



Statera Biopharma and Lay Sciences Inc. Announce Intent to Enter Strategic Partnership to License the Manufacturing Rights to Certain Lay Sciences IgY Products

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Statera expects to acquire option to license Lay Sciences products for respiratory & gastrointestinal disorders

FORT COLLINS, Colo., May 13, 2022 (GLOBE NEWSWIRE) -- [Statera Biopharma](#) (Nasdaq: STAB) (the "Company"), a biopharmaceutical company creating next-generation immune therapies that focus on immune restoration and homeostasis, announced today that the Company intends to enter into a non-binding term sheet with respect to a strategic partnership with [Lay Sciences, Inc.](#) ("Lay Sciences"), a development and commercialization company of innovative solutions, to license worldwide manufacturing rights to certain Lay Sciences' IgY products containing avian antibodies as an active ingredient.

"The strategic partnership with Lay Sciences has the potential to produce near term revenue," said Michael K. Handley, President and Chief Executive Officer of Statera Biopharma. "The agreement allows Statera the right to supply the products for the existing approved markets. Statera also receives the right to license and commercialize current and future products for other indications."

Under the terms of the proposed agreement, Lay Sciences would receive an upfront payment comprised of both equity and cash and would also have the potential to earn royalties and milestones associated with the development of IgY in gastrointestinal and upper respiratory indications.

"Lay Sciences is pioneering a new generation of treatment and prophylaxis with proprietary formulations that protect IgY from gastric acids and proteases that allows for release of antibodies to targeted regions of the gut," said Satish Chandran, Chief Executive Officer, Lay Sciences, Inc. "We are excited to partner with Statera and believe oral polyclonal IgY antibodies allow for therapeutic intervention and for prophylaxis in a targeted manner that will enhance our ability to combat chronic, life-threatening diseases."

About Statera Biopharma

Statera Biopharma (formerly Cytocom, Inc.) is a clinical-stage biopharmaceutical company developing novel immunotherapies targeting autoimmune, neutropenia/anemia, emerging viruses and cancers based on a proprietary platform designed to rebalance the body's immune system and restore homeostasis. Statera has one of the largest platforms of toll-like receptor (TLR) agonists in the biopharmaceutical industry with TLR4 and TLR9 antagonists, and the TLR5 agonists, Entolimod and GP532. TLRs are a class of protein that plays a key role in the innate immune system. Statera is developing therapies designed to directly elicit within patients a robust and durable response of antigen-specific killer T-cells and antibodies, thereby activating essential immune defenses against autoimmune, inflammatory, infectious diseases, and cancers. Statera has clinical programs for Crohn's disease (STAT-201), hematology (Entolimod), pancreatic cancer (STAT-401) and COVID-19 (STAT-205) in addition to potential expansion into fibromyalgia and multiple sclerosis. To learn more about Statera Biopharma, please visit www.staterabiopharma.com.

About Lay Sciences, Inc.

Lay Sciences is a global leader in the development and commercialization of innovative, high value-added solutions to advance clinical performance, define standard of care and improve patient outcomes. Using patent pending and proprietary technologies owned by Lay Sciences or licensed from its partnering companies, ReaGene Biosciences Pvt. Ltd., Prodigy Biotech, Inc. and Kyntox Biotech India Pvt. Ltd., Lay Sciences is dedicated to developing and providing innovative products and devices focused on treating and preventing diseases of the GI tract. The company's flagship product, ImmunIgY™, is the first-in-class antibody-based oral product developed to address the pivotal step in viral entry and infection. For more information, please visit www.myimmunigy.com or www.laysciences.com

Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. All statements other than statements of current or historical fact contained in this press release, including statements regarding the Company's expected clinical development timeline for the Company's product candidates, future financial position, business strategy, new products, budgets, liquidity, cash flows, projected costs, regulatory approvals, the impact of any laws or regulations applicable to the company, and plans and objectives of management for future operations, are forward-looking statements. The words "anticipate," "believe," "continue," "should," "estimate," "expect," "intend," "may," "plan," "project," "will," and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements on the current expectations about future events held by management. While we believe these expectations are reasonable, such forward-looking statements are inherently subject to risks and uncertainties, many of which are beyond the Company's control. The company's actual future results may differ materially from those discussed here for various reasons. The Company discusses many of these risks under the heading "Risk Factors" in the proxy statement/prospectus filed with the SEC on June 10, 2021, as updated by the company's other filings with the SEC. Factors that may cause such differences include, but are not limited to, the outcome of any legal proceedings that have been or may be instituted against the company related to the merger between Cleveland BioLabs and Cytocom; unexpected costs, charges or expenses resulting from the merger; the Company's need for additional financing to meet the Company's business objectives; the Company's history of operating losses; the Company's ability to successfully develop, obtain regulatory approval for, and commercialize the Company's products in a timely manner; the Company's plans to research, develop and commercialize the Company's product candidates; the Company's ability to attract collaborators with development, regulatory and commercialization expertise; the Company's plans and expectations with respect to future clinical trials and commercial scale-up activities; the Company's reliance on third-party manufacturers of the Company's product candidates; the size and growth potential of the markets for the Company's product candidates, and the Company's ability to serve those markets; the rate and degree of market acceptance of the Company's product candidates; regulatory requirements and developments in the United States, the European Union and foreign countries; the performance of the Company's third-party suppliers and manufacturers; the success of competing therapies that are or may become available; the Company's ability to attract and retain key scientific or management personnel; the Company's historical reliance on government funding for a significant portion of the

Company's operating costs and expenses; government contracting processes and requirements; the exercise of significant influence over the Company's company by the Company's largest individual stockholder; the impact of the novel coronavirus ("COVID-19") pandemic on the Company's business, operations and clinical development; the geopolitical relationship between the United States and the Russian Federation as well as general business, legal, financial and other conditions within the Russian Federation; the Company's ability to obtain and maintain intellectual property protection for the Company's product candidates; the Company's potential vulnerability to cybersecurity breaches; and other factors discussed in the Company's SEC filings, including the Company's Annual Report on Form 10-K for the year ended December 31, 2020 and the risk factors discussed under the heading "Risk Factors" in the proxy statement/prospectus the company filed in connection with the merger on June 10, 2021.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. The forward-looking statements included in this press release are made only as of the date hereof. We do not undertake any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments.

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