



Emergent BioSolutions Signs Five-Year Agreement for Large-Scale Drug Substance Manufacturing for Johnson & Johnson's Lead COVID-19 Vaccine Candidate

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- Emergent will provide contract development and manufacturing services beginning in 2021 to produce drug substance at large scale for commercial manufacturing with first two years valued at approximately \$480 million
- For the remaining three years beginning in 2023, Emergent will provide a flexible capacity deployment model to support annual dose requirements

GAITHERSBURG, Md., July 06, 2020 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE:EBS) today announced a five-year manufacturing services agreement with Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for large-scale drug substance manufacturing for Johnson & Johnson's investigational SARS-CoV-2 vaccine, Ad26.COVID-S, recombinant based on the AdVac[®] technology. Emergent will provide contract development and manufacturing (CDMO) services to produce drug substance at large scale over five years, valued at approximately \$480 million for the first two years.

"We are proud to deploy our manufacturing strength to address the COVID-19 pandemic," said Robert G. Kramer Sr., president and chief executive officer of Emergent BioSolutions. "Advancing this collaboration is one of the ways we live our mission – to protect and enhance life."

Under the agreement, Emergent will begin providing large-scale drug substance manufacturing for Johnson & Johnson's adenovirus-based COVID-19 vaccine in 2021, upon successful completion of the activities under the previously executed Technology Transfer Agreement. For the subsequent years beginning 2023, Emergent will provide a flexible capacity deployment model to support additional drug substance batches annually.

"Over the next five years, we are committing our leading CDMO services to advance this important vaccine candidate," said Syed T. Husain, senior vice president and CDMO business unit head at Emergent. "We have the expertise and capabilities to meet the long-term needs of our customers and provide ongoing commercial manufacturing to benefit patients."

This long-term large-scale manufacturing agreement follows and is incremental to the [contract announced in April](#) for drug substance manufacturing technology transfer services and for reserving certain large-scale manufacturing capacity to pave the way for commercial drug substance manufacturing for the COVID-19 vaccine candidate.

Activities will be performed at Emergent's Baltimore Bayview facility, a designated Center for Innovation in Advanced Development and Manufacturing (CIADM) by the U.S. Department of Health and Human Services (HHS), designed for rapid manufacturing of large quantities of vaccines and treatments during public health emergencies.

Emergent's Bayview facility has unique capabilities across four independent suites to produce at clinical scale to get candidates rapidly into the clinic, while at the same time scaling up to enable large-scale manufacturing to up to 4000L to prepare for production of commercial volumes to meet customer demand. The CIADM has the capacity to produce tens to hundreds of millions of doses of vaccine on an annual basis, based upon the platform technology being used.

Financial Considerations

The company will provide an update to its 2020 financial outlook incorporating expectations related to this agreement and any other relevant information when it reports its second quarter financial results.

About Emergent BioSolutions

Emergent BioSolutions is a global life sciences company whose mission is to protect and enhance life. Through our specialty products and contract development and manufacturing services, we are dedicated to providing solutions that address public health threats. Through social responsibility, we aim to build healthier and safer communities. We aspire to deliver peace of mind to our patients and customers so they can focus on what's most important in their lives. In working together, we envision protecting or enhancing 1 billion lives by 2030. For more information visit www.emergentbiosolutions.com. Find us on LinkedIn and follow us on Twitter @emergentbiosolu and Instagram @life_at_emergent.

Emergent's Response to COVID-19

Emergent BioSolutions is deploying its decades of experience in vaccine and hyperimmune development and manufacturing, as well as its molecule-to-market contract development and manufacturing (CDMO) services to provide comprehensive medical countermeasure solutions in response to the COVID-19 pandemic.

Using its established hyperimmune platforms, Emergent is developing two investigational plasma-based treatments - COVID-Human Immune Globulin (COVID-HIG) and COVID-Equine Immune Globulin (COVID-EIG). COVID-HIG is being developed as a human plasma-derived therapy candidate with \$14.5 million in HHS funding and will be evaluated in two studies of the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, for potential treatment of COVID-19 in severe hospitalized and high-risk patients. COVID-EIG is being developed as an equine plasma-derived therapy candidate for potential treatment of severe disease in humans. Both candidates are anticipated to be in Phase 2 clinical studies in 2020. These investigational products are not approved by the U.S. Food and Drug Administration and their safety and effectiveness have not been established.

Emergent is deploying its CDMO capabilities, capacities, and expertise to support the U.S. government's Operation Warp Speed to pave the way for innovators to advance COVID-19 programs. The company is working with four innovators to develop and manufacture COVID-19 vaccine candidates. For the COVID-19 vaccine response, Emergent's integrated CDMO network provides development services from its Gaithersburg facility, drug substance manufacturing at its Baltimore Bayview facility, and drug product manufacturing at its Baltimore Camden and Rockville facilities, all in

Maryland.

For 22 years Emergent has focused on advancing public health, and its multi-pronged approach to tackling COVID-19 demonstrates its commitment to its mission – to protect and enhance life.

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding our ability to produce viable COVID-19 vaccine candidates at the prescribed scale, meet annual dosage requirements in the anticipated timeline and pave the potential pathway to licensure and commercial manufacturing of these candidates, are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including the success of the planned development programs; the timing of and ability to obtain and maintain regulatory approvals for the product candidates; and our commercialization, marketing and manufacturing capabilities. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

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