Vaxart Announces Creation of Manufacturing and Quality Advisory Board

September 21, 2021

Leaders in the Pharmaceutical Industry To Advise Vaxart As It Advances Its Manufacturing Capabilities

SOUTH SAN FRANCISCO, Calif., Sept. 21, 2021 /PRNewswire/ -- Vaxart, Inc. (NASDAQ: VXRT), today announced that it has formed a Manufacturing and Quality Advisory Board.

"We are very excited to be able to tap into the vast knowledge of this group of experts," said Andrei Floroiu, Vaxart's Chief Executive Officer.

"Their insights around state-of-the art manufacturing and quality processes will help us as we progress towards late stage development and commercialization of our vaccine portfolio."

The new advisory board convened its first meeting on August 21. Vaxart also announced last month that it created a Scientific and Clinical Advisory Board drawn from the fields of health care, vaccines and academic research to advise Vaxart as it develops its ground-breaking technology.

The six leaders joining Vaxart's COVID-19 Manufacturing and Quality Advisory Board are John Aunins, Ph.D.; John Carpenter, Ph.D.; Benjamin Del Tito, Ph.D.; Vijay Jethwa, Ph.D.; Robert Schiff, Ph.D.; and Clifford Siporin, Ph.D. Their biographies can be found below:

John Aunins, Ph.D.
Senior Advisor
Former Vice President & Chief Technology Officer
Seres Therapeutics
President
Janis Biologics
Massachusetts

John Aunins, Ph.D., is a 32-year veteran in the biotech field with deep experience in bioprocess development, manufacturing support and project leadership.

He led process and product development teams at Merck Research Laboratories for Vaqta®, Varivax®, Zostavax®, ProQuad®, Rotateq® and Gardasil®. The Vaqta and Gardasil process teams were awarded with ACS Industrial Biotechnology Awards for innovation, contribution to bioengineering and societal impact. More recently, he has been involved in developing a new class of live microbial biotherapeutics for treatment of disorders of the GI microbiome at Seres Therapeutics.

He is a Fellow of the American Institute for Medical and Biological Engineering, and an adjunct Full Professor at the Instituto de Tecnologia Quimica e Biologica (ITQB) in Oeiras, Portugal, and a member of the National Academy of Engineering. He is author of over 50 articles and book chapters and has chaired five international conferences in vaccines and bioprocess technology. John obtained his Ph.D. in Chemical Engineering from MIT in 1989 under Institute Professor Daniel I.C. Wang.

John Carpenter, Ph.D.
Professor
University of Colorado School of Pharmacy
Co-Founder and Co-Director
University of Colorado Center for Pharmaceutical Biotechnology
Colorado

John Carpenter, Ph.D., is Professor of Pharmaceutical Sciences at the University of Colorado School of Pharmacy, and a Co-Founder and Co-Director of the University of Colorado Center for Pharmaceutical Biotechnology.

His research interests include mechanisms for protein degradation and stabilization in pharmaceutical formulations, during bioprocessing and in delivery systems. He has worked for several years to define rational strategies for stabilizing proteins and vaccines during freeze-drying and storage in the dried solid.

He has published more than 300 peer-reviewed papers and is an inventor on more than 30 issued patents. He is Editor for Reviews and Commentaries for *Journal of Pharmaceutical Sciences*. He serves on the Editorial Advisory Boards for Pharmaceutical Research, The AAPS Journal, Journal of Pharmaceutical Sciences, Current Pharmaceutical Biotechnology, Molecular Pharmaceutics and BioPharm International. He has received several teaching awards and The Ebert Prize.

He is a Fellow of the American Association for Advancement of Science and the American Association of Pharmaceutical Scientists (AAPS) and has received the AAPS Research Achievement Award in Biotechnology. He also is the Organizer for the Colorado Protein Stability Conferences.

Benjamin Del Tito, Ph.D.
President
Del Tito Consulting, LLC
Senior Affiliate Consultant
Biologics Consulting
Virginia

Benjamin Del Tito, Ph.D., is currently a consultant to Vaxart and a Senior Affiliate Consultant at Biologics Consulting. He has more than twenty years of experience in both large pharmaceutical and small to mid-sized biotechnology companies specializing in a range of products from protein therapeutics to vaccines to diagnostics. His career has focused on the areas of analytical development, quality control, pre-clinical assay development and validation, quality assurance and regulatory affairs. He is knowledgeable in global drug development (Phase I-IV); IND, IMPD, NDA and BLA submissions; regulatory interactions; and regulatory inspections for both the U.S. and Europe. He has extensive experience in building teams of development and quality professionals for phases of drug development, including early development, clinical manufacturing, licensure and commercial manufacturing.

Del Tito was employed from October 2005 to 2014 at Auxilium Pharmaceuticals, where he oversaw the Quality Control, Quality Assurance and Regulatory Affairs departments. Prior to Auxilium, Dr. Del Tito served as Vice President, Analytical and QC Operations at Neose Technologies, Inc. Prior to Neose, Del Tito served as Senior Director, QC Operations at MedImmune Vaccines, Inc.

Del Tito earned a B.A. in Biology from Millersville University, an M.S. in Biochemistry from Western Kentucky University and a Ph.D. in Molecular Biology from Lehigh University. He is an Adjunct Faculty member at Georgia State University in Atlanta, Georgia.

Vijay Jethwa, Ph.D.
Senior Consultant
Biologics Consulting
North Carolina

Vijay Jethwa, Ph.D., is a senior consultant at Biologics Consulting. He has over 25 years of industry experience in the development, validation and routine performance of potency assays, cell-based bioassays and immunoassays for diagnostics, PK/PD studies, drug substance and drug product characterization, lot release and stability, as well as immunogenicity assessments.

Jethwa started up the new GMP Bioanalytical Laboratories at the Merck Vaccines Facility in Durham, North Carolina. His group developed and transferred analytical methods for the characterization and release of live virus vaccines. Prior to joining Merck, he was at Biogen Idec for over 12 years in various capacities, including leading all CMC activities related to biosimilar development and serving as the site head of the cGMP Bioassay, Microbiology and Virology QC Laboratories. He established GLP testing laboratories at Biogen, including laboratory design, equipment sourcing and validation, supporting antibody and PK/PD testing for various GLP/GCP studies.

Jethwa prepared and presented Quality sections for Regulatory advice meetings and has authored, reviewed and approved sections of several regulatory submissions (IND, IMPD, BLA, etc.).

Robert Schiff, Ph.D.
Founder & CEO
Schiff & Company, Inc.
New Jersey

Robert Schiff, Ph.D., is founder and CEO of Schiff & Company, Inc., a regulatory affairs, compliance and clinical research organization established in 1982.

Prior to founding Schiff & Company, Schiff served with a number of companies, including the Warner Lambert Company as Group Vice President, Diagnostics Research and Development; Hoffmann-La Roche, Inc. as Director, Department of Diagnostic Research and Product Development; the J. T. Baker Chemical Company (Richardson-Vicks) as Director of Research & Development, Diagnostics Division; and the Hyland Division Travenol Laboratories (Baxter) as Manager, Serology Research. He also served as Assistant Professor in the Department of Anatomy at Tufts University Schools of Medicine and Dental Medicine. Dr. Schiff has authored over 50 publications and holds several patents on medical products.

Schiff received his B.S. from the City College of New York, M.S. from Iowa State University and Ph.D. from the University of California at Davis. He was a member of the Graduate Business faculty at Farleigh Dickinson University, and he also lectures on International Business and Compliance with FDA rules and regulations.

Schiff serves on the boards of several companies, is a member of the Editorial Board of the Regulatory Affairs Professional Society, is a Fellow of the Regulatory Affairs Professional Society and is listed in Marquis' Who's Who in America, Who's Who in the World, Who's Who in the East, Who's Who in Science & Engineering, and American Men of Science.

Clifford Siporin, Ph.D.
Founder
Greystone Pharmaceutical Consulting, Inc.
Florida

Clifford Siporin, Ph.D., is the founder of Greystone Pharmaceutical Consulting, Inc., a full service CRO with expertise including contract project management and site monitoring, statistics, manufacturing, IRB, Sponsor, IRB and site auditing, medical and scientific writing, and regulatory affairs (FDA) and product safety issues. Siporin has over 30 years of experience and has accomplishments in all areas of drug development, including significant experience in drug substance and drug product issues as they relate to manufacturing and control, pre-clinical and clinical studies and regulatory parameters related to drug approval, manufacturing, labeling, marketing and distribution.

Previously, he served as Vice President of Drug Development at G.D. Searle and Co., where he was directly responsible for all development phases for in-licensed compounds, line extensions and new dosage forms. He also served in various senior level positions at Warner Lambert Company/Parke Davis. This included responsibility for consolidating all phases of drug development for anti-infective drugs in the U.S. and worldwide. Siporin also served with distinction in several senior-level positions at Pfizer.

Siporin completed his doctorate in Microbiology from the University of Dayton.

About Vaxart

Vaxart is a clinical-stage biotechnology company developing a range of oral vaccines based on its proprietary delivery platform called VAAST™. Vaxart vaccines are designed to be administered using tablets that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary tablet vaccine delivery platform is suitable to deliver vaccines, positioning the company to develop oral versions of currently marketed vaccines and to design vaccines for new indications. Vaxart's development programs currently include tablet vaccines designed to protect against coronavirus, norovirus, seasonal influenza, and respiratory syncytial virus (RSV), as well as a therapeutic vaccine for human papillomavirus (HPV), Vaxart's first immuno-oncology indication. Vaxart has filed broad domestic and international patent applications covering its proprietary technology and creations for oral vaccination using adenovirus and TLR3 agonists.

Note Regarding Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Vaxart's strategy, prospects, plans and objectives, results from pre-clinical and clinical trials, commercialization agreements and licenses, and beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "should," "believe," "could," "potential," "will," "expected," "plan," and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to the Advisory Board's impact on Vaxart's business and future outlook; Vaxart's expectations regarding clinical results and trial data; and Vaxart's expectations with respect to the effectiveness of its product candidates. Vaxart may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in the forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations, and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Vaxart makes, including uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates, and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; decisions by regulatory authorities impacting labeling, manufacturing processes, and safety that could affect the availability or commercial potential of any product candidate, including the possibility that Vaxart's product candidates may not be approved by the FDA or non-U.S. regulatory authorities; that, even if approved by the FDA or non-U.S. regulatory authorities, Vaxart's product candidates may not achieve broad market acceptance; that a Vaxart collaborator may not attain development and commercial milestones; that Vaxart or its partners may experience manufacturing issues and delays due to events within, or outside of, Vaxart's or its partners' control; difficulties in production, particularly in scaling up initial production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations; that Vaxart may not be able to obtain, maintain, and enforce necessary patent and other intellectual property protection; that Vaxart's capital resources may be inadequate; Vaxart's ability to resolve pending legal matters; Vaxart's ability to obtain sufficient capital to fund its operations on terms acceptable to Vaxart, if at all; the impact of government healthcare proposals and policies; competitive factors; and other risks described in the "Risk Factors" sections of Vaxart's Quarterly and Annual Reports filed with the SEC. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

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