

Aytu BioPharma Announces Strategic Shift to Focus on Commercial Operations and Indefinite Suspension of Clinical Development Programs

Following a corporate review, Aytu BioPharma is indefinitely suspending clinical development and removing expenses related to AR101/enzastaurin, Healight, and NT0502, and focusing on revenue growth and near-term cash flow generation

Aytu is expecting to generate positive quarterly Adjusted EBITDA in the first half of calendar 2023

Expected future clinical development savings of more than \$20M

ENGLEWOOD, CO / October 13, 2022 / Aytu BioPharma, Inc. (the Company or “Aytu”) (NASDAQ:AYTU), a pharmaceutical company focused on commercializing novel therapeutics, today announced a shift of the Company’s strategy aimed at accelerating the growth of its commercial business and achieving profitability. As a result, the Company is announcing 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 and enable the Company to achieve quarterly positive Adjusted EBITDA in the first half of calendar 2023.

The Company’s commercial operations include its prescription and consumer health segments which generated net revenue of \$96.7 million in the most recent fiscal year. Excluding R&D expenses related to its now suspended pipeline, the Company had a slightly negative Adjusted EBITDA of \$(961,000) from its commercial operations during the quarter ending June 30, 2022, which included the first ever profitable quarter for the Company’s prescription segment.

Josh Disbrow, Chief Executive Officer of Aytu BioPharma, commented “This strategic realignment enables us to dedicate our resources to growing our prescription and consumer health segments. Coupled with the suspension of clinical development activities and continued execution against our previously planned \$15 million cost cutting program, this shift enables the Company to achieve near-term positive Adjusted EBITDA. In today’s economic environment, we believe strongly it is in the best interest of all stakeholders for us to focus our efforts on accelerating the growth of the commercial businesses and generating positive cash flow.”

Disbrow added, “We understand that the suspension of our AR101 clinical development program is a disappointment to the VEDS community. We did not take this pause of our clinical development efforts lightly and intend to revisit the program at the appropriate time with the expectation of funding all future clinical development with internally generated cash flow or through partnering.”

Management expects to provide a more detailed financial outlook of its strategy at its regularly scheduled quarterly investors call scheduled for mid-November 2022.

About Aytu BioPharma, Inc.

Aytu BioPharma is a pharmaceutical company with 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. The company's consumer health segment is dedicated to becoming a leader in developing and commercializing safe and effective over-the-counter medicines, personal care products, and dietary supplements to improve health and vitality. The company's core consumer health products focus in categories such as hair loss, digestive health, urological health, diabetes management, and allergy. 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 press release, 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: the timing and ability to generate positive EBITDA and cash flows. We also refer you to the risks described in 'Risk Factors' in Aytu's Annual Report on Form 10-K, in Quarterly Reports filed on Form 10-Q, and in the other reports and documents it files with the Securities and Exchange Commission.

Contacts for Investors:

Mark Oki, Chief Financial Officer
Aytu BioPharma, Inc.
moki@aytubio.com

Robert Blum or Roger Weiss
Lytham Partners
AYTU@lythampartners.com

SOURCE: Aytu BioPharma, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/720110/Aytu-BioPharma-Announces-Strategic-Shift-to-Focus-on-Commercial-Operations-and-Indefinite-Suspension-of-Clinical-Development-Programs>