SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AYTU BIOSCIENCE, INC

Form: 8-K

Date Filed: 2018-11-05

Corporate Issuer CIK: 1385818

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 2, 2018**

AYTU BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38247**	**47-0883144**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

373 Inverness Parkway, Suite 206
Englewood, CO 80112
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(720) 437-6580**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement

On November 2, 2018, Aytu BioScience, Inc. (the "Company"), entered into a License, Development, Manufacturing and Supply Agreement (the "Agreement") with TRIS Pharma, Inc. ("TRIS"). Pursuant to the Agreement, TRIS granted to the Company an exclusive license in the United States related to Tuzistra XR. In addition, TRIS has agreed to grant an exclusive license in the United States related to a complementary antitussive referred to as "CCP-08" (together with Tuzistra XR, the "Products") for which marketing approval has been sought by TRIS under a New Drug Application filed with the FDA. As consideration for the license granted, the Company made an upfront cash payment to TRIS and also issued to TRIS shares of Series D Convertible Preferred Stock. Additionally, the Company will pay TRIS milestone payments and certain royalty fees through the term for Tuzistra XR and CCP-08. The Agreement may be terminated by either the Company or TRIS on the occurrence of a material breach of the Agreement and will terminate according to its terms upon expiration of the final royalty payment obligation to TRIS.

The Company expects to file the Agreement as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending December 31, 2018, and intends to seek confidential treatment for certain terms and provisions of the Agreement. The foregoing description of the Agreement is qualified in its entirety by reference to the text of the Agreement, when filed.

Item 7.01 Regulation FD Disclosure

On November 5, 2018, the Company issued a press release announcing the Agreement. A copy of the press release is attached as Exhibit 99.1 and incorporated herein by reference.

In conjunction with the Company's entry into the Agreement and to support the Company's continued growth, the Company expects to issue a secured, non-convertible note (the "Armistice Note") to Armistice Capital for up to $5 million. The Company expects to close on the Armistice Note on or around November 13, 2018, subject to the Company's compliance with certain contractual obligations to certain existing security holders. The Armistice Note is expected to be secured by the future revenue stream from the Products, is expected to carry an annual interest rate of 8%, is not expected to be convertible, and is expected to have a three-year term with principal and interest payable at that time. It is expected that the Company will have the right to repay the Armistice Note at any time for any reason 30 days following the closing of the Armistice Note, at the sole discretion of the Company and for any reason and without penalty.

In accordance with General Instruction B.2 of Form 8-K, the information in the press release attached as Exhibit 99.1 hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall such information be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Cautionary Statement About Forward-Looking Statements

Statements contained herein that are not based upon current or historical fact are forward-looking in nature and constitute forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Such forward-looking statements reflect the company's expectations about its future operating results, performance, and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "upcoming," "plan," "target", "intend" and "expect" and similar expressions, as they relate to the Company, its subsidiaries, or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information currently available to the company and are subject to a number of risks, uncertainties, and other factors that could cause the company's actual results, performance, prospects, and opportunities to differ materially from those expressed in, or implied by, these forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements are qualified in their entirety by this cautionary statement and the Company's SEC filings. Please see the risks and uncertainties detailed in the "Forward-Looking Statements" and "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended June 30, 2018, and in other documents and reports the Company files from time to time with the SEC.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibit is being filed herewith:

Exhibit	Description
99.1	Press Release dated November 5, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AYTU BIOSCIENCE, INC.

Date: November 5, 2018

By: /s/ Joshua R. Disbrow
Joshua R. Disbrow
Chief Executive Officer

Aytu BioScience Enters $3 Billion Cough and Cold Market and Expands Primary Care Portfolio, with Exclusive U.S. Licensing of Revenue-Generating, FDA-Approved Antitussive Tuzistra® XR

Armistice Capital to Make $5M Strategic Investment in Conjunction with Tuzistra XR Acquisition to Accelerate Growth

ENGLEWOOD, CO / ACCESSWIRE / November 5, 2018 / Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty pharmaceutical company focused on global commercialization of novel products addressing significant medical needs, today announced the Company's entry into the $3 billion cough and cold market with an exclusive license of FDA-approved Tuzistra® XR from Tris Pharma.

Tuzistra XR is the only FDA-approved 12-hour codeine-based antitussive. Tuzistra XR is a prescription antitussive consisting of codeine polistirex and chlorpheniramine polistirex in an extended-release oral suspension.

Along with Tuzistra XR, the Company has licensed a complementary antitussive product pending FDA approval. Tuzistra XR and the complementary antitussive, upon FDA approval, will both be marketed in the United States by Aytu's direct sales force. Tuzistra XR is expected to generate revenue this year after launching promptly this cough and cold season. Tuzistra XR generated more than 40,000 prescriptions in 2017.

Tuzistra XR is a patented combination of codeine, an opiate agonist antitussive, and chlorpheniramine, a histamine-1 receptor antagonist, indicated for relief of cough and symptoms associated with upper respiratory allergies or a common cold in adults aged 18 years and older. Tuzistra XR is protected by two Orange Book-listed patents extending to 2031 and multiple pending patents.

According to MediMedia, the US cough cold prescription market is worth in excess of $3 billion at current brand pricing, with 30-35 million annual prescriptions. This market is dominated by short-acting treatments, which require dosing 4-6 times a day. Tuzistra XR was developed using Tris Pharma's liquid sustained release technology, LiquiXR®, which allows for extended drug delivery throughout a 12-hour dosing period.

As part of this transaction, the Company also plans to enter into a strategic financing with Armistice Capital, LLC ("Armistice"), an institutional healthcare investor with over $800M in assets under management. Under the terms of this financing, Armistice is expected to provide the company with up to $5 million in the form of a three-year note, secured by the Tuzistra revenue streams. This funding will further support the Company's growth and enable a rapid launch and integration of the Tuzistra portfolio in Aytu's current operations. Details of the financing will be provided upon its closing, which is expected to occur in seven business days.

Josh Disbrow, Chief Executive Officer of Aytu BioScience explained, “We are thrilled to be partnering with Tris Pharma in acquiring this license to Tuzistra XR and the complementary antitussive therapeutic pending approval. We believe these products align well with our primary care portfolio, and Tuzistra XR provides another attractive, revenue-generating therapeutic asset with clear clinical differentiation and patient benefits. We’re equally excited about the prospect of adding a complementary antitussive to the portfolio as that product gains approval. We thank the Tris Pharma team for entrusting Aytu to build these products into strong brands and look forward to a successful long-term relationship with Tris.”

Tris Pharma’s Founder and Chief Executive Officer, Ketan Mehta said, “The combination of all day, all night, cough/cold relief in a liquid form makes a great deal of sense. We are excited to continue to leverage our technology platform, LiquiXR, to improve patient care. Further, we are delighted to have Aytu BioScience as our partner.”

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any of the securities described herein, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. The securities described herein have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

About Aytu BioScience, Inc.

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on global commercialization of novel products addressing significant medical needs. The company currently markets Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”). Aytu recently acquired exclusive U.S. and Canadian rights to ZolpiMist™, an FDA-approved, commercial-stage prescription sleep aid indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Additionally, Aytu is developing MiOXSYS®, a novel, rapid semen analysis system with the potential to become a standard of care for the diagnosis and management of male infertility caused by oxidative stress. MiOXSYS is commercialized outside of the U.S. where it is a CE Marked, Health Canada cleared, Australian TGA approved, Mexican COFEPRAS approved product, and Aytu is planning U.S.-based clinical trials in pursuit of 510k de novo medical device clearance by the FDA. Aytu’s strategy is to continue building its portfolio of revenue-generating products, leveraging its focused commercial team and expertise to build leading brands within large, growing markets. For more information 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 presentation, 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. 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 relating to gaining market acceptance of our products including Tuzistra XR, obtaining reimbursement by third-party payors, the potential future commercialization of our product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results, of our ongoing and future clinical trials, the anticipated designs of our future clinical trials, anticipated future regulatory submissions and events, our anticipated future cash position and future events under our current and potential future collaboration. We also refer you to the risks described in ’‘Risk Factors’’ in Part I, Item 1A of the Company’s Annual Report on Form 10-K and in the other reports and documents we file with the Securities and Exchange Commission from time to time.

Contact for Investors:

James Carbonara
Hayden IR
(646)-755-7412
james@haydenir.com
SOURCE: Aytu BioScience, Inc.