

# Caladrius Biosciences and Cend Therapeutics Announce Definitive Merger Agreement

April 27, 2022

Combined company to be renamed Lisata Therapeutics upon transaction closing

Combination will create a financially sound Nasdaq-listed company with a diverse product development pipeline, strong existing partnerships and potential for future attractive partnerships

Lisata to combine development pipelines from both companies with an emphasis on advancing Cend's CendR Platform™ technology products in a range of solid tumor oncology indications

The merged company projects a number of potential value-creating data and business development milestones over the next 24 months

Caladrius to make an immediate investment of \$10 million in Cend in connection with a development collaboration agreement to maintain development momentum of the Cend pipeline

Caladrius Management will host a conference call today at 8:30 a.m. Eastern Time

BASKING RIDGE, N.J. and SAN DIEGO, April 27, 2022 (GLOBE NEWSWIRE) -- Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of innovative therapies designed to treat or reverse disease, and Cend Therapeutics, Inc. ("Cend"), a privately-held, clinical-stage biotechnology company focused on a novel approach to enable more effective treatments for solid tumor cancers, today announced that the companies have entered into a definitive merger agreement under which Cend will merge with a wholly owned subsidiary of Caladrius in an all-stock approximate "merger of equals" transaction unanimously approved by the Boards of Directors of each company. Following closing, the combined company will be renamed Lisata Therapeutics, Inc. ("Lisata") and will trade on the Nasdaq under the ticker symbol "LSTA". The merger is currently expected to close in the third quarter of 2022 subject to the approval of Caladrius and Cend stockholders as well as the satisfaction of certain other customary closing conditions and applicable approvals.

"As we communicated to our shareholders frequently over the last year, Caladrius has been seeking to identify and evaluate strategic development opportunities with the aim of consummating transactions that will deliver additional value to our shareholders beyond our current development pipeline. After a comprehensive review of available opportunities and with the aid of specialized consultants, we concluded that a merger with Cend provides Caladrius shareholders with an attractive opportunity for potential value creation by immediately expanding and diversifying our development portfolio," stated David J. Mazzo, PhD, President and CEO of Caladrius. "We believe that Cend's technology has the potential to deliver novel and improved treatments in patients with solid tumor cancers with a lead program in pancreatic cancer that already has shown great promise based on early clinical data. Furthermore, we expect that the complementarity of expertise, experience, and resources between the two companies will accelerate the development and availability to patients of this innovative and potentially important new cancer treatment."

"Our team has spent the past several years developing and advancing a novel and differentiated approach to treat solid tumor cancers. The CendR Platform™ provides a targeted tissue penetration capability which is designed to specifically enhance drug delivery to solid tumors. Cend's lead investigational drug, CEND-1, has been combined with other anticancer products to potentially enable more effective treatment of difficult to treat solid tumor cancers," said David Slack, CEO of Cend. "For us, an attractive aspect of this business combination is the addition of Caladrius' development team, which has experience and expertise in a diverse array of therapeutic areas, including oncology. We are excited to be working together to improve outcomes for cancer patients."

Following the closing of the merger, Lisata is expected to advance CEND-1 as its lead product candidate in a variety of difficult to treat solid tumor applications, including pancreatic ductal adenocarcinoma (PDAC), where the product is being evaluated in ongoing Phase 1 and Phase 2 clinical studies with Cend and its partner in China, Qilu Pharmaceutical. CEND-1 is a proprietary cyclic peptide which undergoes protease mediated cleavage in the tumor microenvironment producing a C-end Rule or "CendR" peptide that potentiates transport across the tumor stroma and improves delivery of anticancer drugs to the tumor. Additional Phase 1b/2 PDAC clinical data is expected as early as 2023. Lisata also plans to initiate an additional trial in PDAC in combination with immunotherapy as well as a trial or trials exploring applications of CEND-1 in other difficult to treat solid tumors, such as hepatocellular, gastric and breast cancers along with additional therapeutic combinations. We see CEND-1's advancement as supported by compelling Phase 1b data previously presented at the 2020 European Society for Molecular Oncology (ESMO), which not only demonstrated favorable safety and tolerability, but importantly, the potential for marked improvement in treatment effectiveness in combination with standard of care drugs for PDAC.1 With its unique tumor-targeted, tissue penetrating technology, we believe that the CendR Platform<sup>TM</sup> holds the potential to enable more effective solid tumor treatment for a range of emerging treatment modalities, including RNA-based drugs. We believe that this could provide Lisata with additional partnering and product opportunities to benefit cancer patients and Lisata shareholders.

### **About the Proposed Transaction**

Under the terms of the definitive merger agreement, David J. Mazzo, Ph.D., current President and CEO of Caladrius will be the Chief Executive Officer of Lisata, David Slack, current President and CEO of Cend, will be Lisata's President and Chief Business Officer, and Kristen K. Buck, MD, current Executive Vice President of R&D and Chief Medical Officer, will continue in those roles with Lisata. Upon closing, shareholders of Cend will receive approximately 60.5 million shares of Caladrius common stock, subject to certain closing conditions, resulting in the shareholders of each company owning approximately 50% of the combined company. The transaction values each company at \$90 million, which for Caladrius represents a 136% premium to its market cap as of the market close on April 26, 2022. At the effective time of the merger, the Board of Directors of Lisata is expected to

comprise four directors designated by Caladrius and four directors designated by Cend, with the possibility of one additional independent director, whose appointment will be mutually agreed upon by both Caladrius and Cend.

#### **Conference Call Details:**

Date: Wednesday, April 27, 2022 Time: 8:30 a.m. Eastern time

Toll-free Dial-in Number: (866) 595-8403 International Dial-in Number: (706) 758-9979

Conference ID: 4166037

A live webcast along with the accompanying slides, which will be used during the webcast, are immediately available on the Events & Presentations page (<a href="https://ir.caladrius.com/news-events/events-presentations">https://ir.caladrius.com/news-events/events-presentations</a>) under the Investors & News section of the Caladrius website.

A telephone replay will also be available through May 4, 2022. To access replay, please dial (855) 859-2056 (Domestic) or (404) 537-3406 (International). At the system prompt, please enter the code 4166037 followed by the sign #.

#### **About Caladrius Biosciences**

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of innovative therapies designed to treat or reverse disease. We are and have been developing first-in-class autologous cell therapy products based on the finely tuned mechanisms for self-repair that exist in the human body. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

The Company's current product candidates include: XOWNA® (CLBS16), the subject of both a recently completed positive Phase 2a study and an ongoing Phase 2b study (<a href="www.freedom-trial.com">www.freedom-trial.com</a>) in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); CLBS12 (HONEDRA® in Japan), recipient of a SAKIGAKE designation in Japan and eligible for early conditional approval for the treatment of critical limb ischemia ("CLI") and Buerger's disease based on the results of an ongoing clinical trial; and CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for diabetic kidney disease ("DKD"). No assurance can be given with respect to the future of these programs. For more information on the Company, please visit <a href="www.caladrius.com">www.caladrius.com</a>.

## **About Cend Therapeutics**

Cend is a clinical-stage biotech company focused on a novel approach to enable more effective treatments for solid tumor cancers. The CendR Platform™ provides a tumor-targeted tissue penetration capability to specifically enhance drug delivery to tumors. Cend is also applying its technology to alter immunosuppression selectively within the tumor microenvironment to enable a patient's immune system and immunotherapies to fight cancer with greater effectiveness. For more information on Cend, please visit <a href="https://www.cendrx.com">www.cendrx.com</a>

## Forward-Looking Statements

This communication contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forwardlooking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "estimate," "expect," "intend," "plan," "predict", "see" and similar expressions and their variants, as they relate to Caladrius, Cend or the management of either company, before or after the aforementioned merger, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to the timing and completion of the proposed merger; Caladrius's continued listing on the Nasdaq Capital Market until closing of the proposed merger; the combined company's listing on the Nasdaq Capital Market after closing of the proposed merger; expectations regarding the capitalization, resources and ownership structure of the combined company; the approach Cend is taking to discover and develop novel therapeutics; the adequacy of the combined company's capital to support its future operations and its ability to successfully initiate and complete clinical trials; the difficulty in predicting the time and cost of development of Cend's product candidates; the nature, strategy and focus of the combined company; the executive and board structure of the combined company; and expectations regarding voting by Caladrius's and Cend's stockholders. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the risk that the conditions to the closing of the transaction are not satisfied, including the failure to timely or at all obtain stockholder approval for the transaction; uncertainties as to the timing of the consummation of the transaction and the ability of each of Caladrius and Cend to consummate the transaction; risks related to Caladrius's ability to correctly estimate its operating expenses and its expenses associated with the transaction; the ability of Caladrius or Cend to protect their respective intellectual property rights; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Caladrius's Annual Report on Form 10-K filed with the SEC on March 22, 2022. Caladrius can give no assurance that the conditions to the transaction will be satisfied. Except as required by applicable law, Caladrius undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

## No Offer or Solicitation

This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the United States Securities Act of 1933, as amended. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

In connection with the proposed transaction between Caladrius and Cend, Caladrius intends to file relevant materials with the SEC, including a registration statement that will contain a proxy statement and prospectus. CALADRIUS URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT CALADRIUS, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and shareholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In addition, investors and stockholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC by contacting Investor Relations by mail at Attn: Investor Relations, Caladrius Biosciences, Inc., 800 Westchester Avenue, Suite N341, Rye Brook, NY 10573. Investors and stockholders are urged to read the proxy statement, prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transaction.

## Participants in the Solicitation

Caladrius and Cend, and each of their respective directors and executive officers and certain of their other members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Caladrius's directors and executive officers is included in Caladrius's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 22, 2022 and amended on April 21, 2022. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement relating to the transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated below.

## Contact:

Investors: Caladrius Biosciences, Inc. John Menditto Vice President, Investor Relations and Corporate Communications Phone: 908-842-0084

1 Dean, A., et al. 1528P: Phase I trial of the first-in-class agent CEND-1 in combination with gemcitabine and nab-paclitaxel in patients with metastatic pancreatic cancer. ESMO Virtual Congress 2020