

# **Aytu BioScience Announces First Commercial Shipment of its 2-10 Minute COVID-19 IgG/IgM Point-of-Care Rapid Test**

## ***First COVID-19 Rapid Tests Delivered to Denver First Responders***

**ENGLEWOOD, CO / April 3, 2020** / Aytu BioScience, Inc. (NASDAQ:AYTU), (the “Company”), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that it began shipping its Coronavirus Disease 2019 (“COVID-2019”) IgG/IgM Rapid Test to U.S. customers. Upon receipt of the initial 100,000 tests, the company completed product relabeling to ensure compliance with FDA guidance on COVID-19 serology test kits.

The Company has received orders for the COVID-19 IgG/IgM Rapid Test from a broad range of healthcare customers including large medical centers, municipalities, first responders, medical practices, and other healthcare customers. The Company expects to have all customer backorders filled in the coming days.

The Company’s first 2,750 COVID-19 Rapid Tests have been purchased by the Denver Police Department for use in screening Denver’s first responders. The test kits were delivered to Denver Chief of Police Paul Pazen and members of his leadership team at Aytu BioScience’s corporate headquarters on April 2, 2020.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, “Upon receipt of our initial product shipment on March 31<sup>st</sup>, we immediately went to work to prepare the test kits for commercial distribution. The Aytu team has worked very hard over the last two days to relabel all 100,000 tests, and we’re now shipping product to our customers across the country. Importantly, we are proud to be assisting our first responders here at home as we delivered over 2,000 tests to Denver Police Chief Pazen and his team. Our public safety personnel are doing outstanding work in our communities throughout this crisis, so we’re glad to be partnering with Denver’s first responders in this fight.”

Mr. Disbrow continued, “The demand for the COVID-19 IgG/IgM Rapid Test has been substantial, so we have increased our order size to 500,000 tests (20,000 kits) to provide a larger supply to healthcare professionals and first responders in need.”

The COVID-19 IgG/IgM Rapid Test is a serology test 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 in China and is CE marked.

The Company believes that serology tests are a potentially powerful tool for identifying anyone who has been infected, whether they had symptoms or not. Antibodies to

coronaviruses typically remain in humans for up to 90 days or more. The Company believes that serological testing is important in identifying the total number of people who have been infected with COVID-19. This type of testing could be particularly important for the immune surveillance of health care workers, first responders, government workers, and others whose infection risks could be heightened by working with COVID-19 infected individuals.

### **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](http://aytubio.com) and visit [innovuspharma.com](http://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 regulatory and commercial risks associated with introducing the COVID-19 Rapid Test, our ability to enforce the exclusivity provisions of the distribution agreement, the reliability of serological testing in detecting COVID-19, shipping delays and their impact on our ability to introduce the COVID-19 Rapid Test, the ability of the COVID-19 Rapid Test to accurately and reliably test for COVID-19, the manufacturer of the COVID-19 Rapid Test's ability to manufacture such testing kits on a high volume scale, manufacturing problems or delays related to the COVID-19 Rapid Test, our ability to satisfy any labelling conditions or other FDA or other regulatory conditions to sell the COVID-19 Rapid Test Kit, the demand or lack thereof for the COVID-19 Rapid Test Kit, our ability to obtain additional COVID-19 Rapid Tests to meet demand, our ability to secure additional tests if the manufacture of the COVID-19 Rapid Tests is unable to meet demand, the 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.

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