Aytu BioPharma Recaps Investor Day Held on January 20, 2026

DENVER, CO / ACCESS Newswire / January 20, 2026 / Aytu BioPharma, Inc. (the "Company" or "Aytu") (Nasdaq:AYTU), a pharmaceutical company focused on advancing innovative medicines for complex central nervous system diseases to improve the quality of life for patients, today provided a summary of the Company's Investor Day, held today, Tuesday, January 20, 2026, at 11:00 a.m. Eastern time in New York City. The Investor Day was conducted both in-person and via webcast.

A replay of the event can be found on the Investors section of the Company's website at https://investors.aytubio.com under Events & Presentations. The event can also be accessed directly at https://app.webinar.net/Qo7DrDvVzq8.

The Investor Day primarily focused on EXXUA™ (gepirone), extended-release tablets ("EXXUA"), the first and only 5HT1a agonist approved by the United States Food and Drug Administration ("FDA") for the treatment of major depressive disorder ("MDD"), which was initially launched last month.

Key Opinion Leaders ("KOLs") in the field of psychiatry and Aytu's senior management team presented on the EXXUA opportunity and led question and answer sessions.

KOL Presentation Highlights

Stephen M. Stahl, MD, PhD, DSc (Hon) reviewed the 5-HT1a receptor and its clinical importance in MDD.

- Selective Serotonin Reuptake Inhibitors ("SSRIs") and Serotonin-Norepinephrine Reuptake Inhibitors ("SNRIs"), collectively Reuptake Inhibitors, 'flood the synapse' with serotonin, non-selectively binding multiple 5-HT receptor types.
    - Specific activation of the 5HT1a receptor, the primary mechanism of action of EXXUA, is thought to promote an antidepressant effect.
    - Activation of the 5HT2a receptor, an effect of both SSRIs and SNRIs, is associated with sexual dysfunction, insomnia, and anxiety.
    - SSRIs and SNRIs may affect thirteen other receptor subtypes, and multiple 5-HT receptor subtypes may affect appetite regulation.
- Reuptake Inhibitors can relieve MDD symptoms, but sometimes at a cost.
    - Drugs designed based on re-uptake inhibition exhibit some symptom relief but also lead to off-target side effects.
- EXXUA acts as a full agonist at presynaptic 5HT1a autoreceptors, enhancing neurotransmission.
    - 5HT1a agonism at autoreceptors is thought to facilitate downregulation of inhibitory 5HT1a autoreceptors, reducing inhibition of serotonergic signaling, improving antidepressant efficacy.
- EXXUA acts as a 5-HT1a-specific partial agonist postsynaptically, contributing to its antidepressant action.

EXXUA does not have actions at receptors known to be associated with sexual side effects and weight gain.

- EXXUA mechanism of action has potential implications for mood, anxiety, cognition, and stress circuits through potential actions in the medial prefrontal cortex, amygdala, hippocampus, dorsal raphe nucleus, and the ventral tegmental area.

Anita Clayton, MD discussed unmet treatment needs and their implications for antidepressant treatment selection in MDD.

- An estimated 21.0 million adults in the US had at least 1 major depressive episode in 2021, representing 8.3% of all US adults.

  Of those, 14.5 million also experience severe impairment, representing 5.7% of all US adults.
- 50% to 60% of patients fail to achieve remission with first-line SSRIs.

  Even if they achieve symptom remission, many patients often do not reach full functional recovery (e.g., cognitive function, workplace productivity, etc.).
- Nearly half of all patients with MDD have been shown to discontinue their first-line treatment.
- Sexual dysfunction and weight gain are significant causes of treatment discontinuation with antidepressants. Of patients taking antidepressants, approximately 50% experience treatment-emergent sexual dysfunction. Additionally, up to 65% experience weight gain with long-term use.
- Implications for EXXUA positioning in clinical practice include the following factors:

  EXXUA does not carry a warning about the risk of sexual dysfunction, unlike many antidepressants that act on serotonin receptors.

  Sexual dysfunction was not reported as an adverse event with an incidence $\geq$ 2% and greater than placebo in pooled MDD studies. EXXUA demonstrates a neutral sexual profile in clinical studies.

  EXXUA demonstrates no clinically significant increase in body weight compared with placebo.

  Mean increase of 1 kg with EXXUA vs. 0 kg with placebo in pivotal Study 1 and 0.3 kg with EXXUA vs. 0.1 kg with placebo in pivotal Study 2.

Christoph Correll, MD discussed EXXUA's clinical trial data, including efficacy and safety.

- Pivotal Study 1 and Study 2 were 8-week, randomized, double-blind, placebo-controlled, flexible-dose, Phase 3 studies in adults with MDD.

  Treatment schedule: Initial dosage of 18.2 mg once daily was titrated to 36.3 mg once daily on Day 4. Dosage could be increased to 54.5 mg once daily after Day 7 and 72.6 mg once daily after an additional 7 days.

  Primary efficacy measure: Change from baseline in the 17-item Hamilton Depression Rating Scale (HAM-D17) total score at Week 8

  Secondary endpoints: Included change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) and Clinical Global Impression-Severity (CGI-S) at Week 8
- In Pivotal Study 1 and Pivotal Study 2 EXXUA demonstrated statistically significant improvement from baseline in the HAM-D17 total score at Week 8 vs placebo (P=0.018 and P=0.032, respectively).

- Change from baseline in the HAM-D 17 total score at Week 8:

	Treatment group	Mean baseline score	LS mean change from baseline	Placebo-subtracted difference (95% CI)
Study 1	**EXXUA** (n=101) (18.2 to 72.6 mg/day)	22.7	9.04	**2.47** (4.41, -0.53)
	Placebo (n=103)	22.8	6.75	
Study 2	**EXXUA** (n=116) (18.2 to 72.6 mg/day)	23.9	10.22	**2.45** (4.47, 0.43)
	Placebo (n=122)	24.2	7.96	

In Study 1, the final dose of EXXUA was 72.6, 54.5, and 36.3 mg/day in 64%, 20%, and 17% of patients, respectively.

In Study 2, the final dose of EXXUA was 72.6, 54.5, 36.3, and 18.2 mg/day in 66%, 22%, 10%, and 2% of patients, respectively.

- Statistically significant remission in symptoms was achieved over placebo as early as week 3.
- Safety and tolerability of EXXUA were evaluated in 1,976 adult patients with MDD in Phase 2 and 3 clinical studies.

Most common adverse reactions were dizziness, nausea, insomnia, abdominal pain, and dyspepsia (5% and twice the incidence of placebo).

Dizziness was mild to moderate and transient.

Incidence dropped from 33.9% at Week 1 to 19.0% by Week 2 and 2.9% by Week 6 in Study 2.

Discontinuation due to adverse events was 3% for placebo and 7% for EXXUA.

No treatment-related serious adverse events led to discontinuation, and no deaths occurred in the study.

Adverse events reported with EXXUA were predominantly early in onset and time limited, with rapid attenuation over the first several weeks of treatment.

Aytu Management Team Presentation Highlights

Josh Disbrow, Chief Executive Officer, provided an overview of the EXXUA opportunity and commented on early positive signs in the days following initial product availability and full commercial launch.

- Aytu views EXXUA as a truly unique opportunity, as it represents a novel way of treating major depressive disorder in adults as the first and only 5HT1a agonist indicated for the treatment of major depressive disorder.

The United States MDD market is over $22 billion, with over 345 million prescriptions written annually for antidepressants.

- EXXUA has a novel product profile and fills a meaningful and very large unmet need.

- The early signs post launch are very positive since initial commercial availability on December 15, 2025, and the final elements of sales force training were completed on January 16, 2026. The full commercial launch of EXXUA is now underway.
- All distributors and wholesalers nationwide are now fully stocked with EXXUA, physicians are engaging, and initial prescriptions have been generated.
- The positioning of EXXUA in the MDD market is unique with respect to its mechanism of action and receptor specificity for 5HT1a.

    EXXUA, as the first and only 5HT1a agonist indicated for the treatment of MDD in adults, is truly novel.

    EXXUA demonstrates no negative impact on sexual function and no clinically or statistically significant weight changes.
- Aytu believes it has a markedly different product that can fill an important gap in treatment, and the early prescriber reactions and traction are providing early evidence of a successful launch.

Ryan Selhorn, Chief Financial Officer, provided an overview of the key EXXUA commercialization agreement deal terms along with highlights of the Company's financials.

- The key terms of the EXXUA commercialization agreement with Fabre-Kramer Pharmaceuticals include:

    Fixed Payments:

        $3 million upfront payment; paid at execution in June 2025.

        An additional $3 million payment will be made within forty-five days of the first anniversary of EXXUA Commercial Launch (as defined), such payment to be made in early calendar year 2027.

            - The additional payment increases to $5 million if Net Sales (as defined) of EXXUA for the first twelve months of commercialization meet or exceed $35 million.

    Royalties (% of Net Sales):

        28% 'base' royalty.

        Additional 3% (capped) on cost of goods sold.

        Increased royalty rate if annual Net Sales are greater than $300 million.

        Upon a royalty trigger or loss of exclusivity ("LOE"), royalty rates reduce.

        Milestones payments beginning at $100 million in annual Net Sales.

            - First milestone of $5 million paid upon Net Sales reaching $100 million.
- Aytu Financial Highlights:

    $32.6 million in cash as of 9/30/25.

        No additional cash requirement expected through profitability.

    Trailing twelve months ("TTM") ending 9/30/25 adjusted EBITDA[1] of $6.7 million.

    TTM operating cash burn of $1.4 million.

    Original EXXUA launch investment budget of $10 million reduced to $6-8 million due to efficiencies and cost management.

    EXXUA expected gross margin of 66-68%.

Compares to TTM companywide GM of 67.6%.

Term loan outstanding of $12.5 million as of 9/30/25.

Reduced high interest liabilities by $7.4 million in TTM.

Fully diluted shares outstanding of 23.6 million as of 9/30/25.

Three institutional investors hold 52.3% of fully diluted shares outstanding.

Gerwin Westfield, PhD, Senior Vice President, Scientific Affairs.

- Dr. Westfield introduced the Investor Day key opinion leaders, who have a combined 40+ years of experience with EXXUA through the FDA review and approval process.

Greg Pyszczymuka, Chief Commercial Officer, described the Company's approach to the EXXUA commercial launch and provided details on elements of the launch plan.

- Launch Overview:

  The EXXUA commercial effort, while efficient in relative spend, will be comprehensive and focused on prescriber adoption and brand growth.

  Heavy emphasis on sales force promotion and metrics-based performance management.

  In addition to the Company's internal sales team, the Company is investing in efficient and rapidly scalable initiatives such as its virtual sales team to significantly broaden Aytu's customer reach.

  Additionally, the Company is leveraging a rolling Contract Sales Organization model which will enable Aytu to scale its in-person promotion based on product performance and cash flows.

  From a non-personal standpoint, a very targeted, media-based compliant consumer promotion approach will be employed.

  The Company is leveraging Aytu's best-in-class patient access program, Aytu RxConnect®, along with full retail distribution for EXXUA through national wholesalers to ensure broad-based product availability at pharmacies throughout the United States.

  Aytu will continue to reinforce with customers that Aytu is committed to an ideal patient access experience and the lowest possible patient out-of-pocket costs when receiving their prescription from an Aytu RxConnect® pharmacy.

  However, if physicians or patients inquire about EXXUA in an area Aytu does not have direct network coverage or a patient simply has a preference for a non-network pharmacy, everyone will have an option to fill their EXXUA prescription.

  Through Aytu's Medical & Scientific Affairs team, the Company is rapidly building out a KOL network and has a strong publication and meeting plan in place.

- Physician Targeting:

  EXXUA physician targeting has been characterized by focus, efficiency, and familiarity in Aytu's approach to launch. The Aytu sales team is initially focusing on a subset of high value psychiatry practices.

High volume prescribers of antidepressants – specifically SSRI's and SNRI's.

- Prescribers with high potential in the MDD therapeutic class and high levels of active patient switching.

Psychiatry practices with a higher propensity to prescribe brands.

Psychiatric practices with familiarity with Aytu – or those psychiatry practices actively prescribing Aytu's attention deficit hyperactivity disorder ("ADHD") products and familiar with the Aytu RxConnect® platform.

- Sales Force Deployment:

Aytu has deployed the Company's 40 plus person sales force and has positioned them well across a large cross section of the United States with high MDD potential and strong Aytu RxConnect® coverage.

Annual MDD Market Opportunity:

- Aligned Territories: 140.0 million total prescriptions ("TRxs").
- Target healthcare practitioners ("HCPs") within Aligned Territories: 18.5 million TRxs.

~5,500 Target HCPs at initial launch.

100% of Target HCPs are aligned Aytu RxConnect® pharmacies.

>50% of branded product TRxs volume written by psychiatrists.

Aytu's sales footprint has also been developed with eye toward expansion as EXXUA performance and Aytu cash flows dictate.

Virtual sales team will be tasked with building broader prescriber awareness for EXXUA beyond Aytu's in-person promotional efforts.

Expected to deliver nearly 20,000 customer contacts during the initial launch phase.

- Integration into Aytu RxConnect® & Payor Considerations:

Aytu RxConnect® is a proprietary, best-in-class patient access program that will play an important role with the launch of EXXUA and the ongoing support for all Aytu medicines.

Aytu RxConnect® offers unique elements to remove the friction prescribers and patients often face when prescribing and filling branded prescriptions.

Offers predictable coverage to patients and prescribers by guaranteeing 100% coverage for commercially insured patients regardless of individual plans.

Creates a low-hassle experience for patients and prescribers by removing common obstacles that occur for branded medications at retail pharmacies by ensuring product availability so patients can initiate therapy without delay.

Provides affordable access to commercially insured patients by guaranteeing capped out-of-pocket copay maximums.

- For EXXUA, patients with valid prescriptions will pay a maximum of $50 for prescriptions regardless of individual plan coverage.

Numerous enhancements and improvements to the Aytu RxConnect® program have been implemented since inception.

- Improvements have been made based on insights gained from the over one million prescriptions filled by the Aytu RxConnect® network.
- Realtime data guides the approach with EXXUA contracting for the approximately 60% of commercially insured MDD patients.
- Approximately 40% of the remaining MDD patients are Medicaid and Medicare for which Aytu expects early favorable coverage depending on the geography.

Aytu is not initially pursuing first-line use for EXXUA and the Company's contracting approach is aligned accordingly.

Aytu's EXXUA launch coverage expectations for all payers align with recent branded product launches for the treatment of MDD.

In summary, the launch of EXXUA will be highly focused with a heavy lean towards a well-informed expansion of promotional resources as cash flows allow to support further prescriber growth and brand adoption.

With the EXXUA commercial launch now underway, the Company expects to provide periodic updates to investors during quarterly earnings calls and investor events.

About Stephen M. Stahl, MD, PhD, DSc (Hon)

Dr. Stahl is an internationally renowned physician-scientist, educator, and author with deep expertise in psychiatry, psychopharmacology, and neuroscience. He received his B.S. and M.D. from Northwestern University and his Ph.D. in pharmacology and physiology from the University of Chicago, and completed clinical training in internal medicine, neurology, and psychiatry at top U.S. institutions. Dr. Stahl has held faculty appointments at Stanford University, UCLA, the Institute of Psychiatry London, and currently serves as Distinguished Health Sciences Clinical Professor at the University of California, Riverside, as well as Adjunct Professor of Psychiatry at the University of California, San Diego. He is also an Honorary Visiting Senior Fellow at the University of Cambridge and Senior Academic Advisor for the California Department of State Hospitals. He is a prolific contributor to medical science with hundreds of articles, textbooks, and scientific presentations, most famously Stahl's Essential Psychopharmacology and Stahl's Essential Psychopharmacology Prescriber's Guide, which are widely used in clinical education worldwide. Dr. Stahl has received numerous honors for his contributions to psychiatric education, including the Lundbeck Foundation Award in Education, multiple book awards from the British Medical Association, and the David A. Mrazek Memorial Award, and his alma mater honors top psychiatry students with the Stephen M. Stahl Award. His career blends clinical leadership, academic scholarship, and teaching, and he continues to influence the field through editorial roles (including Editor-in-Chief of CNS Spectrums), global lectures, and contributions to psychiatric nomenclature and education.

About Anita H. Clayton, MD

Dr. Clayton is a leading American psychiatrist, clinician, and researcher specializing in

women’s mental health, sexual dysfunction, and mood disorders. She serves as Chair of the Department of Psychiatry and Neurobehavioral Sciences and the David C. Wilson Professor of Psychiatry and Neurobehavioral Sciences at the University of Virginia School of Medicine, with a secondary appointment as Professor of Clinical Obstetrics and Gynecology. Dr. Clayton earned her M.D. from the University of Virginia School of Medicine and completed her psychiatry residency and fellowship at UVA, after which she served as a physician in the U.S. Navy before joining the UVA faculty in 1990. Her research focuses on psychopharmacology, mood disorders associated with reproductive life events, sexual dysfunction related to psychiatric illness and treatment, and female sexual disorders. She has published over 200 peer-reviewed papers, developed validated clinical assessment tools, and co-edited Women’s Mental Health: A Comprehensive Textbook. Dr. Clayton has held leadership roles in professional organizations, including past presidency of the International Society for the Study of Women’s Sexual Health and leadership positions with the American Society for Clinical Psychopharmacology. She is a Distinguished Fellow of the American Psychiatric Association and a recognized expert on women’s mental and sexual health.

About Christoph U. Correll, MD

Dr. Correll is a highly influential German-born psychiatrist, clinician, and researcher recognized internationally for his work in psychopharmacology, severe mental illness, and child and adolescent psychiatry. He currently serves as Professor of Psychiatry and Molecular Medicine at The Donald and Barbara Zucker School of Medicine at Hofstra/Northwell in New York and Professor and Chair of the Department of Child and Adolescent Psychiatry, Psychosomatic Medicine and Psychotherapy at Charité – Universitätsmedizin Berlin, Germany. Dr. Correll completed his medical studies at the Free University of Berlin and Dundee University Medical School in Scotland, followed by residencies and fellowship training in psychiatry and child and adolescent psychiatry in New York. He is board-certified in both general and child/adolescent psychiatry and has worked in academic and clinical settings in both the United States and Germany since 1997. A prolific scholar, Dr. Correll has authored or co-authored hundreds of scientific articles on topics such as schizophrenia, bipolar disorder, mood disorders, and the psychopharmacological management of severe psychiatric conditions. His work spans clinical trials, epidemiology, meta-analyses, and evaluation of psychotropic medications, and he has been listed annually since 2014 as one of the most influential scientific minds and top 1% cited scientists in psychiatry. Dr. Correll’s research also addresses the interface of physical health and mental health, comparative effectiveness of psychiatric treatments, and early identification and treatment strategies across the life span. He has received numerous national and international awards for his scientific contributions and is widely regarded as a global expert in psychopharmacology and severe mental illness.

About Aytu BioPharma

Aytu is a pharmaceutical company focused on advancing innovative medicines for complex central nervous system diseases to improve the quality of life for patients. The Company's prescription products include EXXUA™ (gepirone) extended-release tablets (see Full Prescribing Information, including Boxed WARNING) for the treatment of major depressive disorder (MDD), and treatments for attention deficit-hyperactivity disorder (ADHD). Aytu is committed to delivering the Company's medications through best-in-class patient access programs that help to enable optimal patient outcomes. For more information, please visit aytubio.com or follow us on LinkedIn.

About EXXUA

EXXUA is a novel oral selective serotonin 5-HT1A receptor agonist indicated for the treatment of major depressive disorder (MDD) in adults.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increase the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. EXXUA is not approved for use in pediatric patients.

INDICATIONS AND USAGE

EXXUA is indicated for the treatment of major depressive disorder (MDD) in adults.

DOSAGE AND ADMINISTRATION

Important Recommendations Prior to Initiating and During Treatment with EXXUA

Electrocardiogram and Electrolyte Monitoring

Correct electrolyte abnormalities prior to initiating EXXUA. In patients with electrolyte abnormalities, or who are receiving diuretics or glucocorticoids, or who have a history of hypokalemia or hypomagnesemia, also monitor electrolytes during dose titration and periodically during treatment with EXXUA.

Perform an electrocardiogram (ECG) prior to initiating EXXUA, during dosage titration, and periodically during treatment. Do not initiate EXXUA if QTc is > 450 msec at baseline. Monitor ECGs more frequently if EXXUA is used:

- concomitantly with drugs known to prolong the QT interval
- in patients who develop QTc 450 msec during treatment
- in patients with a significant risk of developing torsade de pointes

Do not escalate the EXXUA dosage if the QTcF is > 450 msec.

Bipolar Disorder, Mania, and Hypomania Screening

Screen patients for a personal or family history of bipolar disorder, mania, or hypomania prior to initiating treatment with EXXUA.

Important Administration Instructions

Take EXXUA orally with food at approximately the same time each day. Swallow tablets whole. Do not split, crush, or chew EXXUA.

Recommended Dosage

The recommended starting dosage of EXXUA is 18.2 mg once daily. Based on clinical response and tolerability, the dosage may be increased to 36.3 mg orally once daily on Day 4 and further titrated to 54.5 mg orally once daily after Day 7 and to 72.6 mg orally once daily after an additional week. The maximum recommended daily dosage of EXXUA is 72.6 mg once daily.

Dosage Recommendations in Geriatric Patients

The recommended starting dosage of EXXUA in geriatric patients is 18.2 mg orally once daily. Based on clinical response and tolerability, the dosage may be increased to maximum recommended dosage of 36.3 mg orally once daily after Day 7.

Recommended Dosage in Patients with Renal Impairment

The recommended starting dosage of EXXUA in patients with creatinine clearance < 50 mL/min is 18.2 mg orally once daily. Based on clinical response and tolerability, the dosage may be increased to the maximum recommended dosage of 36.3 mg orally once daily after Day 7. The recommended dosage in patients with creatinine clearance 50 mL/min is the same as in patients with normal renal function.

Recommended Dosage in Patients with Hepatic Impairment

The recommended starting dose of EXXUA in patients with moderate (Child-Pugh B) hepatic impairment is 18.2 mg once daily. Based on clinical response and tolerability, the dosage may be increased to the maximum recommended dosage of 36.3 mg orally once daily after Day 7. EXXUA is contraindicated in patients with severe (Child-Pugh C) hepatic impairment. The recommended dosage in patients with mild (Child-Pugh A) hepatic impairment is the same as patients with normal hepatic function.

Dosage Modifications for Concomitant Use with CYP3A4 Inhibitors

Reduce the EXXUA dose by 50% when used concomitantly with a moderate CYP3A4 inhibitor. EXXUA is contraindicated in patients receiving strong CYP3A4 inhibitors.

Switching a Patient to or from a Monoamine Oxidase Inhibitor (MAOI) Antidepressant

At least 14 days must elapse between discontinuation of an MAOI intended to treat depression and initiation of therapy with EXXUA. Conversely, at least 14 days must be allowed after stopping EXXUA before starting an MAOI antidepressant.

CONTRAINDICATIONS

EXXUA is contraindicated in patients:

- with known hypersensitivity to gepirone or components of EXXUA.
- with prolonged QTc interval > 450 msec at baseline.
- with congenital long QT syndrome.
- receiving concomitant strong CYP3A4 inhibitors.
- with severe hepatic impairment.
- taking, or within 14 days of stopping, MAOIs due to the risk of serious and possibly fatal drug interactions, including hypertensive crisis and serotonin syndrome. Starting EXXUA in a patient treated with reversible MAOIs such as linezolid or intravenous methylene blue is also contraindicated.

WARNINGS AND PRECAUTIONS

Suicidal Thoughts and Behaviors in Adolescents and Young Adults

In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients, and 4,500 pediatric patients, the incidence of suicidal thoughts and behaviors in antidepressant-treated patients aged 24 years and younger was greater than in placebo-treated patients.

There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risk of suicidal thoughts and behaviors across the different indications, with the highest incidence in patients with MDD.

***EXXUA is not approved for use in pediatric patients.**

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy, and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing EXXUA, in patients whose depression is persistently

worse, or who are experiencing emergent suicidal thoughts or behaviors.

QT Prolongation

EXXUA prolongs the QTc interval.

- EXXUA is contraindicated in patients with congenital long QT syndrome and in patients with severe hepatic impairment or in patients receiving concomitant strong CYP3A4 inhibitors as they increase EXXUA plasma concentrations.
- Do not initiate EXXUA if QTc is > 450 msec at baseline.
- Correct electrolyte abnormalities prior to EXXUA initiation. In patients with electrolyte abnormalities, who are receiving diuretics or glucocorticoids, or have a history or hypokalemia or hypomagnesemia, also monitor electrolytes during dose titration and periodically during treatment with EXXUA.
- Perform an ECG prior to EXXUA initiation, during dosage titration, and periodically during treatment. Monitor patients with ECGs more frequently:
    - If EXXUA is used concomitantly with drugs known to prolong the QT interval.
    - In patients who develop QTc 450 msec during treatment with EXXUA. Do not escalate the EXXUA dosage if QTcF is > 450 msec.
    - In patients with a significant risk of developing torsade de pointes, including those with uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, uncontrolled hypertension, high degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism.
- Reduce the EXXUA dosage when used concomitantly with moderate CYP3A4 inhibitors, as they may increase EXXUA concentrations.

Serotonin Syndrome

Concomitant use of EXXUA with SSRIs or tricyclic antidepressants may cause serotonin syndrome, a potentially life-threatening condition with changes including altered mental status, hypertension, restlessness, myoclonus, hyperthermia, hyperreflexia, diaphoresis, shivering, and tremor. The concomitant use of EXXUA with MAOIs is contraindicated. In addition, do not initiate EXXUA in a patient being treated with MAOIs such as linezolid or intravenous methylene blue. If it is necessary to initiate treatment with an MAOI such as linezolid or intravenous methylene blue in a patient taking EXXUA discontinue EXXUA before initiating treatment with the MAOI.

If concomitant use of EXXUA with other serotonergic drugs is clinically warranted, inform patients of the increased risk for serotonin syndrome and monitor for symptoms. Discontinue EXXUA and/or concomitant serotonergic drug immediately if the above symptoms occur and initiate supportive symptomatic treatment.

Activation of Mania or Hypomania

Antidepressant treatment can precipitate a manic, mixed, or hypomanic manic episode. The

risk appears to be increased in patients with bipolar disorder or who have risk factors for bipolar disorder. Prior to initiating treatment with EXXUA, screen patients for a history of bipolar disorder and the presence of risk factors for bipolar disorder (e.g., family history of bipolar disorder, suicide, or depression). EXXUA is not approved for use in treating bipolar depression.

ADVERSE REACTIONS

Most common adverse reactions (incidence of 5% and at least twice incidence of placebo) were dizziness, nausea, insomnia, abdominal pain, and dyspepsia.

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Suicidal Thoughts and Behaviors in Adolescents and Young Adults
- QT Prolongation
- Serotonin Syndrome
- Activation of Mania or Hypomania

To report SUSPECTED ADVERSE REACTIONS, contact Aytu BioPharma at 1-855-298-8246 or http://www.exxua.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Pregnancy

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including EXXUA, during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Antidepressants at 1-866-961-2388 or visiting online at https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/.

Lactation

There is no data on the presence of gepirone in human milk, the effects on the breastfed infant, or the effects on milk production. Gepirone is present in rat milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk. There are reports of breastfed infants exposed to other serotonergic antidepressants experiencing

irritability, restlessness, excessive somnolence, decreased feeding, and weight loss. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EXXUA and any adverse effects on the breastfed infant from EXXUA or from the underlying maternal condition.

OVERDOSAGE

In clinical studies, cases of acute ingestions up to 454 mg (6.25 times the maximum recommended dose) of EXXUA alone or in combination with other drugs, were reported. Signs and symptoms reported with overdose of EXXUA at doses up to 454 mg included vomiting and transient incomplete bundle branch block; an unknown dose of EXXUA produced altered level of consciousness and a 60-second convulsion. **No specific antidotes for EXXUA are known. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.**

Please see Full Prescribing Information for EXXUA.

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. The Company believes that net income 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 to adjusted EBITDA.

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 press release, 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 are described in "Risk

Factors” in Part I, Item 1A of the Company’s 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.

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