

July 16, 2025



Oragenics, Inc. Announces U.S.-Based Drug Manufacturing Agreement to Support ONP-002 Clinical Development

SARASOTA, Fla., July 16, 2025 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a biotechnology company developing intranasal therapeutics for brain-related conditions, today announced it has entered into a manufacturing agreement with Sterling Pharma Solutions, an industry leading CDMO with multiple US-based development and manufacturing facilities. Oragenics has partnered with Sterling Pharma Solutions for the GMP production of its lead drug candidate, ONP-002, for the treatment of concussion.

This agreement is expected to ensure Good Manufacturing Practice (GMP)-compliant drug product supply ahead of the planned Phase IIb clinical trials which the Company expects to start next year. The collaboration marks an important milestone for Oragenics as it secures domestic production capabilities to support its upcoming clinical and regulatory efforts.

“We are excited to partner with Sterling’s facility in Cary, North Carolina, to support the production of ONP-002,” said Janet Huffman, Chief Executive Officer of Oragenics. “This partnership is a critical milestone in our path forward for Phase IIb clinical trials. This partnership reinforces our commitment to quality, efficiency, and U.S.-based innovation and we believe this step will help streamline our clinical development strategy.”

Sterling will produce ONP-002 under strict cGMP conditions for use in Oragenics’ planned Phase IIb trials, a proof-of-concept study which will evaluate early efficacy of ONP-002 in patients with mild traumatic brain injury (mTBI).

Chad Telgenhof, Chief Commercial Officer at Sterling Pharma Solutions, said: “We are pleased to be partnering with Oragenics for the GMP production of its lead molecule for clinical trials. Our scientific expertise in CNS therapies and our ability to meet critical timelines will support the continued path to market for this transformative drug candidate.”

This U.S.-based manufacturing agreement builds upon Oragenics’ broader strategy to develop scalable, accessible, and fast-acting treatments for neurological trauma, beginning with concussion, a condition that currently has no FDA-approved pharmacological therapies.

About Oragenics, Inc.

Oragenics is a biotechnology company focused on developing intranasal therapeutics for neurological disorders. Its lead candidate, ONP-002, is being developed for the treatment of mild traumatic brain injury (mTBI), commonly known as concussion. The Company’s intranasal delivery technology is designed to deliver fast, targeted, and non-invasive therapy

to the brain. For more information, please visit www.oragenics.com.

About Sterling Pharma Solutions

Sterling Pharma Solutions is a global contract development and manufacturing organization (CDMO) with more than 50 years' experience in providing small molecule API development and manufacturing services to the pharmaceutical industry, specializing in handling challenging chemistries. Sterling manages the most complex API challenges from proof-of-concept to commercial manufacture, as well as antibody-drug conjugate (ADC) research and development bioconjugation services.

Sterling has six facilities employing more than 1,350 people: its HQ in Dudley, Cramlington, UK and a site in Newcastle upon Tyne, UK; a European presence in Ringaskiddy, Co. Cork, Ireland; a dedicated bioconjugation and ADCs facility in Deeside, North Wales, UK; and two sites in the US, in Cary, North Carolina and Germantown, Wisconsin. Find out more at www.sterlingpharmasolutions.com.

Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on management's beliefs and assumptions and information currently available. The words "believe," "expect," "anticipate," "intend," "estimate," "project" and similar expressions that do not relate solely to historical matters identify forward-looking statements. Investors should be cautious in relying on forward-looking statements because they are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed in any such forward-looking statements. These factors include, but are not limited to those described in our Form 10-K and other filings with the U.S. Securities and Exchange Commission. All information set forth in this press release is as of the date hereof. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. We do not assume any obligation to publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future developments or otherwise, should circumstances change, except as otherwise required by law.

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Source: Oragenics