SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AYTU BIOSCIENCE, INC

Form: 8-K

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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): **March 23, 2020**

AYTU BIOSCIENCE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38247**	**47-0883144**
(State or other jurisdictionof 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AYTU	The NASDAQ Stock Market LLC

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 8.01 Other Events

On March 23, 2020, Aytu BioScience, Inc. (the "Company"), reported that it has received confirmation from the U.S. Food and Drug Administration (FDA) that the company may begin distribution of its Coronavirus Disease 2019 ("COVID-2019") IgG/IgM Rapid Test throughout the United States. The COVID-19 IgG/IgM Rapid Test is intended for professional use and delivers results between 2 and 10 minutes at the point-of-care.

In addition, the Company expects delivery of its first shipment of 100,000 tests this week. The Company has been in discussions with healthcare distributors, healthcare institutions, medical practices, and government agencies and is working quickly to begin distribution into the U.S. healthcare supply chain.

Item 9.01 Financial Statements and Exhibits.

(d)The following exhibit is being filed herewith:

Exhibit	Description
99.1	Press Release dated March 23, 2020

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: March 23, 2020

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

Aytu BioScience Submits Notice of Commercialization to the FDA, Allowing for Company's Distribution of its 2-10 Minute COVID-19 IgG/IgM Point-of-Care Rapid Test

Commercial Distribution of First 100,000 Tests to Commence Upon Receipt of Inbound Product Shipment

ENGLEWOOD, CO / ACCESSWIRE / March 23, 2020 / Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that it has received confirmation from the U.S. Food and Drug Administration (FDA) that the company may begin distribution of its Coronavirus Disease 2019 ("COVID-2019") IgG/IgM Rapid Test throughout the United States. The COVID-19 IgG/IgM Rapid Test is intended for professional use and delivers results between 2 and 10 minutes at the point-of-care.

Aytu expects delivery of its first shipment of 100,000 tests this week. The initial product shipment is in transit from the manufacturer and, upon receipt, will undergo FDA and U.S. Customs and Border Protection (CBP) clearance processes. The test kits will then be repackaged to comply with FDA's labeling requirements under the most recent coronavirus guidance for serological test kit manufacturers. The Company has been in discussions with healthcare distributors, healthcare institutions, medical practices, and government agencies and is working rapidly to distribute the test into the U.S. healthcare supply chain.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "We are moving as quickly as we can to bring the COVID-19 IgG/IgM Rapid Test to the U.S. professional medical community. With product now in transit to our warehouse in Colorado we're optimistic that we can have test kits ready for sale in the very near term. In the two short weeks since signing our distribution agreement, we have ordered our first 100,000 tests and have received confirmation from FDA that we may begin distribution. We are optimistic that we're now just days away from placing these COVID-19 test kits into the hands of healthcare professionals."

The COVID-19 IgG/IgM Rapid Test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. This point-of-care test has been validated in a 126 patient clinical trial and is CE marked.

About Aytu BioScience, Inc.

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant patient needs. The company currently markets a portfolio of prescription products addressing large primary care and pediatric markets. The primary care portfolio includes (i) Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"), (ii) ZolpiMist™, the only FDA-approved oral spray prescription sleep aid, and (iii) Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup. The pediatric portfolio includes (i) AcipHex® Sprinkle™, a granule formulation of rabeprazole sodium, a commonly prescribed proton pump inhibitor; (ii) Cefaclor, a second-generation cephalosporin antibiotic suspension; (iii) Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions; and (iv) Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various for infants and children with fluoride deficiency. Aytu recently acquired exclusive U.S. distribution rights to the COVID-19 IgG/IgM Rapid Test. This coronavirus test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. This point-of-care test has been validated in a 113 patient clinical trial and has received CE marking.

Aytu recently acquired Innovus Pharmaceuticals, a specialty pharmaceutical company commercializing, licensing and developing safe and effective consumer healthcare products designed to improve men's and women's health and vitality. Innovus commercializes over thirty-five consumer health products competing in large healthcare categories including diabetes, men's health, sexual wellness and respiratory health. The Innovus product portfolio is commercialized through direct-to-consumer marketing channels utilizing the company's proprietary Beyond Human® marketing and sales platform.

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 therapeutic markets. For more information visit aytubio.com and visit innovuspharma.com to learn about the company's consumer healthcare products.

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 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: market and other conditions, the completion of the registered direct offering, the satisfaction of customary closing conditions related to the registered direct offering and the intended use of net proceeds from the registered direct offering, the regulatory and commercial risks associated with introducing the COVID-19 Rapid Test, effects of the business combination of Aytu and the Commercial Portfolio and the recently completed merger ("Merger") with Innovus Pharmaceuticals, including the combined company's future financial condition, results of operations, strategy and plans, the ability of the combined company to realize anticipated synergies in the timeframe expected or at all, changes in capital markets and the ability of the combined company to finance operations in the manner expected, the diversion of management time on Merger-related issues and integration of the Commercial Portfolio, the ultimate timing, outcome and results of integrating the operations the Commercial Portfolio and Innovus with Aytu's existing operations, risks relating to gaining market acceptance of our products, obtaining or maintaining reimbursement by third-party payors for our prescription products, 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 Media and Investors:

James Carbonara
Hayden IR
(646) 755-7412
james@haydenir.com

Contact for COVID-19 IgG/IgM Rapid Test-Related Inquiries:

COVID-19@aytubio.com