Aytu BioPharma Reports Record Quarterly Revenue and Positive Adjusted EBITDA in First Quarter of Fiscal Year 2023

Record Quarterly Net Revenue of $27.7 Million Driven by 34% Growth in Rx Segment

Positive Adjusted EBITDA for the Quarter of $1.4 Million

Leadership Changes Implemented to Focus on Commercial Operations

Company to Host Conference Call Today at 4:30pm ET

ENGLEWOOD, CO / November 14, 2022 / Aytu BioPharma, Inc. (the Company or "Aytu") (Nasdaq:AYTU), a commercial stage pharmaceutical and consumer health company providing pediatric-focused prescription drugs and cost-effective consumer health solutions, today announced financial and operational results for the first quarter of fiscal year 2023 for the period ended September 30, 2022.

Q1 2023 Commercial Highlights (3 months ending September 30, 2022)

- Total net revenue was $27.7 million, a new quarterly record, and an increase of 26% over the $21.9 million in net revenue in the year ago quarter.
- Net revenue from the Company's Rx segment was $18.7 million during Q1 2023 compared to $13.9 million in the year ago quarter, growth of 34%.
    - ADHD products (Adzenys XR-ODT® and Cotempla XR-ODT®) net revenue increased by 24% to $11.6 million from $9.3 million in the year ago quarter.
    - Pediatric products (Poly-Vi-Flor®, Tri-Vi-Flor®, and Karbinal® ER) net revenue increased 73% to $6.6 million from $3.8 million in the year ago quarter.
- Consumer Health revenue during Q1 2023 was $9.0 million, an increase of 12% over the year ago quarter.
- Gross margins increased to 65% in Q1 2023 compared to 57% in the year ago quarter.
- Total Adjusted EBITDA[1] (inclusive of Pipeline R&D which has been indefinitely suspended as of October 13, 2022) was a positive $1.4 million in Q1 2023 compared to $(4.2) million in the year ago quarter. Spend attributable to the now suspended Pipeline R&D was approximately $0.9 million in Q1 2023.
- On October 13, 2022, the Company announced a shift of its strategy aimed at accelerating the growth of its commercial business and achieving profitability. As a result, the Company announced the indefinite suspension of its clinical development programs, including AR101/enzastaurin for the treatment of Vascular Ehlers-Danlos Syndrome (VEDS). The suspension is expected to save the Company over $20 million in projected future study costs.

Management Discussion

“This was truly a transformational quarter for Aytu as we reported record quarterly net revenue and our first ever positive Adjusted EBITDA quarter,” commented Josh Disbrow, Chief Executive Officer of Aytu BioPharma. “The net revenue growth of 26% in the quarter was led by strong performance in our prescription operations, with particularly strong growth in pediatric prescription net revenue of 73%, ADHD prescription net revenue of 24%, along with solid double-digit growth in our consumer health segment. The strategic initiatives we put in place to drive growth and efficiency across our entire organization, coupled with positive market drivers and the leverage we’re achieving through our proprietary Aytu RxConnect platform, positions us to positively change the trajectory of Aytu in the years to come. I am incredibly proud of the hard work by the entire organization to achieve the important milestone of positive Adjusted EBITDA this quarter and look forward to a tremendous fiscal 2023.”

Leadership Changes to Focus on Commercial Operations

In connection with the strategic decision to focus on its commercial business and indefinitely suspend its clinical development programs, the Company announced the following executive leadership changes aimed at aligning the skills of its key leadership team members to the near- and mid-term goals of driving revenue growth, further consolidating expenses, improving gross margins, and driving long-term profitability.

- Appointment of Co-Founder Jarrett Disbrow to newly created role of Chief Business Officer & President, Consumer Health
- Promotion of Topher Brooke to re-created role of Chief Operating Officer (“COO”)
- Promotion of Ryan Selhorn to newly created role of Executive Vice President, Finance and Business Optimization

Greg Pyszczymuka will remain in his role as Chief Commercial Officer, overseeing all aspects of the Rx commercial business, which has grown 34% year-over-year.

In discussing the leadership team and these changes, Disbrow added, “I’m excited to announce these leadership changes through which Jarrett, Topher, and Ryan will take on expanded roles directly aligned to our renewed strategic focus. Our executive team’s collective experience in driving growth of pharma and consumer health companies will serve us very well as we drive toward our near-term goal of achieving profitability.”

“Additionally, with a key focus on growing the Rx business, we’ll continue to rely heavily on Greg Pyszczymuka’s leadership as our Chief Commercial Officer. We’ve experienced strong growth, a significant upgrade in talent, and a streamlining of our commercial operations under Greg’s direction and look forward to Greg and his team continuing our growth trajectory across the Rx portfolio,” Disbrow added.

“Jarrett Disbrow, who co-founded Aytu and has been leading the company with me since inception, is poised to take his deep experience across both Rx and consumer brands to build our consumer health segment into a dynamic, high-growth, consumer-centric enterprise. Jarrett has an exciting vision for this growing business segment and has begun implementing plans for continued expansion, new product launches, and a refacing of the consumer health business.”

“Topher Brooke’s executive leadership at both large global and smaller specialty and biotech business units, coupled with his entrepreneurial orientation as the Co-Founder of pediatric-centric biotech Rumpus Therapeutics, makes him especially well-suited to step into the newly re-established role of Chief Operating Officer. As COO, Topher will lead the Grand Prairie manufacturing transition as we move to significantly increase prescription margins by outsourcing the production of Adzenys XR-ODT and Cotempla XR-ODT to a global contract manufacturer. He will also lead regulatory and quality affairs, scientific and medical affairs, strategy, and corporate and business development going forward.”

“Finally, Ryan Selhorn, currently Senior Vice President, Finance and Operations for the Consumer Health segment, will increase his responsibilities in the newly created corporate leadership role of Executive Vice President, Finance and Business Optimization. Ryan’s prior experience as a public company Chief Financial Officer, in both pharma and consumer health, coupled with his expertise in organizational improvement, dovetails perfectly into our revised strategic plans. He will lead the ongoing consolidation and streamlining of internal processes while spearheading numerous financial projects expected to drive efficiencies and significant cost savings throughout the organization.”

“I am thankful for these leaders and their enthusiasm as we move into this next phase of the Company’s growth and renewed focus,” Disbrow concluded.

Segment Reporting

	Quarter Ended September 30,	
	2022	2021
	(In thousands)	
Consolidated revenue:		
Rx Segment	$ 18,652	$ 13,883
Consumer Health Segment	9,003	8,014
Consolidated revenue	$ 27,655	$ 21,897
Rx Segment		
ADHD	$ 11,585	$ 9,327
Pediatric	6,558	3,798
Other*	509	758
	$ 18,652	$ 13,883

*Other includes COVID-related test kits and discontinued or deprioritized products.

Q1 2023 Financial Results

Net revenue for the first quarter of fiscal 2023 was $27.7 million, compared to $21.9 million for the first quarter of fiscal 2022, a 26% increase year-over-year.

Net revenue from the Rx segment in the first quarter of fiscal 2023 was $18.7 million, an increase of 34% over the same quarter last year. ADHD brands Adzenys XR-ODT and Cotempla XR-ODT experienced 24% growth in net prescription revenue to $11.6 million in the first quarter of fiscal 2023. The Prescription Pediatric portfolio comprised of Poly-Vi-Flor, Tri-Vi-Flor, and Karbinal ER experienced 73% growth in net prescription revenue to $6.6 million in the first quarter of fiscal 2023.

Net revenue from the Consumer Health segment was $9.0 million in the first quarter of fiscal 2023, an increase of 12% over the same quarter last year.

Gross profit increased to $18.0 million, or 65% of net revenue, in the first quarter of fiscal 2023, compared to $12.5 million, or 57% of net revenue, in the same quarter last year. The improvement was primarily driven by sales gains in the higher margin ADHD and Pediatric portfolios and continuing cost reduction efforts.

Operating expenses, excluding impairment expense and amortization of intangible assets, were $18.5 million in the first quarter of fiscal 2023 compared to $19.2 million in the same quarter last year. Research and development expenses were $1.1 million in the first quarter of fiscal 2023 compared to $1.7 million in the same quarter last year. Of this $1.1 million, $0.9 million were expenses associated with the recently suspended pipeline programs.

Net loss during the year ago first quarter was impacted by an impairment of $19.5 million as a result of the decline in the Company’s market capitalization, and after a qualitative and quantitative analysis was performed on the goodwill and other intangible assets associated with the Rx Segment. There were no impairments during the first quarter of fiscal 2023.

Net loss for the first quarter of fiscal 2023 was $(2.9) million, or $(0.06) per share, compared to $(27.9) million, or $(1.09) per share for the same quarter last year. Net loss from operations for the first quarter of fiscal 2023 was $(1.7) million.

Adjusted EBITDA (see Table A-1) was $1.4 million in the first quarter of fiscal 2023, compared to $(4.2) million in the year ago quarter.

Balance Sheet and Operational Improvements

Cash and cash equivalents on September 30, 2022 were $23.8 million. As part of the Company’s indefinite suspension of its clinical development programs, the Company expects to save over $20 million in projected future study costs.

The manufacturing transfer to a global contract manufacturer of the ADHD products remains on track to be completed in calendar 2023, and this transition is expected to further improve gross margins of Adzenys XR-ODT and Cotempla XR-ODT by 15% or more.

Subsequent to the end of the quarter, the Company announced an agreement with the

Avenue Venture Opportunities Fund, L.P. (“Avenue Venture Debt Fund” or “Avenue”) to extend the interest-only period of the Company’s existing senior secured loan facility held with Avenue. This amendment to the original secured loan agreement, which was executed in January 2022, extends the interest-only period to January of 2024. The maturity date of the Avenue secured loan is January 2025 and remains subject to additional interest-only period extensions upon the achievement of certain milestones by the Company. The extension of the interest-only period will conserve cash and save the Company over $3 million in calendar 2023 principal payments by deferring those payments into 2024 and 2025. In exchange for this extension, the Company and Avenue agreed to reset the exercise price of the warrants issued in conjunction with the original loan agreement to $0.43, corresponding to the warrant exercise price associated with the Company’s latest equity financing.

Conference Call Details

Aytu will host a conference call today, Monday, November 14th, 2022, at 4:30 PM Eastern Time to discuss financial results for the first fiscal quarter of 2023 for the quarter ended September 30, 2022.

The conference call will be available via telephone by dialing toll free 877-545-0523 for U.S. callers or for international callers 973-528-0016 and using entry code 883834. A webcast of the call may be accessed at https://www.webcaster4.com/Webcast/Page/2142/46981.

A webcast replay will be available on the Investors News/Events section of the Company’s website through. A telephone replay of the call will be available approximately one hour following the call, through November 28, 2022, and can be accessed by dialing 877-481-4010 for U.S. callers or 919-882-2331 for international callers and entering replay access code 46981.

About Aytu BioPharma, Inc.

Aytu BioPharma is a pharmaceutical company commercializing a portfolio of commercial prescription therapeutics and consumer health products. 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 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. Aytu’s consumer health segment markets a range of over-the-counter medicines, personal care products, and dietary supplements addressing a range of common conditions including diabetes, allergy, hair regrowth, and gastrointestinal conditions. To learn more, please visit

aytubio.com.

Forward-Looking Statement

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 Company’s ability to efficiently wind down clinical development and reduce spend associated with AR101 and Healight™, the Company’s ability to complete the manufacturing transfer of Adzenys XR-ODT® and Cotempla XR-ODT®, the company’s overall financial and operational performance, 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.

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

(Three Month Period Unaudited)

	Three Months Ended September 30,	
	2022	2021
Product revenue, net	$ 27,655	$ 21,897
Cost of sales	9,623	9,441
Gross profit	18,032	12,456
Operating expenses		
Research and development	1,064	1,652
Selling and marketing	10,102	9,297
General and administrative	7,322	8,216
Impairment expense	–	19,453
Amortization of intangible assets	1,197	1,537
Total operating expenses	19,685	40,155
Loss from operations	(1,653)	(27,699)
Other expense		
Other expense, net	(1,100)	(40)
Loss from contingent consideration	(128)	(219)
Total other expense	(1,228)	(259)
Loss before income tax	(2,881)	(27,958)
Income tax expense (benefit)	–	(107)
Net loss	$ (2,881)	$ (27,851)
Weighted average number of common shares outstanding	50,358,134	25,597,319
Basic and diluted net loss per common share	$ (0.06)	$ (1.09)

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

	(unaudited) September 30, 2022	June 30, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 23,811	$ 19,360
Accounts receivable, net	27,924	21,712
Inventory, net	12,871	10,849
Prepaid expenses	9,024	7,375
Other current assets	785	633
Total current assets	74,415	59,929
Property and equipment, net	2,672	3,025
Operating lease right-of-use asset	2,976	3,271
Intangible assets, net	69,108	70,632
Other non-current assets	829	766
Total non-current assets	75,585	77,694
Total assets	$ 150,000	$ 137,623
Liabilities		
Current liabilities		
Accounts payable and other	$ 14,667	$ 10,987
Accrued liabilities	41,431	44,187
Short-term line of credit	8,087	3,813
Current portion of debt	925	96
Other current liabilities	8,094	5,359
Total current liabilities	73,204	64,442
Debt, net of current portion	13,560	14,279
Other non-current liabilities	9,330	12,810
Total liabilities	96,094	91,531
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding as of June 30, 2022 and June 30, 2021	–	
Common Stock, par value $.0001; 200,000,000 shares authorized; shares issued and outstanding 62,429,445 and 38,578,825, respectively, as of September 30, 2022 and June 30, 2022	6	4
Additional paid-in capital	345,253	334,560
Accumulated deficit	(291,353)	(288,472)
Total stockholders' equity	53,906	46,092
Total liabilities and stockholders' equity	$ 150,000	$ 137,623

Table A-1 – Segment Adjusted EBITDA (Quarterly)

(in thousands)	Rx	Consumer Health	Pipeline R&D	Three Months Ended September 30, 2022	Rx	Consumer Health	Pipeline R&D	Three Months Ended September 30, 2021
Reconciliation of net loss to Adjusted EBITDA:								
Net loss	$ (1,179)	$ (827)	$ (875)	$ (2,881)	$ (25,022)	$ (1,394)	$ (1,435)	$ (27,851)
Addback:								
Depreciation and amortization	1,574	281	–	1,855	2,094	413	–	2,507
Impairment expense	–	–	–	–	19,453	–	–	19,453
Stock based compensation	1,153	15	9	1,177	1,193	14	312	1,519
Other expense, net	1,062	38	–	1,100	7	33	–	40
Loss from contingent considerations	128	–	–	128	219	–	–	219
Income tax benefit	–	–	–	–	(107)	–	–	(107)
Adjusted EBITDA	$ 2,738	$ (493)	$ (866)	$ 1,379	$ (2,163)	$ (934)	$ (1,123)	$ (4,220)

[1] Aytu uses the term EBITDA, 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 by segments allows investors to evaluate the various performance of these segments. 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 loss is the performance measure calculated and presented in accordance with U.S. GAAP that is most directly comparable to EBITDA.

SOURCE: Aytu BioPharma, Inc.

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