharma, Inc.

Aytu is a pharmaceutical company focused on commercializing novel therapeutics. 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), Karbinal® ER (carbinoxamine maleate), an extended-release antihistamine suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines available in various formulations for infants and children with fluoride deficiency. 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 ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("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 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 overall financial and operational performance, potential adverse changes to the Company's 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, our partners performing their required activities, our anticipated future cash position, regulatory and compliance challenges and future events under current and potential future collaborations. We also refer you to (i) the risks described in "Risk Factors" in Part I, Item 1A of our most recent Annual Report on Form 10 K and in the other reports and documents it files with the United States Securities and Exchange Commission.

Footnote 1

Aytu uses the term adjusted EBITDA, which is a term not defined under United States

generally accepted accounting principles (“U.S. GAAP”). 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 adjusted EBITDA by certain categories allows investors to evaluate the various performance of these categories. The Company’s method of computation of adjusted EBITDA may or may not be comparable to other similarly titled measures used by other companies. We believe that net income (loss) is the performance measure calculated and presented in accordance with U.S. GAAP that is most directly comparable to adjusted EBITDA. See below for a reconciliation of net income (loss) to adjusted EBITDA.

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Aytu BioPharma, Inc.
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended September 30,	
	2024	**2023**
Net revenue	$ 16,574	$ 17,817
Cost of sales	4,589	4,779
Gross profit	11,985	13,038
Operating expenses:		
Selling and marketing	5,659	6,091
General and administrative	5,125	6,295
Research and development	426	595
Amortization of intangible assets	921	924
Restructuring costs	784	–
Total operating expenses	12,915	13,905
Loss from operations	**(930)**	**(867)**
Other income, net	542	584
Interest expense	(994)	(1,283)
Derivative warrant liabilities gain (loss)	2,880	(5,907)
Income (loss) from continuing operations before income tax expense	**1,498**	**(7,473)**
Income tax expense	(405)	–
Net income (loss) from continuing operations	**1,093**	**(7,473)**
Net income (loss) from discontinued operations, net of tax	381	(647)
Net income (loss)	**$ 1,474**	**$ (8,120)**
Basic weighted-average common shares outstanding	6,068,019	5,482,037
Diluted weighted-average common shares outstanding	9,099,601	5,482,037
Net income (loss) per share:		
Basic – continuing operations	$ 0.18	$ (1.36)
Diluted – continuing operations	$ (0.20)	$ (1.36)
Basic – discontinued operations, net of tax	$ 0.06	$ (0.12)
Diluted – discontinued operations, net of tax	$ 0.04	$ (0.12)
Basic – net income (loss)	$ 0.24	$ (1.48)
Diluted – net loss	$ (0.15)	$ (1.48)

Aytu BioPharma, Inc.
Unaudited Consolidated Balance Sheets

(in thousands, except share data)

	September 30, 2024	June 30, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,108	$ 20,006
Accounts receivable, net	23,159	23,526
Inventories	11,739	12,141
Prepaid expenses and other current assets	5,732	5,097
Current assets of discontinued operations	–	1,121
Total current assets	60,738	61,891
Non-current assets:		
Property and equipment, net	692	693
Operating lease right-of-use assets	1,225	829
Intangible assets, net	51,205	52,453
Other non-current assets	1,971	2,185
Non-current assets of discontinued operations	–	44
Total non-current assets	55,093	56,204
Total assets	**$ 115,831**	**$ 118,095**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,513	$ 10,314
Accrued liabilities	33,723	38,143
Revolving credit facility	4,270	2,395
Current portion of debt	1,857	1,857
Other current liabilities	7,889	8,962
Current liabilities of discontinued operations	–	557
Total current liabilities	61,252	62,228
Non-current liabilities:		
Debt, net of current portion	10,430	10,877
Derivative warrant liabilities	9,402	12,745
Other non-current liabilities	4,921	4,529
Total non-current liabilities	24,753	28,151
Stockholders' equity:		
Preferred stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, par value $.0001; 200,000,000 shares authorized; 6,149,202, and 5,972,638 shares issued and outstanding, respectively	1	1
Additional paid-in capital	348,324	347,688
Accumulated deficit	(318,499)	(319,973)
Total stockholders' equity	29,826	27,716
Total liabilities and stockholders' equity	**$ 115,831**	**$ 118,095**

Aytu BioPharma, Inc.
Unaudited Reconciliation of Net Income (Loss) to Adjusted EBITDA
(in thousands)

	Three Months Ended September 30,	
	2024	2023
Net income (loss) – GAAP	**$ 1,474**	**$ (8,120)**
Interest expense	994	1,283
Income tax expense	405	–
Depreciation and amortization	1,334	1,554
Stock-based compensation expense	173	725
Other income, net	(542)	(584)
Derivative warrant liabilities (gain) loss	(2,880)	5,907
One-time transactions	–	851
Non-recurring legal fees	402	–
Restructuring costs	784	–
Pipeline research and development costs	168	152
Net (income) loss from discontinued operations, net of tax	(381)	647
Adjusted EBITDA – non-GAAP	**$ 1,931**	**$ 2,415**

Aytu BioPharma, Inc.
Unaudited Fiscal 2024 Quarterly and Full Year Consolidated Statements of Operations Adjusted for Discontinued Operations
(in thousands)

	Three Months Ended				Twelve Months Ended
	June 30, 2024	March 31, 2024	December 31, 2023 (as adjusted)	September 30, 2023	June 30, 2024
Net revenue	$ 14,593	$ 14,025	$ 18,748	$ 17,817	$ 65,183
Cost of sales	3,541	3,664	4,145	4,779	16,129
Gross profit	11,052	10,361	14,603	13,038	49,054
Operating expenses:					
Selling and marketing	5,422	5,352	5,218	6,091	22,083
General and administrative	4,028	4,831	4,800	6,295	19,954
Research and development	1,042	611	521	595	2,769
Amortization of intangible assets	921	920	918	924	3,683
Restructuring costs	1,912	244	–	–	2,156
Total operating expenses	13,325	11,958	11,457	13,905	50,645
(Loss) income from operations	**(2,273)**	**(1,597)**	**3,146**	**(867)**	**(1,591)**
Other income, net	120	70	96	584	870
Interest expense	(1,253)	(1,257)	(1,266)	(1,283)	(5,059)
Derivative warrant liabilities gain (loss)	1,463	1,017	(577)	(5,907)	(4,004)

Loss on debt extinguishment	(594)	–	–	–	(594)
(Loss) income from continuing operations before income tax expense	**(2,537)**	**(1,767)**	**1,399**	**(7,473)**	**(10,378)**
Income tax expense	(695)	(245)	(828)	–	(1,768)
Net (loss) income from continuing operations	**(3,232)**	**(2,012)**	**571**	**(7,473)**	**(12,146)**
Net loss from discontinued operations, net of tax	(1,385)	(875)	(791)	(647)	(3,698)
Net loss	**$ (4,617)**	**$ (2,887)**	**$ (220)**	**$ (8,120)**	**$ (15,844)**

Aytu BioPharma, Inc.
Unaudited Fiscal 2024 Reconciliation of Net Loss Adjusted for Discontinued Operations to Adjusted EBITDA
(in thousands)

	Three Months Ended				Twelve Months Ended
	June 30, 2024	March 31, 2024	December 31, 2023 (as adjusted)	September 30, 2023	June 30, 2024
Net loss – GAAP	**$ (4,617)**	**$ (2,887)**	**$ (220)**	**$ (8,120)**	**$ (15,844)**
Interest expense	1,253	1,257	1,266	1,283	5,059
Income tax expense	695	245	828	–	1,768
Depreciation and amortization	1,398	1,449	1,510	1,553	5,910
Stock-based compensation expense	243	699	707	725	2,374
Other income, net	(120)	(70)	(96)	(584)	(870)
Derivative warrant liabilities (gain) loss	(1,463)	(1,017)	577	5,907	4,004
One-time transactions	150	–	–	851	1,001
Restructuring costs	1,912	244	–	–	2,156
Loss on extinguishment of debt	594	–	–	–	594
Pipeline research and development costs	599	136	96	152	983
Net loss from discontinued operations, net of tax	1,385	875	791	647	3,698
Adjusted EBITDA – non-GAAP	**$ 2,029**	**$ 931**	**$ 5,459**	**$ 2,414**	**$ 10,833**

SOURCE: Aytu BioPharma, Inc.

View the original press release on accesswire.com