# Aytu BioScience Announces Manufacture and Delivery of Healight(TM) Devices for Use in COVID-19 Clinical Study

Delivery of Investigational Endotracheal Ultraviolet-A Light Catheter Devices Enables Near-Term Initiation of Planned Clinical Studies in Severely III COVID-19 Patients

**ENGLEWOOD, CO / August 17, 2020 /** Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company (the "Company") focused on commercializing novel products that address significant patient needs, today announced the delivery of Healight™ investigational devices. The delivery of these pilot scale Healight devices, designed and developed by Sterling Medical Devices ("Sterling"), enables the initiation of COVID-19 investigational clinical studies, which are expected to begin in the near-term.

Since Aytu signed a master services agreement with Sterling in April for Healight, the Company, Sterling, and its collaborators have sourced Healight device components and finalized design of the investigational devices for use in upcoming clinical studies.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "A significant amount of work has gone into the development of the Healight investigational device, and we thank all of our collaborators for their efforts. We are looking forward to taking the next steps and advancing Healight as quickly as possible. As the COVID-19 pandemic continues, the investigation and development of novel potential therapies remains a high priority for numerous companies, and Aytu is proud to be part of this important effort. If Healight demonstrates safety and effectiveness in upcoming, planned studies, we are hopeful it can become an important tool in the COVID-19 fight."

The Healight technology platform employs proprietary methods of administering intermittent ultraviolet (UV) A light via a novel respiratory tract device. Pre-clinical findings indicate the technology's significant impact on reducing a wide range of viral and bacterial loads, including the coronavirus HCoV-229E. Recently published pre-clinical data have been the basis of discussions with the FDA for a path to enable human use for the potential treatment of SARS-CoV-2 in intubated patients in the intensive care unit (ICU). Beyond the initial pursuit of a potential SARS-CoV-2 ICU indication, additional experimental studies of mixed infection suggest broader potential clinical applications for the technology across a range of viral and bacterial pathogens. This may include nosocomial bacteria implicated in ventilator-associated pneumonia (VAP).

### **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 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.

Aytu also operates a subsidiary focused on consumer health, 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

# **About Sterling Medical Devices**

Founded in 1998, Sterling Medical Devices (SMD), specializes in the product design and engineering of medical devices for the healthcare industry. Dedicated to resolving their clients' medical device design and engineering challenges, SMD addresses the whole development process, including, product design and human factors, systems, software, electronics, mechanical, quality, compliance, and global regulatory submissions. The company utilizes the latest tools and technology to streamline the engineering process to speed regulatory registrations, clearances, and/or approvals of Class I, II, and III devices. To date, the company has spearheaded the production of over 1,100 projects for more than 300 clients. SMD is internationally recognized and is FDA QSR 21 CFR Part 820 and Part 11 compliant, ISO 13485 registered, and IEC 62304, ISO 14971, IEC 60601, and IEC 62366

compliant. For more information, please visit www.sterlingmedicaldevices.com or call 201.227.7569 x2.

## **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, the effectiveness of the COVID-19 rapid rest, market acceptance of the National Cancer Institute or other independently conducted studies' testing results, the regulatory, clinical, manufacturing, and commercial risks associated with the investigational Healight device, effects of the business combination of Aytu and the Commercial Portfolio and the 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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