



Aclaris Therapeutics Announces Exclusive, Global License Agreement with Biosion, Inc., adding Potential Best-in-Class Biologics Assets to Pipeline

November 18, 2024

**- Enhances Aclaris' pipeline with complementary biologics portfolio -
- Expands leadership team with addition of seasoned biotech executives -
- Management to host conference call today at 8:30 AM ET -**

WAYNE, Pa., Nov. 18, 2024 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today announced that it has entered into an exclusive license agreement with Biosion, Inc. (Biosion) for worldwide rights (excluding Greater China) to BSI-045B, a potential best-in-class, clinical-stage, novel anti-TSLP monoclonal antibody, and BSI-502, a potential best-in-class, pre-clinical stage, novel bispecific antibody that is directed against both TSLP and IL4R.

"This transformative transaction, which marks the completion of our strategic review process, accelerates our evolution into becoming a leading immunology company with both small and large molecule drugs," said Dr. Neal Walker, Interim CEO and Chair of the Board of Directors of Aclaris. "Despite recent advances with anti-TSLP and anti-IL4R therapies, there remains substantial unmet need for more effective and convenient treatment options. BSI-045B's compelling Phase 2a proof-of-concept data in atopic dermatitis, together with BSI-502's dual-targeting approach, complement our existing ITK inhibitor portfolio, resulting in a pipeline of differentiated assets that targets multiple high-value indications. In addition, the proceeds from the private placement financing announced this morning bolsters our balance sheet and provides us with enhanced financial flexibility to support our strategic growth while maintaining our cash runway into 2028."

In a completed Phase 2a, single-arm, proof-of-concept trial in the United States in 22 patients with moderate to severe atopic dermatitis, BSI-045B was observed to have a pharmacodynamic, safety and efficacy profile that could position it as a potential best-in-class therapy. BSI-045B is also being advanced in multiple Phase 2 studies in China by Biosion's regional partner, Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. (CTTQ), targeting both severe asthma and chronic rhinosinusitis with nasal polyps, accelerating the potential to show proof-of-concept across additional indications.

"This strategic transaction brings together Biosion's and Aclaris' innovative programs with Aclaris' development capabilities in immunology," said James Loerop, Chief Business Officer of Aclaris. "With our expanded portfolio, we have created a diversified pipeline of strategic opportunities across various immunologic and respiratory indications."

Biosion is a global biotechnology company that has built a pipeline of innovative biologics through its internally derived proprietary technologies. "Our proprietary antibody discovery platforms have enabled us to rapidly identify and optimize novel antibodies with exceptional potency and selectivity," said Mingjiu Chen, Ph.D., Founder and CEO of Biosion. "BSI-045B and BSI-502 demonstrate the power of our discovery capabilities in generating potential first and best-in-class therapeutics."

Expanded Leadership Team

Concurrent with the Biosion transaction, Aclaris has made two key additions to its leadership team:

- Hugh Davis, Ph.D., joins as President and Chief Operating Officer, bringing over 35 years of experience in biologics development, clinical pharmacology, and business development from leadership roles at Biosion, Frontage, GSK, and Johnson & Johnson.
- Steven Knapp, PharmD, joins as Executive Vice President, Head of Regulatory & Quality, with over 35 years of regulatory and quality experience from senior positions at Biosion, Antares, Valeant, and BMS.

"Having led key functions in the development of multiple approved biologics, I'm particularly excited about the potential of BSI-045B and BSI-502," said Hugh Davis, Ph.D. "I am thrilled to join the world class scientific leadership team at Aclaris. Together with their existing compelling portfolio, Aclaris is now well positioned to advance innovative small and large molecule programs through clinical development in the quest to deliver exceptional therapies for patients worldwide."

About BSI-045B

BSI-045B is a humanized anti-thymic stromal lymphopoietin (TSLP) monoclonal antibody that specifically binds to human TSLP, blocking its interaction with the receptor complex and disrupting signal transduction. This mechanism prevents immune cells targeted by TSLP from releasing proinflammatory cytokines. BSI-045B is currently in clinical development, and its safety and efficacy have not been evaluated by regulatory authorities.

About BSI-502

BSI-502 is a humanized anti-TSLP and anti-interleukin 4 receptor (IL4R) bispecific antibody that blocks both the upstream TSLP receptor signal transduction and downstream IL4R activation thereby inhibiting this central proinflammatory pathway. BSI-502 is currently in pre-clinical development, and its safety and efficacy have not been evaluated by regulatory authorities.

Conference Call and Webcast

Management will conduct a conference call at 8:30 AM ET today to discuss the Biosion transaction and a corporate update. To access the live webcast of the call and the accompanying slide presentation, please visit the "Events" page of the "Investors" section of Aclaris' website, www.aclaristx.com. The webcast will be archived for at least 30 days on the Aclaris website.

Advisors

Leerink Partners and Cantor acted as financial advisors to Aclaris in connection with the license transaction.

Cooley LLP acted as corporate counsel and DLA Piper LLP (US) acted as IP counsel to Aclaris.

Morgan, Lewis & Bockius acted as counsel to Biosion.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of drug candidates powered by a robust R&D engine exploring protein kinase regulation. For additional information, please visit www.aclaristx.com.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "anticipate," "believe," "expect," "intend," "may," "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include expectations regarding the potential benefits of the transaction with Biosion, Inc., including the potential benefits of the license agreement and the potential of BSI-045B and BSI-502 to be best-in-class therapies and the potential commercial opportunities for these drug candidates, as well as statements about the proceeds from the private placement and Aclaris' cash sufficiency and runway. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris' reliance on third parties over which it may not always have full control, Aclaris' ability to enter into strategic partnerships on commercially reasonable terms, the uncertainty regarding the macroeconomic environment and other risks and uncertainties that are described in the Risk Factors section of Aclaris' Annual Report on Form 10-K for the year ended December 31, 2023, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "SEC Filings" page of the "Investors" section of Aclaris' website at www.aclaristx.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to Aclaris as of the date of this release, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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