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): June 27**, 2020**

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))

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 7.01 Regulation FD Disclosure.

On June 27, 2020, Aytu BioScience, Inc. (the “Company”) and Biolidics, Limited (“Biolidics”) signed a letter of intent to, among other things, document the parties’ mutual intention to enter into a joint development agreement (the “Joint Development Agreement”) in order to advance the development of and, if successful, commercialize a new SARS-CoV-2 diagnostic test (the "Proposed Collaboration"). The Company and Biolidics are in the process of negotiating the definitive terms of this Proposed Collaboration. The Company and Biolidics believe a next generation SARS-CoV-2 test may address an important clinical need as the 2019 Novel Coronavirus (“SARS-CoV-2 coronavirus” or “COVID-19”) health crisis continues to unfold and the needs associated with patient testing continue to evolve. Stockholders are reminded that there can be no assurance the Company will enter into a Joint Development Agreement with Biolidics for the Proposed Collaboration or that a new SARS-CoV-2 diagnostic test will be successfully developed. The Company will make the appropriate announcement(s) if and when there are further material developments relating to the Proposed Collaboration.

As previously announced, the Company also has a distribution agreement in place with L.B Resources, Limited (L.B. Resources) and is sourcing an FDA Emergency Use Authorized SARS-CoV-2 IgG/IgM antibody test kits (“Orient Gene Test Kit(s)”) manufactured by Zhejiang Orient Gene Biotech, Limited (“Orient Gene”). The Orient Gene Test Kits received Emergency Use Authorization (“EUA) from the U.S. Food and Drug Administration (“FDA”) on May 29, 2020 following the completion of the FDA’s commissioning of an independent validation, which was conducted by the National Cancer Institute. This independent laboratory evaluation demonstrated high sensitivity and specificity of the test. Virtually all antibody test kits in the Company’s warehouse and those tests that have been sold to date have been sourced from Orient Gene. Through its relationship with L.B. Resources in sourcing the Orient Gene Test Kits, the Company believes it has access to adequate supply of these FDA EUA Orient Gene Test Kits now and expects to have supply as needed in the future.

Accordingly, and in connection with the planned Joint Development Agreement, the Company and Biolidics have mutually agreed to terminate their distribution agreement with effect from June 27, 2020. Each party shall release the other party of all the obligations and duties under the Agreement, and all monies paid by the Company to Biolidics for inventory orders placed but not received will be returned. This termination does not materially affect the Company’s supply of test kits. Also, in connection with the planned Joint Development Agreement, Biolidics has begun the process to voluntarily withdraw its application to the US FDA for EUA pursuant to the FDA Serology Test Policy.

Forward-Looking Statement

This current report on Form 8-K 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: (i) whether negotiations between us and Biolidics will be successful and result in the entry into a Joint Development Agreement for the development of a new SARS-CoV-2 diagnostic test, (ii) the ability to successfully develop and commercialize a new SARS-CoV-2 diagnostic test even if we are able to enter into a Joint Development Agreement with Biolidics, market and consumer acceptance of any new SARS-CoV-2 diagnostic test developed if any, if we enter into a Joint Development Agreement with Biolidics, (iii) our ability to obtain FDA clearance for a new SARS-CoV-2 diagnostic test if it is developed, (iv) our ability to successfully market and sell any of our COVID-19 Rapid Test kits, whether supplied by L.B Resources or Biolidics (the “COVID-19 Rapid Test Kits”), as a result of increased scrutiny and media attention around the accuracy of serology tests in the detection of SARS-CoV-2 coronavirus, (v) the adequacy of our supply of COVID-19 Rapid Test Kits to meet future demand, or (vi) our ability to enforce our exclusive U.S. distribution agreement with Orient Gene and our ability to obtain future Orient Gene Test Kits from Orient Gene. We also refer you to the risks described in "Risk Factors" in Part I, Item 1A of our 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.

In accordance with General Instruction B.2 of Form 8-K, the information under this Item 7.01 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 of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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: June 29, 2020

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