March 16, 2023

Cabaletta Bio Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

– Company expecting Investigational New Drug (IND) clearance in the first half of 2023 for CABA-201, a 4-1BB-containing fully human CD19-CAR T cell therapy, with potential to generate initial clinical data by the first half of 2024 –

PHILADELPHIA, March 16, 2023 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies for patients with autoimmune diseases, today reported financial results for the fourth quarter and full year ended December 31, 2022, and provided a business update.

“As we seek FDA clearance for CABA-201 in the next few months, we believe that our specifically designed product candidate for autoimmune patients, our experience with efficient autoimmune cell therapy clinical trial design coupled with timely implementation of complicated autoimmune cell therapy trials and our exclusive translational research partnership with Georg Schett, M.D., which is currently delivering actionable clinical insights, provide us with the opportunity to deliver potentially transformative outcomes for patients with a broad range of autoimmune diseases,” said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. “In parallel, we continue to make progress on our pipeline of clinical-stage CAART legacy product candidates, with 1-month safety and persistence data for the combination sub-study in the DesCAARTes™ trial for DSG3-CAART anticipated in the first half of 2023 and recruitment in the MusCAARTes™ trial for MuSK-CAART ongoing. Looking ahead, we are confident in our ability to advance our autoimmune-focused pipeline for patients with serious unmet need and deliver on multiple upcoming value-creating milestones.”

Recent Operational Highlights and Upcoming Milestones

Chimeric Antigen Receptor T cells for Autoimmunity (CARTA) Strategy

CABA-201: Autologous, engineered T cells with a chimeric antigen receptor containing a fully human CD19 binder and a 4-1BB co-stimulatory domain as a potential treatment for a broad range of autoimmune diseases where B cells contribute to the initiation and/or maintenance of disease.

- **Unveiled new development candidate, CABA-201, a 4-1BB containing CD19-CAR T cell therapy product candidate for autoimmune diseases:** On October 11, 2022, Cabaletta announced CABA-201, a newly designed cell therapy candidate that includes a fully human CD19 binder exclusively in-licensed from Nanjing IASO Biotherapeutics, Co., Ltd, or IASO. According to public communication by IASO, the binder has been clinically evaluated in approximately 20 cancer patients in a dual-

CD19xCD22 CAR T candidate with a 4-1BB costimulatory domain in an investigator-initiated trial. We believe the tolerability data reported by IASO in these patients support clinical development in patients with autoimmune diseases.

- **Established exclusive translational research partnership with Georg Schett, M.D., a pioneer and global leader in the application of CD19-targeting cell therapies for autoimmune disease:** Dr. Schett is senior author of the landmark publications demonstrating the potential of CD19-targeting cell therapies in autoimmunity to reset the immune system, enabling long-term remission of disease off therapy. The September 2022 *Nature Medicine* publication reported complete responses in five out of five patients with moderate to severe, refractory, systemic lupus erythematosus, or SLE, durable to up to 17 months of follow-up off of SLE-related therapies. In February 2023, a report was published in the *Lancet Rheumatology* showing rapid and significant clinical responses following the same treatment regimen in a patient with refractory myositis (anti-synthetase syndrome subtype) within three months that was durable throughout the six month follow up period. In all patients, new, naïve B cells repopulated within 2 to 5 months of CAR T infusion, with no evidence of recurrence of disease or autoantibodies following repopulation.

- **Investigational New Drug application clearance expected in the first half of 2023 with initial clinical data anticipated in the first half of 2024, subject to timely clearance of our IND by the FDA:** Cabaletta expects to obtain clearance of its IND application from the U.S. Food and Drug Administration (FDA) for its lead product candidate, CABA-201, in the first half of 2023. Pending clearance by the FDA, Cabaletta plans to initiate clinical evaluation of CABA-201, and anticipates initial clinical data in the first half of 2024.

Chimeric AutoAntibody Receptor T (CAART) cells Strategy

DSG3-CAART: Desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as a potential treatment for patients with mucosal pemphigus vulgaris (mPV).

- **Progressing in combination sub-study of DesCAARTes™ trial:** In September 2022 and October 2022, Cabaletta presented updated DSG3-CAART data which provided a rationale to prioritize the enrollment of the cohort in the combination sub-study (2.5 billion cells in combination with intravenous immunoglobulin [IVIg] and cyclophosphamide), with the goal of addressing possible cytokine and autoantibody effects on CAART activity. Cabaletta anticipates reporting 1-month safety and persistence data for the combination sub-study in the first half of 2023 and 6-month data for the combination sub-study in the second half of 2023.

MuSK-CAART: Muscle-specific kinase (MuSK) chimeric autoantibody receptor T (MuSK-CAART) cells as a potential treatment for patients with MuSK-associated myasthenia gravis.

- **Initiated first-in-human MusCAARTes™ trial:** In November 2022, Cabaletta initiated the MusCAARTes™ trial for MuSK-CAART in patients with MuSK autoantibody-positive MG. With insights generated from the DesCAARTes™ trial, the study design has been accelerated through (i) initiation at a dose of 500 million cells (versus 20 million cells in DesCAARTes™), (ii) use of a “2+4” dosing scheme, and (iii) early

implementation of a combination approach. The trial is an open-label study consisting of an accelerated dose escalation phase, followed by a cohort expansion phase at the final selected dose. The Company expects to report 6-month data for the combination cohort of the MusCAARTes™ trial in the first half of 2024.

- **Preclinical data supporting IND application and MusCAARTes™ trial design published in *Nature Biotechnology*:** In January 2023, *Nature Biotechnology* published preclinical data demonstrating that MuSK-CAART had similar efficacy as CD19-CAR T cells for depletion of MuSK-specific B cells and retained cytolytic activity in the presence of soluble anti-MuSK antibodies. These data contributed to the Company's IND application for the recently initiated Phase 1 MusCAARTes™ clinical study of MuSK-CAART. These data were developed through a sponsored research agreement between Cabaletta Bio and University of Pennsylvania professor Aimee Payne, M.D., Ph.D., Cabaletta Bio co-founder and Scientific Advisory Board co-chair.

Corporate Highlights

- **Raised $32.6 million in net proceeds from oversubscribed offering:** In December 2022, Cabaletta closed a public offering of pre-funded warrants, in lieu of common stock, to purchase 6,213,776 shares of common stock at a price of $5.51999 per pre-funded warrant and 126,815 shares of its common stock at a price of $5.52 per share. Net proceeds from the offering were approximately $32.6 million, after deducting underwriting discounts, commissions and offering expenses payable by the Company.

Upcoming Events

Cabaletta will participate in the upcoming 22nd Annual Needham Virtual Healthcare Conference, which is being held from April 17 – 20, 2023.

Fourth Quarter and Full Year 2022 Financial Results

- Research and development expenses were $12.4 million and $39.3 million for the three months ended December 31, 2022, and the full year ended December 31, 2022, respectively, compared to $9.9 million and $32.5 million for the three months ended December 31, 2021, and the full year ended December 31, 2021, respectively.

- General and administrative expenses were $3.9 million and $14.8 million for the three months ended December 31, 2022, and the full year ended December 31, 2022, respectively, compared to $4.0 million and $13.8 million for the three months ended December 31, 2021, and the full year ended December 31, 2021, respectively.

- As of December 31, 2022, Cabaletta had cash, cash equivalents and investments of $106.5 million, compared to $122.2 million as of December 31, 2021.

The Company expects that its cash, cash equivalents and investments as of December 31, 2022, will enable it to fund its operating plan into the first quarter of 2025.

About Cabaletta Bio

Cabaletta Bio (Nasdaq: CABA) is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies that have the potential to provide

a deep and durable, perhaps curative, treatment for patients with autoimmune diseases. The CABA™ platform encompasses two strategies: the CARTA (chimeric antigen receptor T cells for autoimmunity) strategy, with CABA-201, a 4-1BB-containing CD19-CAR T, as the lead product candidate, and the CAART (chimeric autoantibody receptor T cells) strategy, with multiple clinical-stage candidates, including DSG3-CAART for mucosal pemphigus vulgaris and MuSK-CAART for MuSK myasthenia gravis. The expanding CABA™ platform may offer potentially curative therapies for patients with a broad range of autoimmune diseases. Cabaletta Bio's headquarters are located in Philadelphia, PA.

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 expectations regarding: Cabaletta's ability to grow its autoimmune-focused pipeline; the ability to capitalize on and potential benefits resulting from the translational research partnership with Georg Schett, M.D., and the exclusive license agreement with IASO Bio; the company's business plans and objectives; the timing of its IND clearance for CABA-201, initiation of clinical evaluation of CABA-201 and generation of initial clinical data for CABA-201; statements regarding anticipated significance of, and timing of release of, safety and persistence data and combination cohort data; statements regarding regulatory filings for its development programs, including the planned timing of such regulatory filings and potential review by such regulatory authorities; the expectation that Cabaletta Bio may improve outcomes for patients suffering from mPV, MG, or other autoimmune diseases; the progress and results of its DesCAARTes™ Phase 1 trial and MusCAARTes™ Phase 1 trial, including Cabaletta's ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the trial; the ability to accelerate Cabaletta's pipeline and develop meaningful therapies for patients, including in collaboration with academic and industry partners and the ability to optimize such collaborations on its development programs; use of capital, expenses, future accumulated deficit and other financial results in the future; ability to fund operations into the first quarter of 2025; and the anticipated contribution of the members of Cabaletta's executives to the company's operations and progress.

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; the risk that signs of biologic activity or persistence may not inform long-term results; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of DSG3-CAART, MuSK-CAART and CABA-201; the risk that the results observed with the similarly-designed construct employed in the recent *Nature Medicine* and *Lancet Rheumatology* publications are not indicative of the results we seek to achieve with CABA-201; risks related to clinical trial site activation or enrollment rates that are lower than expected; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to volatile market and economic conditions; risks related to the impact of public health epidemics affecting countries or regions in which Cabaletta has operations or does business, such as COVID-19; Cabaletta's ability to retain and recognize the intended incentives conferred by Orphan Drug Designation and Fast Track Designation for its product candidates, as applicable; 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 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.

CABALETTA BIO, INC.
SELECTED FINANCIAL DATA
(unaudited; in thousands, except share and per share data)

Statements of Operations

	Three months ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
	Unaudited			
Operating expenses:				
Research and development	12,400	9,919	39,300	32,494
General and administrative	3,902	3,974	14,839	13,819
Total operating expenses	16,302	13,893	54,139	46,313
Loss from operations	(16,302)	(13,893)	(54,139)	(46,313)
Other income				
Interest income	610	5	1,164	24
Net loss	(15,692)	(13,888)	(52,975)	(46,289)
Net loss per voting and non-voting share, basic and diluted	$ (0.52)	$ (0.49)	$ (1.81)	$ (1.80)

Selected Balance Sheet Data

	December 31,

	2022	2021
	Unaudited	
Cash, cash equivalents and investments	$ 106,547	$ 122,222
Total assets	116,968	126,336
Total liabilities	12,448	8,380
Total stockholders' equity	104,520	117,956

Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com

Sarah McCabe
Stern Investor Relations, Inc.
212-362-1200
sarah.mccabe@sternir.com

Cabaletta Bio®

Source: Cabaletta Bio