

Aytu BioScience Announces Global Agreement to Distribute Pinnacle IVD Corporation's 15-Minute COVID-19 Antigen Test

Pinnacle Plans to Scale U.S. Manufacturing Capacity to 25 Million Tests Per Month

Cost-Effective 15-Minute Rapid Antigen Test Demonstrates 100% Specificity for COVID-19 Detection When Compared with RT-PCR

ENGLEWOOD, CO / September 8, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company (the "Company") focused on commercializing novel products that address significant patient needs announced today that the Company has signed an agreement to distribute the Pinnacle Covid RAD Rapid Antigen Detection Test worldwide. The rapid antigen test, which delivers results in fifteen minutes, tests for the presence of the SARS-CoV-2 virus antigen via a nasopharyngeal sample and can be conducted without the use of laboratory equipment.

Pinnacle IVD Corporation plans to scale U.S. manufacturing capacity for the Covid RAD Rapid Antigen Detection Test to 25 million tests per month.

The Covid RAD Rapid Antigen Detection Test was developed by U.S.-based Pinnacle IVD Corporation, a leader in colon cancer screening and other in-vitro diagnostics. The Pinnacle Covid RAD Rapid Antigen Detection Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2 in nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider.

In a study of 162 patients the Covid RAD Rapid Antigen Detection Test demonstrated 100% specificity and 84.3% sensitivity when nasopharyngeal swab results were compared with RT-PCR. Positive predictive value of the test was 100%, and negative predictive value was 96.3% in the study. These results have been included in the company's Emergency Use Authorization submission to the U.S. Food and Drug Administration.

Product inquiries may be sent to COVID-19@aytubio.com. Additional information about the Covid RAD Rapid Antigen Detection Test can be found at **[aytuhealth.com](https://www.aytuhealth.com)**.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, stated, "We continue to find ways to help in the COVID-19 fight. This high-performing antigen test - that directly detects the presence of the COVID-19 virus antigen - requires no laboratory equipment and enables medical professionals to deploy large-scale testing in a rapid and simple-to-use format. Antigen testing has become a primary screening tool as we seek to decentralize testing and speed up turnaround times."

Mr. Disbrow continued, "In many instances patients are waiting multiple days to receive their

COVID test results, so having a simple, fifteen-minute test helps open up a key bottleneck in the testing process. We're pleased to be partnering with Pinnacle IVD Corporation and believe this test can help curtail the spread of COVID-19 as we begin to reopen the global economy."

Charlie Balentine, President of Pinnacle IVD Corporation, stated, "We are pleased to have Aytu BioScience as our distribution partner for the COVID RAD test. Pinnacle worked quickly to develop this test and is poised to scale manufacturing capacity substantially in order to meet the high demand for antigen tests. Through this partnership with Aytu we look forward to being a part of the solution in the fight against COVID-19."

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 also distributes a COVID-19 IgG/IgM rapid test. This antibody 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.

Aytu also operates a consumer health subsidiary, Innovus Pharmaceuticals, Inc. ("Innovus"), 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 Rx and consumer health 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.

About Pinnacle IVD Corporation

Pinnacle IVD Corporation manufactures and distributes *in vitro* diagnostic test kits for various disease states. In addition to the COVID RAD Rapid Antigen Detection test, Pinnacle IVD Corporation also manufactures the COVID NEO IgG/IgM antibody test, a 15 minute *in vitro* diagnostic test that requires one drop of blood from a finger stick, serum, plasma, or whole blood specimen. COVID NEO and COVID RAD can be used independently or together and were designed to be highly sensitive and specific at the point of care, without the need for additional laboratory equipment.

For more information visit the company's website at www.pblabs.com.

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: the regulatory and commercial risks associated with introducing the Pinnacle COVID RAD Rapid Antigen Detection Test (the "RAD Test"), the accuracy of the RAD Test as compared to other COVID-19 tests, market acceptance of the RAD Test, the ability to obtain FDA approval or authorization for the RAD Test, our ability to obtain sufficient RAD Tests to meet consumer demand, if any, Pinnacle's ability to scale up manufacturing to meet customer demand, if any, reputation risks if the RAD Test is not as effective as anticipated, and that the current regulatory environment continues to permit the sale of the RAD Test without FDA approval. 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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