April 28, 2026

Cabaletta Bio and Cellares Announce 10-Year Commercial Supply Agreement for Rese-cel

Agreement facilitates flexible, scalable automated industrialized production of rese-cel for many thousands of patients per year at a cost per batch that is among the lowest in the industry

Initial translational data from the first two patients dosed with rese-cel manufactured by Cellares will be presented at the ASGCT conference in May

PHILADELPHIA and SOUTH SAN FRANCISCO, Calif., April 28, 2026 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a late-stage clinical biotechnology company focused on developing and launching curative targeted cell therapies designed specifically for patients with autoimmune diseases, and Cellares, the first Integrated Development and Manufacturing Organization (IDMO), today announced a commercial agreement to supply rese-cel (resecabtagene autoleucel) using Cellares' automated Cell Shuttle and through future implementation of Cellares' Cell Q platform. The Companies believe Cellares' automated platforms for manufacturing and QC release can enable flexible low-cost scaling of commercial production of rese-cel to thousands of batches per year with minimal capital investment.

Advancing a scalable manufacturing model for rese-cel in autoimmune diseases
"As we advance rese-cel to our planned BLA submission in myositis next year, we believe industrialized automated manufacturing has the potential to support our ability to expand patient access to thousands of patients per year with minimal capital investment," said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. "By providing a flexible, scalable, efficient, low-cost and globally transferable manufacturing supply platform for rese-cel, our partnership with Cellares expands our already robust supply chain and complements our current CDMO partners."

Cabaletta's manufacturing strategy for rese-cel is designed to provide redundancy, reliability, and scalability with cost efficiency and long-term price predictability. Cabaletta believes that Cellares' manufacturing technology platform within its IDMO Smart Factory network is well-positioned to support this strategy by enabling production for thousands of patients per year with minimal capital investment, reducing manufacturing costs through decreased labor requirements, improving costs and lead times associated with scheduling, and facilitating the potential for rapid global expansion, if successful.

Building toward long-term industrialized supply with manufacturing cost efficiency

"Autoimmune diseases require a manufacturing infrastructure that operates at an order of magnitude greater scale than traditional oncology CAR T programs. This 10-year commercial agreement with Cabaletta reflects confidence in the Cell Shuttle and Cell Q

platforms," said Fabian Gerlinghaus, Co-Founder and Chief Executive Officer, Cellares. "We look forward to continuing to support rese-cel's journey and helping potentially bring this treatment to many more patients."

Under the agreement, Cellares is expected to provide future commercial supply of rese-cel, pending FDA approval, using its automated manufacturing and quality control platforms. Under the terms of the agreement, Cabaletta has secured the ability to supply thousands of batches per year over a 10-year period with minimal capital investment. The companies anticipate the per batch cost to be among the lowest in the industry for autologous cell therapy production. The agreement builds on the Companies' existing collaboration since 2023 to automate and industrialize rese-cel and is intended to enhance Cabaletta's long-term manufacturing strategy, subject to continued technical progress, clinical results, regulatory alignment, and other implementation activities.

Upcoming Cabaletta milestones with Cellares-manufactured rese-cel
Cabaletta anticipates reporting the initial translational data with rese-cel manufactured by Cellares at the upcoming ASGCT conference in May 2026 to supplement the engineering run data that has previously been presented. This initial data is intended to confirm Cellares' capability, including supply chain logistics, for manufacturing and supplying rese-cel under current Good Manufacturing Practice (cGMP). Longer-term clinical data from patients receiving Cellares-manufactured rese-cel are expected in 2H26.

About rese-cel
Rese-cel (resecabtagene autoleucel) is an investigational, autologous CAR T cell therapy engineered with a fully human CD19 binder and a 4-1BB co-stimulatory domain, designed specifically for the treatment of autoimmune diseases. Administered as a single, weight-based infusion, rese-cel has demonstrated the ability to transiently, reliably and deeply deplete CD19-positive cells, with the goal of resetting the immune system and achieving durable clinical responses without the need for chronic therapy. Cabaletta is evaluating rese-cel in the RESET™ (REstoring SElf-Tolerance) clinical development program, which includes multiple ongoing company-sponsored trials across a broad range of autoimmune diseases in rheumatology, neurology and dermatology.

About Cabaletta Bio
Cabaletta Bio (Nasdaq: CABA) is a late-stage clinical biotechnology company focused on developing and launching curative targeted cell therapies designed specifically for patients with autoimmune diseases. The CABA™ platform encompasses two complementary strategies which aim to advance the discovery and development of engineered T cell therapies with the potential to become deep and durable, perhaps curative, treatments for a broad range of autoimmune diseases. The lead CARTA (Chimeric Antigen Receptor T cells for Autoimmunity) strategy is prioritizing the development of rese-cel, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy. Rese-cel is currently being evaluated in the RESET™ (REstoring SElf-Tolerance) clinical development program spanning multiple therapeutic areas, including rheumatology, neurology and dermatology. Cabaletta Bio's headquarters and labs are located in Philadelphia, PA. For more information, please visit www.cabalettabio.com and connect with us on LinkedIn.

About Cellares
Cellares is the first Integrated Development and Manufacturing Organization (IDMO), providing global cell therapy development and manufacturing services through an Industry

4.0 approach to the mass manufacture of the living drugs of the 21st century. The company enables drug sponsors to develop, scale, and commercialize cell therapies with the capacity, reliability, and economics required to meet total patient demand.

Cellares' fully automated platforms — Cell Shuttle™ for end-to-end cell therapy manufacturing and Cell Q™ for automated in-process and release quality control — are deployed across its network of IDMO Smart Factories worldwide. These technologies deliver industry-leading manufacturing economics, higher process success rates, and the ability to produce up to 10× more cell therapy batches than conventional CDMOs with comparable footprint and headcount, resulting in the lowest cost of manufacturing in the industry. The Cell Shuttle™ is the first cell therapy manufacturing platform to receive the FDA's Advanced Manufacturing Technology (AMT) designation, and has demonstrated a 100% automation success rate across more than a dozen automated processes.

Cellares has achieved key clinical validation milestones, including FDA clearance of IND Amendments enabling active clinical manufacturing on the Cell Shuttle™ platform, and the successful dosing of first patients in partner clinical trials — marking the platform's transition from development-stage technology to clinically validated manufacturing infrastructure. These milestones span multiple therapeutic areas and cell therapy modalities, including both oncology and autoimmune indications.

Headquartered in South San Francisco, California, Cellares operates its first commercial-scale IDMO Smart Factory in Bridgewater, New Jersey, with additional facilities in Leiden, the Netherlands, and Kashiwa City, Japan. Through its global manufacturing network, Cellares is purpose-built to support both clinical and commercial programs and to expand access to life-saving cell therapies worldwide. For more information, visit www.cellares.com and follow Cellares on LinkedIn.

Cabaletta Bio Forward-Looking Statements
This press release contains “forward-looking statements” of Cabaletta Bio within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, express or implied statements regarding: Cabaletta’s business plans and objectives as a whole; Cabaletta’s ability to realize its vision of launching curative targeted cell therapies designed specifically for patients with autoimmune diseases; Cabaletta’s ability to successfully complete research and further development and commercialization of its drug candidates in current or future indications, including the timing and results of Cabaletta’s clinical trials; Cabaletta’s expectations around the potential success and therapeutic benefits of rese-cel, including the potential of rese-cel to transiently, reliably and deeply deplete CD19-positive cells and to reset the immune system and achieve durable clinical responses without the need for chronic therapy; Cabaletta’s plans to submit a BLA for rese-cel in myositis in 2027 and obtain regulatory approval from the FDA and other regulatory authorities; Cabaletta’s plans to implement automated manufacturing of rese-cel with Cellares’ Cell Shuttle and future plans to implement Cellares’ Cell Q platform, including the timing of initial translational data and longer-term clinical data from patients receiving Cellares-manufactured rese-cel and its expectation that such platforms can enable scalability to produce rese-cel for thousands of patients per year with minimal capital investment; the anticipated benefits of the 10-year commercial supply agreement with Cellares, including expectations regarding manufacturing cost efficiency, competitive per batch cost, minimal capital investment, reduced labor requirements, improved scheduling flexibility, and the

potential for rapid global expansion, if successful; Cabaletta's expectations that Cellares' automated platforms will confirm manufacturing capability, including supply chain logistics, for manufacturing and supplying rese-cel under cGMP; and Cabaletta's plans to present initial translational data at the ASGCT conference in May 2026.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks related to regulatory filings and potential clearance; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of rese-cel; the risk that the results observed with the similarly-designed construct employed in academic publications, including due to the dosing regimen, are not indicative of the results we seek to achieve with rese-cel; risks that results from one program may not translate to results for another program; risks that modifications to trial design or approach may not have the intended benefits and that the trial design may need to be further modified; risks related to clinical trial site activation, delays in enrollment generally or enrollment rates that are lower than expected; delays related to assessment of clinical trial results; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to volatile market and economic conditions and public health crises; risks related to Cabaletta's ability to protect and maintain its intellectual property position; risks related to fostering and maintaining successful relationships with Cabaletta's collaboration and manufacturing partners; uncertainties related to the initiation and conduct of studies and other development requirements for its product candidates; the risk that any one or more of Cabaletta's product candidates will not be successfully developed and/or commercialized; and the risk that the initial or interim results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Cabaletta's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Cabaletta's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in Cabaletta's other subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Cabaletta undertakes no duty to update this information unless required by law.

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Source: Cabaletta Bio