



Lifecore Biomedical Selected by Nirsum Labs to Provide CDMO Services Supporting Clinical Development of Innovative Opioid Use Disorder Treatment

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Development Services Span Tech Transfer, Process Assessment and Method Validation for Fill and Finish of NRS-033 for Planned Phase 2 Trial

Lifecore to Leverage Differentiated Capabilities and Knowledge in Fill and Finish to Support Nirsum's NIH-Funded NRS-033 Development Program

CHASKA, Minn., Dec. 19, 2024 (GLOBE NEWSWIRE) -- Lifecore Biomedical, Inc. (NASDAQ: [LECB](#)) ("Lifecore"), a fully integrated contract development and manufacturing organization ("CDMO"), today announced that it has been selected by Nirsum Laboratories, Inc. ("Nirsum") to provide CDMO services focused on supporting Nirsum's clinical development of its lead development candidate, NRS-033. The activities to be conducted under the agreement include the assessment and technology transfer of the fill and finish process for NRS-033. These assessments will rely upon Lifecore's differentiated expertise in the fill and finish of sterile injectable pharmaceutical products, potentially allowing Lifecore to create an overarching development and commercialization plan for the entire fill and finish process for NRS-033.

NRS-033 is a novel treatment for opioid use disorder (OUD) and alcohol use disorder (AUD). NRS-033, which is wholly owned and internally discovered by Nirsum, is currently entering Phase 2 clinical development. The newly signed agreement will position Lifecore to provide Nirsum with filled syringes for use in clinical development of NRS-033.

"With growing concerns about opioid and alcohol addiction in the U.S. and beyond, we're grateful for the opportunity to support Nirsum on this important and promising treatment. Our agreement will enable Lifecore to apply our experience with complex formulations to the assessment, enhancement and validation of the fill and finish process for NRS-033," said Paul Josephs, chief executive officer of Lifecore. "We are excited to add Nirsum to our growing list of customers and appreciate that their team has entrusted us to collaborate with them on these activities."

"We believe that opioid and alcohol use disorders are enormous unmet needs, each with just a few decades-old, FDA-approved treatment options available. We believe NRS-033 will be a key innovation, solving the critical problem of short therapeutic retention of available therapies that results in high relapse rates for abstinence-seeking patients with OUD and AUD. By improving therapeutic retention with NRS-033, Nirsum aims to give hope to the millions of Americans with OUD and AUD," said Nikej Shah, M.D., chief executive officer of Nirsum Labs. "We are excited to begin our work with Lifecore to potentially help bring our important therapy through further clinical development and commercialization."

About Lifecore Biomedical

Lifecore Biomedical, Inc. (Nasdaq: [LECB](#)) is a fully integrated contract development and manufacturing organization (CDMO) that offers highly differentiated capabilities in the development, fill and finish of sterile injectable pharmaceutical products in syringes, vials, and cartridges, including complex formulations. As a leading manufacturer of premium, injectable-grade hyaluronic acid, Lifecore brings more than 40 years of expertise as a partner for global and emerging biopharmaceutical and biotechnology companies across multiple therapeutic categories to bring their innovations to market. For more information about the company, visit Lifecore's website at www.lifecore.com.

About Nirsum Labs

Nirsum Laboratories, Inc. is a development stage biotechnology company committed to making addiction curable. Nirsum is developing NRS-033 in OUD and AUD, which are high unmet needs with pressing public health urgency. NRS-033's development is funded in part through a Cooperative Agreement with the United States National Institutes of Health (HEAL Initiative award [UH3DA048234](#) and [U01DA061643](#)). For more information about the company, visit Nirsum's website at www.nirsum.com.

Important Cautions Regarding Forward-Looking Statements

This press release contains forward-looking statements regarding future events and our future results that are subject to the safe harbor created under the Private Securities Litigation Reform Act of 1995 and other safe harbors under the Securities Act of 1933 and the Securities Exchange Act of 1934. Words such as "anticipate", "estimate", "expect", "project", "plan", "intend", "believe", "may", "might", "will", "should", "can have", "likely" and similar expressions are used to identify forward-looking statements. In addition, all statements regarding our anticipated future operating and financial expectations, customer opportunities and relationships, and potential market size or opportunities for customer products are forward-looking statements. All forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially, including such factors among others, as the company's ability to successfully enact its business strategies, including with respect to installation, capacity generation and its ability to attract demand for its services, and its ability expand its relationship with its existing customers or attract new customers; the scope or anticipated markets for any products to be manufactured by Lifecore, the ability for customers to obtain regulatory approvals on their anticipated timing, or at all, the nature of the competitive landscape for us or our customers, the impact of inflation on Lifecore's business and financial condition; changes in business conditions and general economic conditions both domestically and globally, including rising interest rates and fluctuation in foreign currency exchange rates; Lifecore's ability to access sufficient capital to fund its business strategies; and other risk factors set forth from time to time in Lifecore's SEC filings, including, but not limited to, the Annual Report on Form 10-K for the year ended May 26, 2024 (the "2024 10-K"). For additional information about factors that could cause actual results to differ materially from those described in the forward-looking statements, please refer to our filings with the Securities and Exchange Commission, including the risk factors contained in the 2024 10-K. Forward-looking statements represent management's current expectations as of the date hereof and are inherently uncertain. Except as required by law, we do not undertake any obligation to update forward-looking statements made by us to reflect subsequent events or circumstances.

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