Novavax and Catalent Biologics Enter Strategic Partnership: Allowing Catalent Biologics to Expand Gene Therapy Footprint with Acquisition of Novavax' Manufacturing Assets and Capabilities

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GAITHERSBURG, Md., June 27, 2019 (GLOBE NEWSWIRE) -- Novavax, Inc. (NASDAQ: NVAX), a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases, and Catalent Biologics' Paragon Gene Therapy unit, the leading viral vector development and manufacturing partner for gene therapies, today announced an arrangement under which Paragon Gene Therapy will assume the leases to two Novavax product development and manufacturing facilities, giving it immediate access to state-of-the-art manufacturing equipment, people and space to accelerate the growth of its gene therapy development and manufacturing business.

This arrangement significantly reduces Novavax' operating costs and provides a cash payment at closing of approximately $18 million. This cost savings and cash infusion allow Novavax to focus on advancing NanoFlu™ and ResVax™ through the next phases of clinical development and regulatory review.

Under the terms of the agreement, Paragon Gene Therapy will purchase from Novavax all of the related manufacturing equipment and facility assets; in addition, over 100 of Novavax' highly qualified manufacturing and quality employees will transfer to Paragon. Concurrently, Novavax will be entering into a long-term arrangement with Paragon to provide process development and manufacturing services for specified Novavax programs. The transactions are expected to close in July 2019.

"This alliance is a true win-win-win for Paragon, Novavax and our employees," said Stanley C. Erck, President and Chief Executive Officer of Novavax. "This mutually beneficial transaction allows Paragon to quickly support the growth of its gene therapy development and manufacturing business and simultaneously offers Novavax a strategic and cost-effective approach to addressing its manufacturing needs into the future."

Most Novavax employees at the two sites will transfer to Paragon and will continue to provide process and analytical development and, potentially, manufacture GMP materials for Novavax' clinical trial supplies for NanoFlu and ResVax, among other new projects. These employees will also provide continuity and support of Novavax' biologics license applications and post-licensure activities. Over the longer term, Paragon will be available to manufacture commercial quantities of the vaccines for Novavax.

"Novavax' advanced GMP development and manufacturing capabilities and, even more importantly, its very strong team of experts, will help accelerate our gene therapy manufacturing strategy and rapid growth," said Pete Buzy, President of Paragon's gene therapy business. "We welcome the new Novavax employees to the Paragon family and look forward to working closely together in this strategic collaboration to advance Novavax' innovative recombinant vaccines platform and expand our ability to serve the burgeoning gene and cell therapy market."

"This transaction allows Novavax to focus on discovery, clinical work, regulatory licensure and commercialization of innovative vaccines that may improve on existing approaches to prevent serious infectious diseases. We are happy to have found a great home for our valued team members transferring to Paragon where they can make a real difference in developing new gene therapies and we thank them for their important contributions to Novavax' progress" Mr. Erck said.

About Novavax

Novavax, Inc. (Nasdaq:NVAX), is a late-stage biotechnology company that drives improved health globally through the discovery, development, and commercialization of innovative vaccines to prevent serious infectious diseases. ResVax™, its RSV vaccine for infants via maternal immunization, is the only vaccine in a Phase 3 clinical program and is designed to prevent severe lower respiratory tract infection which is the second leading cause of death in children under one year of age worldwide. Novavax is also advancing NanoFlu™, its quadrivalent influenza nanoparticle vaccine, to address key factors that can lead to the poor effectiveness of currently approved flu vaccines. Novavax is a leading innovator of recombinant vaccines; its proprietary recombinant technology platform combines the power and speed of genetic engineering to efficiently produce a new class of highly immunogenic nanoparticles addressing urgent global health needs.

For more information, visit www.novavax.com and connect with us on Twitter and LinkedIn.

About Catalent Biologics

Catalent Biologics has 20+ years' experience in development, manufacturing, and analytical services for new biological entities, biosimilars, gene therapies and antibody-drug conjugates. Catalent has worked with 600+ mAbs and 80+ proteins, and more than 115 clinical trials and 11 marketed products have used GPEx® cell line engineering technology. A further 20 commercially-approved products have employed Catalent Biologics' capabilities through to aseptic fill/finish. Using advanced protein improvement technology and tailored solutions from DNA through to clinical and commercial supply, Catalent Biologics brings better biologic treatments to patients, faster. For more information, visit biologics.catalent.com.

Paragon Gene Therapy, a unit of Catalent Biologics, is an industry leader focusing on transformative technologies, including gene therapies (AAV), next-generation vaccines, and oncology immunotherapies. Paragon Gene Therapy has two facilities in Baltimore, Maryland dedicated to process development through commercial manufacturing of most scalable AAV platforms across multiple serotypes. Since 2016, Paragon Gene Therapy has completed over 100 clinical GMP AAV batches across 40 programs.

Forward-Looking Statements

Statements herein relating to the future of Novavax and the ongoing development of its vaccine and adjuvant products are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include those identified under the heading "Risk Factors" in the Novavax Annual Report on Form 10-K for the year ended December 31, 2018, and Quarterly Report on Form 10-Q for the period ended March 31, 2019, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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