



Orchestra BioMed™ Enhances Management Team with Appointment of Regulatory Affairs and Combination Product Expert Bob Laughner as Vice President, Regulatory Affairs

April 28, 2020

New Hope, PA - Orchestra BioMed, Inc. ("Orchestra BioMed" or the "Company"), a biomedical innovation company developing transformative therapeutic products for large unmet needs in procedure-based medicine, today announced the appointment of Bob Laughner, an expert in global regulatory affairs for combination products, as Vice President, Regulatory Affairs. Mr. Laughner will play a lead role in advancing Orchestra BioMed's Virtue® Sirolimus AngiInfusion™ Balloon (SAB) through global regulatory approvals.

"Bob has successfully spearheaded combination product development and regulatory efforts for a number of global medical device and biopharmaceutical companies, where he ultimately secured approvals and implemented life-cycle management strategies for their respective technologies," said Darren R. Sherman, president, chief operating officer and co-founder of Orchestra BioMed. "We welcome Bob to our leadership team and look forward to his guidance as we work with our partner Terumo to advance Virtue SAB for the treatment of artery disease. We believe that Bob will also add value in advancing BackBeat CNT™ and other pipeline product candidates based on SirolimusEFR™, our extended focal release sirolimus formulation used in Virtue SAB."

Mr. Laughner brings over a decade of leadership experience in combination product development and successful implementation of regulatory strategies for global medical device and biopharmaceutical companies. Before joining Orchestra BioMed, he served as the Regulatory Director, Medical Device and Combination Products at AstraZeneca, where he drove combination product regulatory strategies across the product portfolio. In this role, Mr. Laughner managed combination product regulatory submissions and meetings with the FDA and other global regulatory agencies, while also evaluating new technologies and implementing guidelines for their development, regulatory approval and life-cycle management. Prior to that, Mr. Laughner served as the Associate Director, Combination Products at MedImmune, an AstraZeneca company, where he developed regulatory strategies and submissions for combination products in their biologic portfolio and developed strategies to evaluate the safety and effectiveness of drug delivery systems, including novel and wearable technologies. Prior to MedImmune, Mr. Laughner was a regulatory scientist at Cook Medical, where he provided regulatory and scientific support in the development, testing, and regulatory approval for combination products and medical devices, including many novel technologies. Mr. Laughner has been involved in the development of international standards for drug delivery devices as an expert for various ISO committees, and is currently Co-Chair of the Association for the Advancement of Medical Instrumentation's committee on Devices for Administration of Medicinal Products and Catheters. Mr. Laughner holds an M.S. in pharmacology and a B.A. in biology from Indiana University-Bloomington and holds certification in regulatory affairs from the Regulatory Affairs Professional Society.

"I share Orchestra BioMed's commitment to providing high-impact solutions that address large unmet patient needs in procedure-based medicine. The Company's innovative therapies, Virtue SAB and BackBeat CNT, have the potential to significantly improve treatment of artery disease and hypertension, respectively," said Bob Laughner. "I'm delighted to be a part of the Orchestra BioMed team and look forward to advancing these important new therapies through the regulatory process."

About Orchestra BioMed™

Orchestra BioMed is a biomedical innovation company focused on developing transformative therapeutic products for large unmet needs in procedure-based medicine. The Company is led by a highly accomplished, multidisciplinary management team and board of directors with extensive experience in all phases of medical device development. Orchestra BioMed's partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products it develops. Orchestra BioMed was formed in 2018 by assembling a pipeline of multiple late-stage clinical product candidates originally developed by the Company's founding team. The Company's flagship product candidates are Virtue® Sirolimus AngiInfusion™ Balloon (SAB) for the treatment of artery disease, the leading cause of mortality, and BackBeat Cardiac Neuromodulation Therapy™ for the treatment of hypertension, the leading risk factor for death worldwide. Orchestra BioMed has a global strategic partnership with Terumo Corporation, one of the world's largest medical device companies, for development and commercialization of Virtue SAB. Together, the companies plan to initiate a U.S. pivotal trial for the use of Virtue SAB in the treatment of coronary in-stent restenosis in 2020 which will be the first in a series of pivotal trials aimed at achieving regulatory approvals in multiple indications worldwide. The Company has additional product candidates in its pipeline and plans to thoughtfully expand its product pipeline in the future through acquisitions, strategic collaborations, licensing, and organic development.

Forward-Looking Statements

Some of the statements made herein constitute forward-looking statements. These statements relate to future financial and other performance or anticipated plans and are identified by words such as "may," "will," "should," "expect," "could," "scheduled," "plan," "intend," "anticipate," "believe," "estimate," "potential," "propose" and "continue" or negative variants of such terms. These and similar forward-looking statements discuss the Company's future expectations and plans. The Company operates in a very competitive and rapidly changing environment. New risks emerge from time to time. Given these risks and uncertainties, the Company cautions against placing undue reliance on these forward-looking statements. These statements are only estimates of future performance. Actual performance or events may not meet such expectations or estimates and may, in fact, differ materially.

Although the Company believes that the expectations reflected in the forward-looking statements made herein are reasonable, the Company cannot and does not guarantee future results, levels of activity, performance, or achievements. Moreover, the Company does not assume any responsibility for the accuracy and completeness of such forward-looking statements in the future. The Company does not plan and, subject to applicable law,

undertakes no obligation to update any of the forward-looking statements made herein after the date hereof in order to conform such statements to actual results.

Investor Contact:

Bob Yedid
LifeSci Advisors
646-597-6989
Bob@lifesciadvisors.com

Media Contact:

Gloria Gasaatura
LifeSci Communications
646-970-4688
GGasaatura@lifescicomms.com