

Khona Scientific & Benuvia Operations Sign LOI to Advance Biosynthetic Development of Controlled-Substance APIs

The engagement will explore the use of cellular fermentation to make key starting materials required for pharmaceutical manufacturing.

LONE TREE, CO, UNITED STATES, January 7, 2026 /EINPresswire.com/ -- Benuvia Operations, LLC ("Benuvia"), a U.S.-based pharmaceutical development and manufacturing company specializing in regulated and controlled-substance active pharmaceutical ingredients (APIs), today announced the signing of a Letter of Intent (LOI) with Khona Scientific Inc. ("Khona"), a synthetic biotechnology company specializing in the biosynthesis of complex natural compounds.

Under the LOI, the companies intend to collaborate on the evaluation and development of biosynthetic pathways for the commercial production of select controlled-substance APIs. The collaboration combines Benuvia's expertise in regulated pharmaceutical development, GMP manufacturing, and controlled-substance compliance with Khona's patented biosynthesis technology and precision fermentation capabilities.

Through this collaboration, the parties will assess scalable, compliant, and sustainable approaches to API production that utilize biosynthetically derived key starting materials. The goal is to support a more resilient and diversified pharmaceutical supply chain for customers domestically and internationally, while maintaining the highest standards of quality, regulatory compliance, and controlled-substance oversight.

"Benuvia brings strong experience in controlled-substance development, regulatory strategy, and GMP execution," said Paul Orlady, CEO of Khona Scientific. "This LOI establishes a framework to evaluate how our BiDS™ platform can be applied to the development of biosynthetic routes for APIs that require the highest levels of quality, control, and compliance."

"This Letter of Intent reflects Benuvia's continued focus on expanding compliant and scalable pathways for the development of highly regulated APIs," said Terry Novak, CEO of Benuvia Operations. "Khona's biosynthetic capabilities present a compelling opportunity to evaluate alternative starting-material strategies that may enhance supply-chain resilience while maintaining the stringent quality, regulatory, and controlled-substance requirements expected by our partners and regulators. We look forward to exploring how our respective strengths can be aligned through this collaboration."

Framework for Technical Evaluation and Future Collaboration

The LOI outlines a framework for technical collaboration, information exchange, and development evaluation activities, with any future definitive agreements subject to regulatory considerations and mutual alignment on technical, commercial, and compliance objectives. Any subsequent manufacturing or commercialization activities would be conducted in accordance with applicable DEA, FDA, and international regulatory requirements.

The collaboration framework was constructed with the support of Madrone Process Development, LLC, which assisted both organizations in aligning technical objectives, regulatory considerations, and development pathways. Madrone helped establish a structured approach for evaluating biosynthetic starting materials within regulated pharmaceutical manufacturing environments.

About Benuvia Operations, LLC

Benuvia Operations, LLC is a U.S.-based pharmaceutical development and manufacturing company specializing in regulated and controlled-substance APIs. The company provides end-to-end capabilities spanning process development, analytical services, regulatory support, and GMP manufacturing. Benuvia supports pharmaceutical and biotechnology partners developing complex small-molecule therapeutics, with particular expertise in cannabinoids, central nervous system (CNS) compounds, and other highly regulated molecules. Learn more at www.benuvia.com.

About Khona Scientific Inc.

Khona Scientific Inc. is a synthetic biology company enabling the biosynthetic production of complex natural compounds. Headquartered in Lone Tree, Colorado, with critical laboratory operations in Boulder, Colorado, Khona leverages its patented BiDS™ biosynthesis platform to integrate enzymatic pathways into cellular “assembly lines,” producing key starting materials for a range of commercial applications. Learn more at www.khonascientific.com.

About Madrone Process Development, LLC

Madrone Process Development, LLC is a Texas-based process development consultancy supporting pharmaceutical, nutraceutical, and food-sector companies in bridging the gap between unregulated and regulated environments. Madrone focuses on optimizing manufacturing processes while supporting regulatory alignment, technology transfer, and scale-up across diverse development and commercialization pathways.

Forward-Looking Statements

This press release may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “project,” “will,” and similar expressions may identify forward-looking statements. Actual results may differ materially due to risks and uncertainties beyond the companies’ control. These statements are based on

information currently available, and the companies assume no obligation to update such statements except as required by applicable law.

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