UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 21, 2023

CABALETTA BIO, INC.
(Exact name of Registrant as Specified in its Charter)

Delaware	**001-39103**	**82-1685768**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

2929 Arch Street, Suite 600, Philadelphia, PA	**19104**
(Address of principal executive offices)	**(Zip Code)**

(267) 759-3100
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.00001 per share	CABA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On July 21, 2023, upon the recommendation of its Nominating and Corporate Governance Committee (the "NCG Committee"), the Board of Directors (the "Board") of Cabaletta Bio, Inc. (the "Company") appointed Shawn Tomasello to join the Board, effective as of July 21, 2023 (the "Effective Date"), to fill the newly created vacancy on the Board resulting from an increase in the size of the Board from five (5) to six (6) directors. Ms. Tomasello will serve as a Class I director until her term expires at the 2026 annual meeting of stockholders of the Company at which time she will stand for election by the Company's stockholders. The Board determined that Ms. Tomasello is independent under the applicable listing standards of The Nasdaq Stock Market ("Nasdaq").

On the Effective Date, Ms. Tomasello was also appointed to the Compensation Committee of the Board (the "Compensation Committee"). The Board has determined that Ms. Tomasello meets the requirements for independence of compensation committee members under the applicable listing standards of Nasdaq and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In addition, effective as of the Effective Date: (i) Catherine Bollard, M.D. resigned as a member and Chair of the Compensation Committee, (ii) Mark Simon was appointed as the new Chair of the Compensation Committee and also resigned as Chair of the NCG Committee, and (iii) Scott Brun, M.D. was appointed as the new Chair of the NCG Committee.

In addition, on the Effective Date, the Board approved the formation of the Science and Technology Committee of the Board (the "S&T Committee") to assist with the Board's oversight of the Company's research and development, manufacturing and technical operations and to advise the Board with respect to the Company's scientific, pre-clinical and clinical activities. The newly created S&T Committee is composed of Dr. Bollard, Dr. Brun and Ms. Tomasello, with Dr. Bollard serving as the Chair of the S&T Committee.

As of the Effective Date, the Board's committee composition is as follows:

- Audit Committee: Richard Henriques (Chair), Mark Simon and Scott Brun, M.D.
- Compensation Committee: Mark Simon (Chair), Shawn Tomasello and Richard Henriques.
- NCG Committee: Scott Brun, M.D. (Chair), Catherine Bollard, M.D. and Mark Simon.
- S&T Committee: Catherine Bollard, M.D. (Chair), Scott Brun, M.D. and Shawn Tomasello.

In connection with the formation of the S&T Committee, the Board approved the Company's Second Amended and RestatedNon-Employee Director Compensation Policy (the "Second A&R Director Compensation Policy"), effective as of the Effective Date, in order to establish compensation for the S&T Committee. Under the Second A&R Director Compensation Policy, the Company will pay a cash retainer of $7,500 per year to the members of the S&T Committee and a cash retainer of $15,000 to the Chair of the S&T Committee. No further changes were made to the terms of the Company's existing amended and restated non-employee director compensation policy. The foregoing description of the terms of the Second A&R Director Compensation Policy does not purport to be complete and is qualified in its entirety by reference to the full text of the Second A&R Director Compensation Policy which will be filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023.

As a non-employee director, Ms. Tomasello will receive cash compensation for her Board and committee service in accordance with the Second A&R Director Compensation Policy. In addition, under the Second A&R Compensation Policy, upon her election as a director on the Effective Date, Ms. Tomasello was granted an option to purchase 44,000 shares of the Company's common stock at an exercise price per share of $13.48. This option shall vest in substantially equal quarterly installments over three years from the Effective Date, provided, however, that all vesting shall cease if the director ceases to have a service relationship, unless the Board determines that the circumstances warrant continuation of vesting. Ms. Tomasello is not a party to any transaction with the Company that would require disclosure under Item 404(a) of Regulation S-K, and there are no arrangements or understandings between Ms. Tomasello and any other persons pursuant to which she was selected as a director. In addition, Ms. Tomasello entered into an indemnification agreement with the Company consistent with the form of indemnification agreement entered into between the Company and its existing non-employee directors, a copy of which was filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 (FileNo. 333-234017) filed with the Securities and Exchange Commission on September 30, 2019. Pursuant to the terms of this agreement, the Company may be required, among other things, to indemnify Ms. Tomasello for some expenses, including attorneys' fees, judgments, fines and settlement amounts respectively incurred by her in any action or proceeding arising out of her respective service as one of the Company's directors.

Item 7.01. Regulation FD Disclosure.

On July 24, 2023, the Company issued a press release announcing Ms. Tomasello's appointment to the Board. A copy of this press release is furnished as Exhibit 99.1 to this report on Form 8-K.

On July 24, 2023, the Company also posted to the "Investors & Media" section of the Company's website at*www.cabalettabio.com* an updated corporate presentation (the "Corporate Presentation") to disclose Ms. Tomasello's position on the Board and provide updated data from its study of desmoglein 3 chimeric autoantibody receptor T ("DSG3-CAART") cells as a potential treatment for patients with mucosal pemphigus. A copy of the Corporate Presentation is furnished hereto as Exhibit 99.2 to this report on Form 8-K.

The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On July 24, 2023, the Company issued the Corporate Presentation reiterating guidance that it anticipates reporting 3-month clinical data on efficacy endpoints and tolerability for patients dosed with CABA-201 by the first half of 2024.

With respect to the CAART strategy, the Company included an update indicating the completion of the 1-month safety and persistence evaluation from the DesCAARTes™ trial for DSG3-CAART for the cohort in the combinationsub-study where patients are pre-treated with intravenous immunoglobulin ("IVIg") and cyclophosphamide (without fludarabine) prior to DSG3-CAART infusion. DSG3-CAART peak persistence and persistence over the initial 29 days post-infusion in the three mucosal pemphigus vulgaris subjects dosed was modestly increased by the cyclophosphamide only combination therapy. The Company announced the initiation of enrollment in an additional cohort in the combination sub-study with DSG3-CAART where patients are pretreated with IVIg, cyclophosphamide and fludarabine prior to DSG3-CAART infusion. The cohort is designed to evaluate the ability to improve DSG3-CAART engraftment and persistence.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Issued by the Company on July 24, 2023, furnished herewith.
99.2	Corporate Presentation, dated July 24, 2023, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CABALETTA BIO, INC.

Date: July 24, 2023

By: /s/ Steven Nichtberger
Steven Nichtberger, M.D.
President and Chief Executive Officer

Exhibit 99.1

Cabaletta Bio®

Cabaletta Bio Appoints Global Commercial Leader Shawn Tomasello to Board of Directors

– Ms. Tomasello created and led global commercial and medical affairs functions at Kite Pharma from pre-launch through its acquisition by Gilead Sciences –

PHILADELPHIA, July 24, 2023 – 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 announced the appointment of Shawn Tomasello to its Board of Directors. Ms. Tomasello has over 35 years of experience in the life sciences industry, including specific expertise in CD19-CAR T therapy, where she most recently served as the Chief Commercial Officer of Kite Pharma, Inc. between 2015 and 2018, leading the worldwide commercialization effort for the CD19-CAR T cell therapy, Yescarta®, and playing a key role in its acquisition by Gilead Sciences, Inc. As part of her appointment to the Board of Directors, Ms. Tomasello will become a member of the Compensation Committee and the newly formed Science & Technology Committee.

"Shawn is a recognized biopharmaceutical leader with a proven track record building large-scale commercial organizations to bring transformative therapies to patients in need, including having overseen the global commercial launch of the leading approved CD19-CAR T cell therapy," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "Shawn's experience in pre-launch planning, scaling and commercializing a CD19-CAR T therapy globally will provide important additional perspective to our Board of Directors as we continue to expand and advance our CABA-201 development program."

Ms. Tomasello brings over three decades of experience in the life sciences industry and most recently served as the Chief Commercial Officer of Kite Pharma, now part of Gilead Sciences, where she oversaw the global commercialization of Yescarta®, the first approved CAR-T therapy for non-Hodgkin lymphoma. Prior to joining Kite Pharma, she was the Chief Commercial Officer of Pharmacyclics LLC, now part of AbbVie Inc., where she led both commercial and medical affairs. Before that, Ms. Tomasello held senior leadership positions at Celgene Corporation, including President of the Americas, Hematology and Oncology, where she led the company through five successful product launches encompassing 11 indications and played a critical role in acquisitions. Previously, she was National Director of Hematology for Rituxan® at Genentech, Inc. Earlier in her career, Ms. Tomasello held positions at Pfizer Laboratories, Miles Pharmaceuticals, Inc. and Proctor & Gamble Company. She holds an M.B.A. from Murray State University and a B.S. in Marketing from the University of Cincinnati.

"I am excited to join Cabaletta's Board of Directors and to support the company's vision to develop and potentially launch the first targeted curative cell therapies for patients with autoimmune diseases," said Shawn Tomasello. "I look forward to applying my decades of experience building and scaling global commercial organizations in the life sciences industry to bring CABA-201 closer to patients with autoimmune disease and support development of the broader CABA™ platform."

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 fully human CD19-CAR T, as the lead product candidate being evaluated in systemic lupus erythematosus and myositis, 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 is designed to develop potentially curative therapies that offer deep and durable responses for patients with a broad range of autoimmune diseases. Cabaletta Bio's headquarters and labs 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 its expectations regarding: Cabaletta Bio's ability to grow its autoimmune-focused pipeline; its plans around CABA-201, including its expectations for the expansion and advancement of the CABA-201 development program and potential launch of CABA-201; the company's business plans and objectives, including on a global scale; the potential curative effect of the therapies associated with the CABA™ platform; and the anticipated contribution of the members of our board of directors, specifically Ms. Tomasello, and our executives to our 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; 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 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.

Contacts:

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William Gramig
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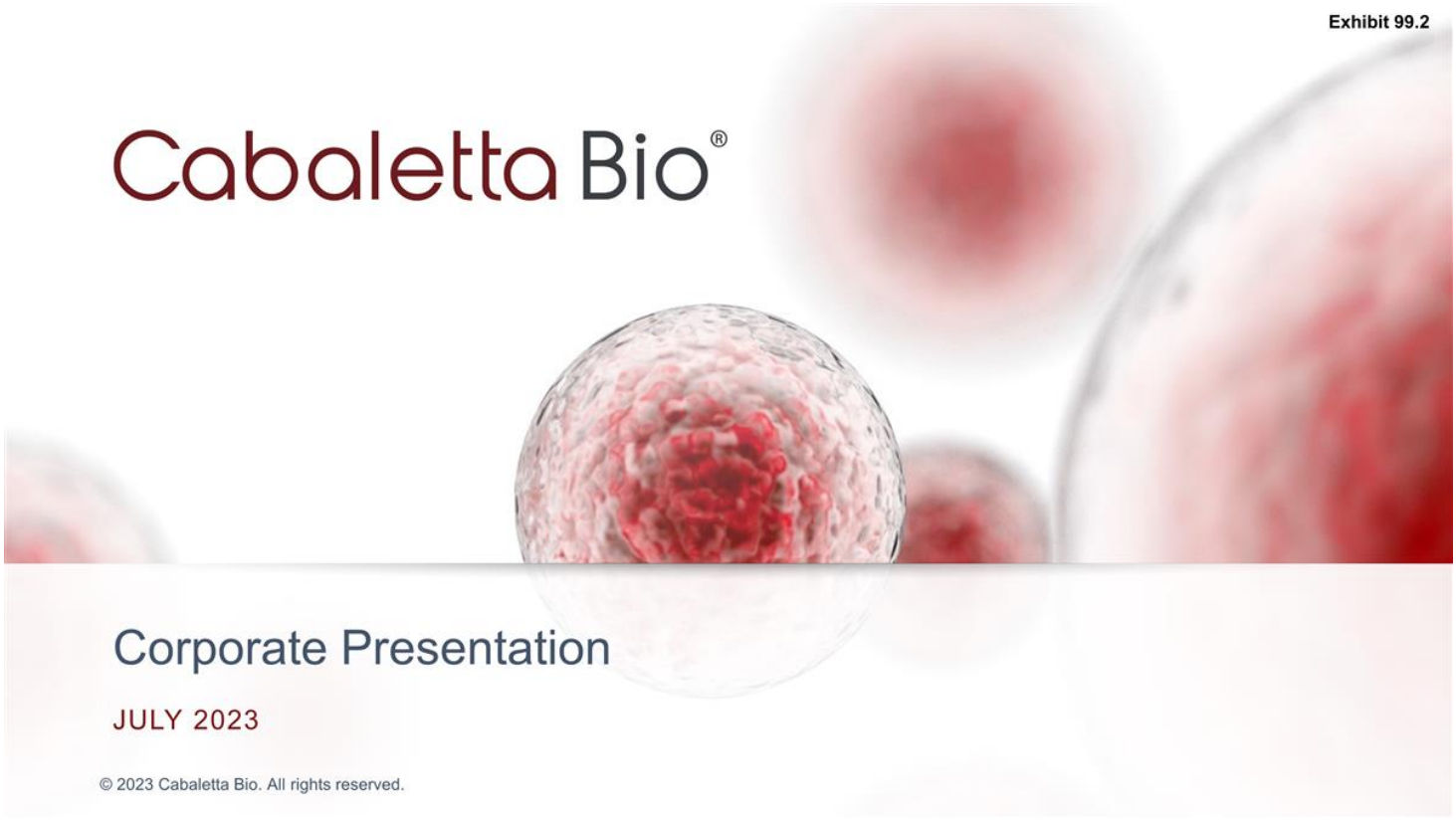
william.gramig@sternir.com

Exhibit 99.2

Cabaletta Bio®



Corporate Presentation

JULY 2023

Disclaimer

The following presentation, including any printed or electronic copy of these slides, the talks given by the presenters, the information communicated during any delivery of the presentation and any question and answer session and any document or material distributed at or in connection with the presentation (collectively, the "Presentation") has been prepared by Cabaletta Bio, Inc. ("we," "us," "our," "Cabaletta" or the "Company") and is made for informational purposes only. This Presentation does not purport to be a prospectus, to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this Presentation unless stated otherwise, and this Presentation shall not under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof. This Presentation may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business, operations, and financial conditions, and include, but are not limited to, express or implied statements regarding our current beliefs, expectations and assumptions regarding: our business, future plans and strategies for our CAAR T and CARTA technologies and CABA™ platform; our ability to grow our autoimmune-focused pipeline; the ability to capitalize on and potential benefits resulting from the translational research partnership with Professor Georg Schett and the exclusive license agreement with IASO Bio; our expectations around the potential success and therapeutic benefits of CABA-201, including our belief that CABA-201 may enable an "immune system reset" and provide deep and durable responses for patients with autoimmune diseases; our plans for (i) a Phase 1/2 clinical trial of CABA-201 in patients with SLE, including our anticipated progress, clinical trial design, ability to leverage our experience in autoimmune cell therapy and lupus product development and (ii) a Phase 1/2 clinical trial of CABA-201 in patients with myositis, including our anticipated progress, clinical trial design and ability to leverage our experience in autoimmune cell therapy; our planned initial clinical data read-out in the first half of 2024 for patients treated with CABA-201; our ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and advance the trial as planned in our Phase 1/2 clinical trials of CABA-201; the timing any planned regulatory filings for our development programs; the progress and results of our DesCAARTes™ Phase 1 trial, including the significance and impact around reported safety and clinical and translational data of cohorts from our DesCAARTes™ trial, and our ability to advance dose escalation and initiate combination cohorts and to optimize our targeted cell therapy; our ability to implement a pre-treatment regimen, the outcomes of such pre-treatment regimen and the potential ability to enhance *in vivo* DSG3-CAART exposure; the therapeutic potential and clinical benefits of our product candidates; the expectation that Cabaletta may improve outcomes for patients suffering from systemic lupus erythematosus, myositis, mucosal pemphigus vulgaris, myasthenia gravis, or other autoimmune diseases; our ability to escalate dosing as high as 15 billion cells in cohort A6m, initiate dosing in a combination cohort or otherwise; our ability to evaluate, and the potential significance of, the relationship between DSG3-CAART persistence and potential clinical responses in patients with mPV; our ability to safely retreat additional patients and whether we will continue to observe a lack of immune-mediated clearance of DSG3-CAART cells after retreatment and repeat dosing of patients; our ability to successfully complete our preclinical and clinical studies for our product candidates, including our ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the trial; the ability of MuSK-CAART to target B cells that differentiate into antibody secreting cells, which produce autoantibodies against muscle-specific kinase; our ability to obtain and maintain regulatory approval of our product candidates, including our expectations regarding the intended incentives conferred by and ability to retain Orphan Drug Designation and Fast Track Designation for our product candidates, as applicable; the further expansion and development of our modular CABA™ platform across a range of autoimmune diseases; our ability to contract with third-party suppliers and manufacturers, implement an enhanced manufacturing process and further develop our internal manufacturing strategy, capabilities and facilities; our potential commercial opportunities, including value and addressable market, for our product candidates; our expectations regarding our use of capital and other financial results; and our ability to fund operations into the fourth quarter of 2025. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements.

Various risks, uncertainties and assumptions could cause actual results to differ materially from those anticipated or implied in our forward-looking statements. Such risks and uncertainties include, but are not limited to, risks related to the success, cost, and timing of our product candidate development activities and preclinical studies and clinical trials, risks related to our ability to demonstrate sufficient evidence of safety, efficacy and tolerability in our preclinical studies and clinical trials of CABA-201, DSG3-CAART and MuSK-CAART, the risk that the results observed with the similarly-designed construct, including, but not limited to, due to dosing regimen, are not indicative of the results we seek to achieve with CABA-201, our plans to evaluate additional cohorts in the DesCAARTes™ trial, including a cohort implementing a pre-treatment regimen, the risk that signs of biologic activity or persistence may not inform long-term results, the risk that persistence observed with effective CART-19 oncology studies in combination with lymphodepletion is not indicative of, or applicable to, clinical responses in patients with mPV, risks related to clinical trial site activation or enrollment rates that are lower than expected, our ability to protect and maintain our intellectual property position, risks related to our relationship with third parties, uncertainties related to regulatory agencies' evaluation of regulatory filings and other information related to our product candidates, our ability to retain and recognize the intended incentives conferred by any Orphan Drug Designation and Fast Track Designations, the risk that any one or more of our product candidates will not be successfully developed and commercialized, the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies, the impact of COVID-19 on the timing, progress, interpretability of data, and results of ongoing or planned clinical trials and risks relating to as a result of extraordinary events or circumstances such as the COVID-19 pandemic, and any business interruptions to our operations or to those of our clinical sites, manufacturers, suppliers, or other vendors resulting from the COVID-19 pandemic or similar public health crisis. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ materially from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our other and subsequent filings with the Securities and Exchange Commission. Certain information contained in this Presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this Presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. The Company is the owner of various trademarks, trade names and service marks. Certain other trademarks, trade names and service marks appearing in this Presentation are the property of third parties. Solely for convenience, the trademarks and trade names in this Presentation are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Cabaletta Bio®

Cabaletta®: Pursuing cures for a broad range of autoimmune diseases

Leveraging years of experience with cellular therapy in autoimmunity to initiate CABA-201 clinical trials

CARTA Strategy | CABA-201 (4-1BB CD19-CAR T) to be evaluated in SLE & myositis Phase 1/2 studies

Advancing SLE & myositis trials with efficient designs – including starting dose & parallel cohorts

- *1.0 x 10^6 cells/kg initial dose of CABA-201 is identical to dose used in academic SLE[1] and myositis[2] studies*
- *Parallel cohorts with 6 patients each – SLE study with 1) LN & 2) Non-renal SLE; myositis study with 1) DM, 2) ASyS & 3) IMNM*

CABA-201 has been specifically engineered for patients with autoimmune diseases

- *Fully human CD19 binder with data in ~20 oncology patients – clinical safety profile supporting further evaluation in autoimmunity*
- *Same 4-1BB costimulatory domain and similar CD19 binder affinity[3] as used in the academic SLE[1] & myositis studies[2]*

Potential to cure a broad range of autoimmune diseases where B cells have a role initiating or maintaining disease

CAART Strategy | DSG3-CAART & MuSK-CAART clinical studies evaluating combination regimens

DesCAARTes™ trial of DSG3-CAART in mucosal pemphigus vulgaris

- *Enrolling in combination sub-study cohort using pre-treatment with IVIg, cyclophosphamide and fludarabine*

MusCAARTes™ trial in MuSK myasthenia gravis – leveraging insights from experience with DSG3-CAART

- *Initiated in 4Q22; received FDA Fast Track Designation & Orphan Drug Designation*

Initial CABA-201 3-month clinical efficacy and tolerability data expected by 1H24[4]

CARTA – Chimeric Antigen Receptor T cells for Autoimmunity; CAART – Chimeric AutoAntibody Receptor T cells; IND – Investigational New Drug; SLE – Systemic lupus erythematosus; DM – Dermatomyositis; ASyS – Anti-synthetase syndrome; IMNM – Immune-mediated necrotizing myopathy

1. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.
2. Müller, Fabian, et al. "CD19-targeted CAR T cells in refractory antisynthetase syndrome." The Lancet (2023).
3. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human anti-CD19 CARs for T-cell therapy." Journal of Cellular Physiology 236.8 (2021): 5832-5847.

4. Assumes no dose-limiting toxicities are observed in the cohort and uninterrupted enrollment occur in the trials.

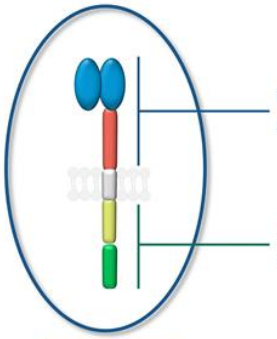
One CABA™ platform, two strategies to address autoimmune diseases

Complementary strategies to optimize clinical outcomes using cellular therapies in autoimmune diseases

CARTA

Chimeric **A**ntigen **R**eceptor **T** cells for **A**utoimmunity

*Potential to '**reset the immune system**' in patients with **autoimmune diseases driven by B cells**, through generalized transient B cell depletion and **repopulation of healthy B cells**[1,2]*



Fully Human Anti-CD19 Targeting Domain

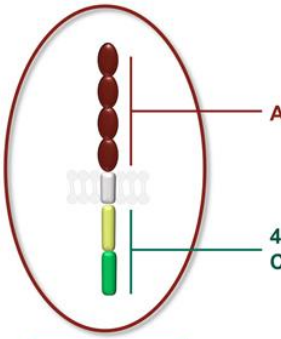
4-1BB Costimulatory Domain & CD3-Zeta Signaling Domain

CABA-201

CAART

Chimeric **A**uto**A**ntibody **R**eceptor **T** cells

*In autoimmune diseases with a **limited number of well-defined pathogenic autoantibodies**, permanent **antigen-specific B cell depletion** may provide an **elegant biologic solution** to disease*[3]



Autoantigen Targeting Domain

4-1BB Costimulatory Domain & CD3-Zeta Signaling Domain

DSG3-CAART

1. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." *Nature Medicine* (2022): 1-9.
2. Müller, Fabian, et al. "CD19-targeted CAR T cells in refractory antisynthetase syndrome." The Lancet (2023).
3. Ellebrecht, Christoph T., et al. "Reengineering chimeric antigen receptor T cells for targeted therapy of autoimmune disease." *Science* 353.6295 (2016): 179-184.

CABA™ platform may apply across a range of autoimmune diseases

Biologic opportunity for cure or treatment may be possible in dozens of autoimmune diseases*

Neurology
- **Myasthenia Gravis**[1,2,3,5]
- Multiple Sclerosis[6]
- Neuromyelitis Optica[3]
- CIDP (Chronic Inflammatory Demyelinating Polyneuropathy)[1,2]
- Anti-NMDAR Encephalitis[3,6]
- Lambert-Eaton Syndrome[5]

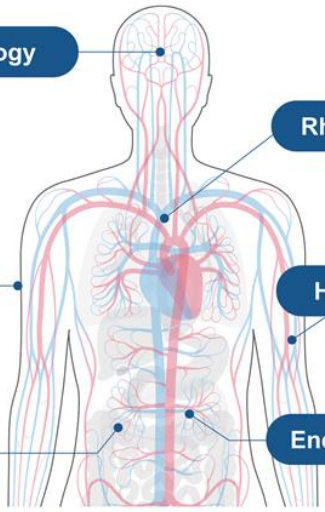
Rheumatology
- **Systemic Lupus Erythematosus**[3,4,5,6]
- Rheumatoid Arthritis[2,3,4]
- **Myositis**[5]
- **Systemic sclerosis**[6]
- ANCA-Associated Vasculitis[3,4,5]

Dermatology
- **Pemphigus Vulgaris**[1,2,3]
- Pemphigus Foliaceus[1,2,3]
- Epidermolysis Bullosa Acquisita[3]
- Bullous Pemphigoid[1,2,3]

Hematology
- Immune Thrombocytopenic Purpura[3]
- Thrombotic Thrombocytopenic Purpura[1,2,3]
- Antiphospholipid Syndrome[4,5]
- Autoimmune Hemolytic Anemia[3]

Nephrology
- **Lupus Nephritis**[3,4]
- Membranous Nephropathy[1,2,3]
- Goodpasture's Syndrome[1,2,3,4]

Endocrinology
- Type 1 Diabetes[3,6]
- Graves' Disease[3,5]
- Hashimoto's Disease[5]



- *Illustrative list of autoimmune diseases where B cells may play a role in initiating or maintaining disease, and where biologic opportunity for cure or treatment with CAART or CARTA approach may be possible.*
- *Diseases **in bold** represent where clinical studies are underway or plan to be initiated by Cabaletta or by Professor Schett*

1. Koneczny, Inga. "Update on IgG4-mediated autoimmune diseases: new insights and new family members." Autoimmunity Reviews (2020): 102646.
2. Huijbers, Maartje G., et al. "IgG4-mediated autoimmune diseases: a niche of antibody-mediated disorders." Annals of the New York Academy of Sciences 1413.1 (2018): 92.
3. Ludwig, Ralf J., et al. "Mechanisms of autoantibody-induced pathology." Frontiers in immunology 8 (2017): 603.
4. Suurmond, Jolien, and Betty Diamond. "Autoantibodies in systemic autoimmune diseases: specificity and pathogenicity." The Journal of clinical investigation 125.6 (2015): 2194-2202.
5. Xiao, Ze Xiu, Joseph S. Miller, and Song Guo Zheng. "An updated advance of autoantibodies in autoimmune diseases." Autoimmunity Reviews (2020): 102743.
6. Hampe, Christiane S. "B cells in autoimmune diseases." Scientifica 2012 (2012).

Pipeline targeting autoimmune diseases where cure is possible

CABA™ Platform	Indication		Program	Discovery	Preclinical	Phase 1/2	Phase 2/3
CARTA *Chimeric Antigen Receptor T cells for Autoimmunity*	**Myositis (IIM, Idiopathic Inflammatory Myopathy)[1]**	Dermatomyositis	**CABA-201** *4-1BB CD19-CAR T*				
		Anti-Synthetase Syndrome				*IND cleared*	
		Immune-Mediated Necrotizing Myopathy					
	Systemic Lupus Erythematous (SLE)[1]	Lupus Nephritis					
		Non-Renal SLE				*IND cleared*	
	Multiple Undisclosed Indications						
CAART[2] *Chimeric AutoAntibody Receptor T cells*	**Mucosal Pemphigus Vulgaris**		**DSG3-CAART[3]**				
	MuSK Myasthenia Gravis		**MuSK-CAART[3]**				

1. CABA-201 is being evaluated in separate clinical trials for myositis and SLE.
2. Additional CAART pipeline candidates include PLA2R-CAART in preclinical stage for PLA2R membranous nephropathy, DSG3/1-CAART in discovery stage for mucocutaneous pemphigus vulgaris & 2 undisclosed targets in discovery stage.
3. Currently being evaluated in a Phase 1 trial.

Cabaletta Bio®

Academic data: Immune system reset in autoimmune patients[1-6]

Exclusive translational research partnership with key investigator informs Cabaletta's CD19 clinical strategy

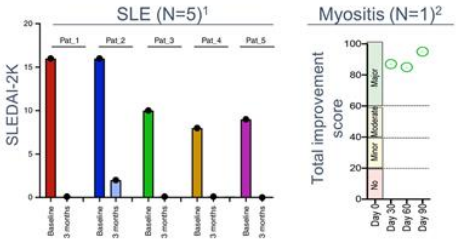
Emerging clinical data with 4-1BB CD19-CAR T[7] in…

7 Systemic lupus erythematosus patients[1,2]

3 Anti-synthetase syndrome patients[3-5]

1 Systemic sclerosis patient[6]

Robust improvement in clinical disease activity within 3 months of CD19-CAR T treatment



- ***Rapid and deep CD19⁺ B cell depletion***
- ***Return of healthy B cells within 7 months***
- ***Favorable safety data with CD19-CAR T regimen***
- ***Clinical SLE responses up to 24 mo with no relapses reported[2]***

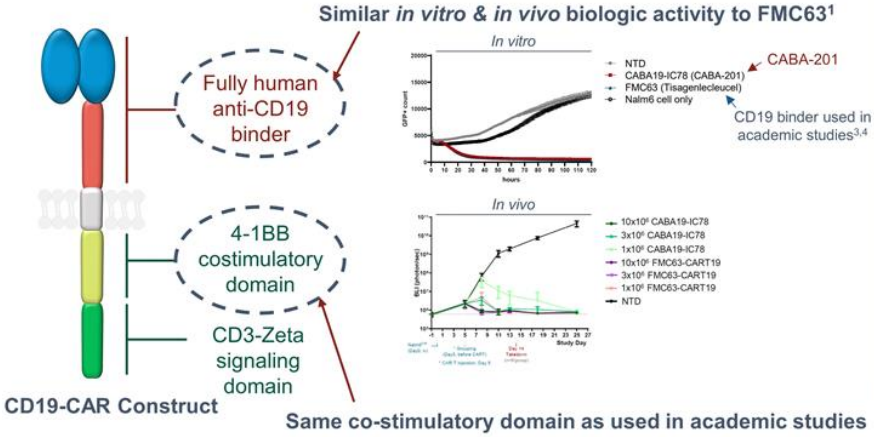
SLE – Systemic lupus erythematosus; SLEDAI-2K – Systemic Lupus Erythematosus Disease Activity Index 2000

1. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.
2. Taubmann, J., et al. "OP0141 Long Term Safety and Efficacy Of CAR-T Cell Treatment in Refractory Systemic Lupus Erythematosus-Data from the First Seven Patients." (2023): 93-94.
3. Müller, Fabian, et al. "CD19-targeted CAR T cells in refractory antisynthetase syndrome." The Lancet (2023).
4. Taubmann, Jule, et al. "Rescue therapy of antisynthetase syndrome with CD19-targeted CAR-T-cells after failure of several B cell depleting antibodies." Rheumatology (Oxford, England) (2023): kead330.
5. Pecher, Ann-Christin, et al. "CD19-Targeting CAR T Cells for Myositis and Interstitial Lung Disease Associated With Antisynthetase Syndrome." JAMA 329.24 (2023): 2154-2162.
6. Bergmann, Christina, et al. "AB0816 Treatment of a Patient with Severe Diffuse Systemic Sclerosis (Ssc) Using CD19-targeting CAR-T-cells." (2023): 1621-1621.
7. The construct utilized in these studies has a similar design to CABA-201, sharing the 4-1BB costimulatory domain, but is a different construct.

CABA-201: CD19-targeting CAR T therapy for autoimmune diseases

Cabaletta's CD19 binder with similar *in vitro* & *in vivo* activity to FMC63[1,2] (binder used in academic studies[3,4])

CABA-201



Clinical data reported by IASO using licensed CD19 binder in oncology[5]

- **Fully human binder**
  Evaluated as dual-CAR combined with CD22 binder with standard Flu/Cy preconditioning
- **Data reported in ~20 patients to date**
  B cell leukemia and lymphoma in IIT in China
- **Safety data supports autoimmune development**

SLE – Systemic lupus erythematosus; IIT – Investigator-initiated trial; Flu/Cy – Fludarabine/Cyclophosphamide; CRS – Cytokine release syndrome; ICANS – Immune effector cell-associated neurotoxicity syndrome

1. Peng, Binghao J, et al. "Preclinical specificity and activity of CABA-201, a fully human 4-1BB containing CD19 CAR T therapy for treatment-resistant autoimmune disease." Poster presented at: American Society Gene and Cell Therapy 26th Annual Meeting; 2023 May 19; Los Angeles, CA.
2. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human anti-CD19 chimeric antigen receptors for T-cell therapy." Journal of Cellular Physiology 236.8 (2021): 5832-5847.
3. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.
4. Müller, Fabian, et al. "CD19-targeted CAR T cells in refractory antisynthetase syndrome." The Lancet (2023).
5. Evaluated as part of CT120, a dual-CD19xCD22 CAR T product candidate under development by Nanjing IASO Biotherapeutics, Co., Ltd. (IASO Bio).

CABA-201

Myositis: Strong scientific rationale & significant disease burden

~66K U.S. patients with IIM subtypes with B cell involvement; frequently severe, with limited treatment options

1 Autoimmune disease with B cell involvement

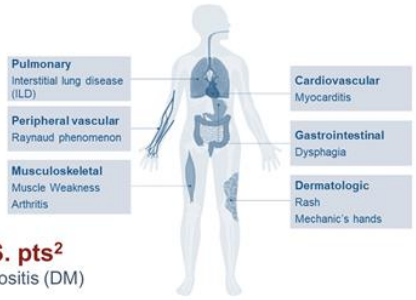
- Idiopathic inflammatory myopathies (IIMs, or myositis) are a group of autoimmune diseases characterized by inflammation and muscle weakness

2 High burden on function & quality of life[1]

- Typically, mid-adult onset & more common in females
- Symptoms may include weakness, fatigue, pain, shortness of breath and difficulty swallowing
- Mainstay of therapy is glucocorticoids with a steroid-sparing agent (i.e. methotrexate, azathioprine, rituximab), and increasing use of IVIg (intravenous immunoglobulin)
  - Many patients have disease that remains refractory
  - Therapies carry potential long-term side effects
- High mortality rate due to interstitial lung disease (ILD), cardiovascular disease and/or malignancy

Potential manifestations & subtype prevalence

Key myositis subtypes based on underlying immune mechanisms & clinical characteristics[1]



~43K U.S. pts[2]
Dermatomyositis (DM)

~17K U.S. pts[3,4]
Anti-synthetase syndrome (ASyS)

~6K U.S. pts[5]
Immune-mediated necrotizing myopathy (IMNM)

1. Lundberg, Ingrid E., et al. "Idiopathic inflammatory myopathies." Nature Reviews Disease Primers 7.1 (2021): 86.
2. Kronzer, Vanessa L., et al. "Incidence, Prevalence, and Mortality of Dermatomyositis: A Population-Based Cohort Study." Arthritis Care & Research 75.2 (2023): 348-355.
3. Badshah, Aliena, et al. "Antisynthetase syndrome presenting as interstitial lung disease: a case report." Journal of Medical Case Reports 13.1 (2019): 1-6.
4. Coffey, Caitryn, et al. "Incidence of Antisynthetase Syndrome and Risk of Malignancy in a Population-based Cohort (1998-2019)" [abstract]. Arthritis Rheumatol. 2021; 73 (suppl 9).
5. Shelly, Shahar, et al. "Incidence and prevalence of immune-mediated necrotizing myopathy in adults in Olmsted County, Minnesota." Muscle & Nerve 65.5 (2022): 541-546.

Phase 1/2 study design for CABA-201 in patients with myositis

CABA-201 to be evaluated in patients with active myositis, including DM, ASyS & IMNM

Phase 1/2 Study of CABA-201

Open label trial to evaluate CABA-201 in subjects with active idiopathic inflammatory myopathy (IIM, or myositis)

Parallel Cohorts

DM	ASyS	IMNM
(N = 6)	(N = 6)	(N = 6)

SCREENING → CABA-201 INFUSION → MONITORING → Next Patient

Dose of 1x10^6 cells/kg[1]

Equivalent to dose of 4-1BB-containing CD19-CAR T used in recent academic studies[2,3]

Study Endpoint & Objectives

Primary objective: Safety & tolerability of CABA-201 in subjects with active myositis within 28 days of infusion

Key secondary objectives include CABA-201 effects on:

- Myositis clinical disease activity;
- Myositis serology; and
- Pharmacokinetics / pharmacodynamics

Key Inclusion Criteria

- Age ≥ 18 to ≤ 65 years
- Evidence of active disease
- Disease activity despite prior or current treatment with standard of care treatments

Key Exclusion Criteria

- Cancer-associated myositis
- Significant lung or cardiac impairment
- Treatment with B cell depleting agent within ~6 months
- Treatment with biologic agent within ~3 months

Consistent track record of execution by team across multiple clinical studies evaluating novel cell therapy candidates for patients with autoimmune diseases

DM – Dermatomyositis; ASyS – Anti-synthetase syndrome; IMNM – Immune-mediated necrotizing myopathy

1. Subjects will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to a single dose CABA-201.
2. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.
3. Müller, Fabian, et al. "CD19-targeted CAR T cells in refractory antisynthetase syndrome." The Lancet (2023).

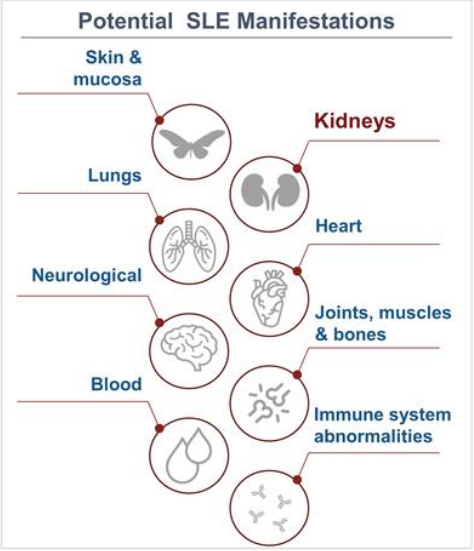
CABA-201

SLE & Lupus Nephritis: High unmet clinical need

Up to 320,000 SLE patients in the U.S., ~40% with LN, who face increased risk of kidney failure & death

SLE is a chronic autoimmune disease that affects ~160-320K[1] patients in the U.S. & over 3 million people worldwide[2]

- Potential for life-threatening complications
- Disproportionately affects
  - young women
  - people of color[3,4]
- Significant unmet need remains despite current therapies, which require chronic administration and carry significant treatment-related risks



Lupus nephritis (LN) is a serious complication of SLE, affecting ~40% of SLE patients[3]

- Within 10 years of LN diagnosis:
  - End-stage renal disease: 17%[3]
  - Mortality: 12%[5]
- Current therapies include steroids, immunosuppressive agents and biologics[3]
  - Many patients progress and/or relapse
  - Significant risk of adverse effects
  - Require long-term administration

1. Helmick CG, Felson DT, Lawrence RC, Gabriel S, Hirsch R, Kwoh CK, Liang MH, Kremers HM, Mayes MD, Merkel PA, Pillemer SR, Reveille JD, Stone JH; National Arthritis Data Workgroup. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part I. Arthritis Rheum. 2008 Jan;58(1):15-25.
2. Tian, J., Zhang, D., Yao, X., Huang, Y., & Lu, Q. (2023). Global epidemiology of systemic lupus erythematosus: a comprehensive systematic analysis and modelling study. Annals of the Rheumatic Diseases, 82(3), 351-356.
3. Hoover PJ, Costenbader KH. Insights into the epidemiology and management of lupus nephritis from the US rheumatologist's perspective. Kidney Int. 2016 Sep;90(3):487-92.
4. Lewis, M. J., & Jawad, A. S. (2017). The effect of ethnicity and genetic ancestry on the epidemiology, clinical features and outcome of systemic lupus erythematosus. Rheumatology, 56(suppl_1), i67-i77.
5. Hahn, B. H., Mcmahon, M. A., Wilkinson, A., Wallace, W. D., Daikh, D. I., Fitzgerald, J. D., ... & Grossman, J. M. (2012). American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. Arthritis care & research, 64(6), 797-808.

CABA-201

Phase 1/2 study design for CABA-201 in patients with SLE

CABA-201 to be evaluated in patients with active SLE with or without renal involvement

Fast Track Designation

Phase 1/2 Study of CABA-201

Open label trial to evaluate CABA-201 in subjects with active SLE

Parallel Cohorts

SLE with lupus nephritis (N = 6)	SLE without renal involvement (N = 6)

SCREENING → CABA-201 INFUSION → MONITORING → Next Patient

Dose of 1x10^6 cells/kg[1]

Equivalent to dose of 4-1BB-containing CD19-CAR T used in recent academic studies[2,3]

Study Endpoint & Objectives

Primary objective: Safety & tolerability of CABA-201 in subjects with SLE with active LN or SLE without renal involvement within 28 days of infusion

Key secondary objectives include CABA-201 effects on:

- SLE clinical disease activity, and
- SLE serology, as well as
- Pharmacokinetics / pharmacodynamics

Key Inclusion Criteria

- Age ≥ 18 to ≤ 65 years
- Clinical SLE per the 2019 EULAR/ACR classification criteria
- Positive ANA titer or anti-dsDNA antibody
- Disease activity despite prior or current treatment with standard of care

Key Exclusion Criteria

- Treatment with B cell depleting agent within 6 months
- Treatment with biologic agent within 3 months

Consistent track record of execution by team across multiple clinical studies evaluating novel cell therapy candidates for patients with autoimmune diseases

SLE – Systemic lupus erythematosus; EULAR – European League Against Rheumatism; ACR – American College of Rheumatology

1. Subjects will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to a single dose CABA-201.
2. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.
3. Müller, Fabian, et al. "CD19-targeted CAR T cells in refractory antisynthetase syndrome." The Lancet (2023).

Accelerating development of CABA-201 for autoimmune diseases

Our product candidate, people & partnership enable accelerated progress while integrating unique insights

Efficient clinical trial designs for CABA-201 facilitate rapid & broad development program

1 Product – Candidate with 4-1BB co-stim domain; similar binding activity to academic CD19-CAR T[1-4]

- Efficient clinical trial designs across multiple autoimmune diseases
  - CABA-201 fully human binder clinical tolerability profile based on use in ~20 oncology patients
  - 4-1BB co-stimulatory domain identical to that used in academic CD19-CAR T study[1,2]

2 People – Singular focus on potentially curative cell therapies for autoimmune disease since 2018

- Deep understanding and experience with logistically complicated cell therapy programs in autoimmune patients
  - Novel insights on clinical designs from prior FDA discussions and 4 timely submitted and cleared IND filings
  - Track record at a dozen US sites with implementation of complicated cell therapy logistics in autoimmune patients
  - Leadership with experience developing both SLE products that were FDA approved in the past 65 years

3 Partnership – Exclusive translational research partnership has provided early, actionable insights

- Scientific and clinical data sharing has significantly impacted our timelines as well as clinical strategy and design

SLE – Systemic lupus erythematosus

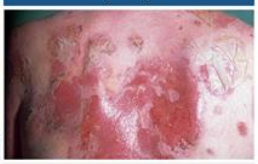
1. Peng, Binghao J, et al. "Preclinical specificity and activity of CABA-201, a fully human 4-1BB containing CD19 CAR T therapy for treatment-resistant autoimmune disease." Poster presented at: American Society Gene and Cell Therapy 26th Annual Meeting; 2023 May 19; Los Angeles, CA.
2. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human anti-CD19 chimeric antigen receptors for T-cell therapy." Journal of Cellular Physiology 236.8 (2021): 5832-5847.
3. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.
4. Müller, Fabian, et al. "CD19-targeted CAR T cells in refractory antisynthetase syndrome." The Lancet (2023).

Cabaletta Bio®

DSG3-CAART

Overview of pemphigus vulgaris & current treatment landscape

Current treatments require broad immunosuppression associated with safety risks and transient efficacy

	Mucosal PV[1] (25%)	Mucocutaneous PV[2] (75%)
		
Associated Antibody	**Anti-DSG3**	**Anti-DSG3 + Anti-DSG1**
Clinical Signs	Painful blisters of the mucous membranes (mouth, nose, larynx, esophagus, eyes, genitalia, rectum)	Blisters on orifices and skin
U.S. Disease Prevalence	**3,250 to 4,750**	**9,750 to 14,250**

CROT = 8+ weeks without lesions while off systemic therapy

Broad immunosuppression[3,6]

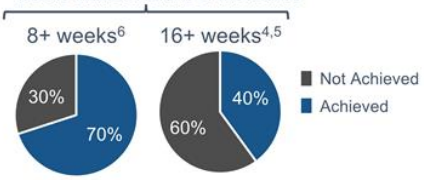
Modestly effective & poorly tolerated

Rituximab plus steroids (~3,500 mg/yr)[4]

Transient remission

~30% relapse in 1 year & >50% relapse in 2 years[6]

% of patients failing to achieve any 8+ or 16+ weeks without lesions or medicines



Safety risks

- 22% annual serious adverse event (SAE) rate[4]
- 4-9%[3,4,5] annual risk of severe infection in PV
- ~1.9% lifetime risk of fatal infection[7]

1. Image credit: D@nderm.
2. http://www.vgrd.org/archive/cases/2004/pv/DSCN4996%20copy.JPG
3. Joly, Pascal, et al. "First-line rituximab combined with short-term prednisone versus prednisone alone for the treatment of pemphigus (Ritux 3): a prospective, multicentre, parallel-group, open-label randomised trial." The Lancet 389.10083 (2017): 2031-2040.
4. Werth, Victoria P., et al. "Rituximab versus Mycophenolate Mofetil in Patients with Pemphigus Vulgaris." New England Journal of Medicine (2021).
5. Rituximab label, 08/2020 revision.
6. Kushner, Carolyn J., et al. "Factors Associated With Complete Remission After Rituximab Therapy for Pemphigus." JAMA dermatology (2019).
7. Tony, Hans-Peter, et al. "Safety and clinical outcomes of rituximab therapy in patients with different autoimmune diseases: experience from a national registry (GRAID)." Arthritis research & therapy 13.3 (2011): 1-14.

DSG3-CAART

Ongoing DesCAARTes™ study in patients with mucosal PV

Orphan Drug Designation

Fast Track Designation

Favorable tolerability to date, but only modest persistence increase observed with IVIg & Cy

DesCAARTes™ study of DSG3-CAART

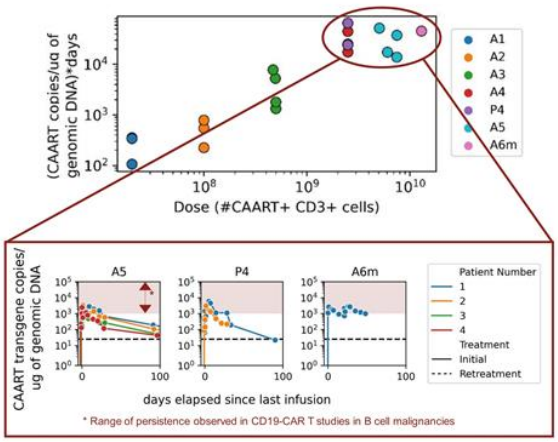
Ongoing open-label Phase 1 study to determine the maximum tolerated dose & to evaluate safety of DSG3-CAART

Cohorts	Combination (Pre-Treatment)	Dose*
A1 – A4	--	20M to 2.5B
A5	--	5 to 7.5B
A6m	--	Up to 15B
P4	IVIg / Cyclophosphamide (Cy)	2.5B
P4F	IVIg / Cy / Fludarabine (Flu)	2.5B

Primary objective:
Determine the maximum tolerated dose of DSG3-CAART

Primary endpoint:
Adverse events, including dose-limiting toxicities (DLTs), related to DSG3-CAART within 3 months of infusion

DSG3-CAART Peak Persistence[1]



Combination cohort (P4F) with fludarabine / Cy / IVIg currently enrolling and designed to evaluate the ability to improve DSG3-CAART engraftment & persistence

1. Volkov J, et al. "Correlative findings following DSG3-CAART infusion with & without combination preconditioning therapy in patients with Pemphigus Vulgaris (DesCAARTes study)." Poster presented at: American Society Gene and Cell Therapy 26th Annual Meeting; 2023 May 18; Los Angeles, CA.

* *20M, 2.5B, 5.0B to 7.5B and 10B to 15B refers to the number of DSG3-CAART cells infused for patients in dosing cohorts A1 to A6m (M – millions; B – billions).*

MuSK-CAART

High unmet need in MuSK myasthenia gravis

Study timelines being evaluated based on emerging data from DesCAARTes™ study

Orphan Drug Designation

Fast Track Designation

1 Compelling biologic rationale, similar to PV

- IgG4-dominant disease
- Autoantibody titers drop after rituximab[1,2]
- Pathogenic B cells incompletely eliminated by rituximab and persist during relapse[3]
- Circulating anti-MuSK antibody titers may be ~90% lower than anti-DSG3 antibody in PV[4,5,6]

2 Differentiated market opportunity

- Total U.S. MG prevalence 50,000 to 80,000 patients
- MuSK+ MG comprises 6-7.5% of total MG population
- Compared to AChR+ MG, MuSK+ disease is typically more severe with limited treatment options
- MuSK+ disease has early onset, 7:1 females

MusCAARTes™ study of MuSK-CAART

Ongoing open-label study to determine the maximum tolerated dose & to evaluate safety of MuSK-CAART

Part	Cohort	Subjects
A – Monotherapy Dose Escalation[7] Dose increasing from 500M with 2 (+4) design	A1-A3	2 (+4) per cohort
A – Adaptive Combination Cohorts[7] Combination cohorts[8], starting at A2 dose	A4+	2 (+4) per cohort
B – Expansion Expanded subject enrollment at final selected dose	B	~12

Study Endpoint & Objectives

Primary Endpoint: Adverse Events, including DLT

Secondary & Tertiary Objectives: CAART expansion/persistence, effect on serum anti-MuSK antibody titer, use of concomitant systemic medications, effect on clinical symptoms, manufacturing success rate

* 500M refers to the number of MuSK-CAART cells infused for patients in dosing cohort A1 (M – millions).

1. Hain, Berit, et al. "Successful treatment of MuSK antibody–positive MG with rituximab." Muscle & Nerve. 33.4 (2006): 575-580.
2. Illa, Isabel, et al. "Sustained response to Rituximab in anti-AChR and anti-MuSK positive Myasthenia Gravis patients." Journal of neuroimmunology 201 (2008): 90-94.
3. Jiang, Ruoyi, et al. "Single-cell repertoire tracing identifies rituximab-resistant B cells during myasthenia gravis relapses." JCI insight 5.14 (2020).
4. Matthews, Ian, et al. "Muscle-specific receptor tyrosine kinase autoantibodies—a new immunoprecipitation assay." Clinica chimica acta 348.1-2 (2004): 95-99.
5. McConville, John, et al. "Detection and characterization of MuSK antibodies in seronegative myasthenia gravis." Annals of neurology 55.4 (2004): 580-584.
6. Marino, Mariapaola, et al. "Long-lasting rituximab-induced reduction of specific—but not total—IgG4 in MuSK-positive myasthenia gravis." *Frontiers in immunology* 11 (2020): 613.

7. A total of 6 subjects will need to have received the final selected dose in Part A of the study.
8. Cohorts A3 and A4 will be enrolled concurrently after cohort A2 is well-tolerated with a preference for enrollment into A4.

Cabaletta Bio®

Manufacturing strategy

Three-stage approach allows for efficient allocation of capital while leveraging experienced partners

Stage 1: Penn	**Stage 2:** CDMOs & CABA Process	**Stage 3:** Commercialization & Scale-Up
2019 –	2021 –	Data-gated, staged investment
• Cell processing capacity secured through Penn partnership • SOPs previously used to develop multiple clinical stage CAR T products • Clinical vector validated	• CDMOs for vector and cell processing with commercial support capabilities Oxford Biomedica WuXi AppTec[1]	• Leasing followed by engineering and build out of Cabaletta-owned manufacturing facility, and/or • Establishment of a strategic partnership to rapidly & reliably scale manufacturing, leveraging the partner's manufacturing expertise Cabaletta Bio®

1. Currently contracted for MuSK-CAART product candidate.

Cabaletta Bio leadership

LEADERSHIP TEAM

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President, CEO & Chairman

MERCK · tengion · Penn

Samik Basu, M.D.
Chief Scientific Officer

Adaptimmune · MERCK

Gwendolyn Binder, Ph.D.
President, Science & Technology

Adaptimmune · Penn

David J. Chang, M.D., M.P.H., FACR
Chief Medical Officer

AstraZeneca · Penn

Arun Das, M.D.
Chief Business Officer

Goldman Sachs · Children's Hospital of Philadelphia

Michael Gerard
General Counsel

Spark · SANDOZ A Novartis Division

Heather Harte-Hall
Chief Compliance Officer

Adaptimmune · Pfizer

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Bristol-Myers Squibb

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Track record of operational success evaluating novel cell therapy candidates in autoimmunity across preclinical, clinical, manufacturing & regulatory domains

Cabaletta®: Pursuing cures for a broad range of autoimmune diseases

Leveraging years of experience with cellular therapy in autoimmunity to initiate CABA-201 clinical trials

CARTA Strategy | CABA-201 (4-1BB CD19-CAR T) to be evaluated in SLE & myositis Phase 1/2 studies

Advancing SLE & myositis trials with efficient designs – including starting dose & parallel cohorts

- *1.0 x 10^6 cells/kg initial dose of CABA-201 is identical to dose used in academic SLE[1] and myositis[2] studies*
- *Parallel cohorts with 6 patients each – SLE study with 1) LN & 2) Non-renal SLE; myositis study with 1) DM, 2) ASyS & 3) IMNM*

CABA-201 has been specifically engineered for patients with autoimmune diseases

- *Fully human CD19 binder with data in ~20 oncology patients – clinical safety profile supporting further evaluation in autoimmunity*
- *Same 4-1BB costimulatory domain and similar CD19 binder affinity[3] as used in the academic SLE[1] & myositis studies[2]*

Potential to cure a broad range of autoimmune diseases where B cells have a role initiating or maintaining disease

CAART Strategy | DSG3-CAART & MuSK-CAART clinical studies evaluating combination regimens

DesCAARTes™ trial of DSG3-CAART in mucosal pemphigus vulgaris

- *Enrolling in combination sub-study cohort using pre-treatment with IVIg, cyclophosphamide and fludarabine*

MusCAARTes™ trial in MuSK myasthenia gravis – leveraging insights from experience with DSG3-CAART

- *Initiated in 4Q22; received FDA Fast Track Designation & Orphan Drug Designation*

Initial CABA-201 3-month clinical efficacy and tolerability data expected by 1H24[4]

CARTA – Chimeric Antigen Receptor T cells for Autoimmunity; CAART – Chimeric AutoAntibody Receptor T cells; IND – Investigational New Drug; SLE – Systemic lupus erythematosus; DM – Dermatomyositis; ASyS – Anti-synthetase syndrome; IMNM – Immune-mediated necrotizing myopathy

1. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.
2. Müller, Fabian, et al. "CD19-targeted CAR T cells in refractory antisynthetase syndrome." The Lancet (2023).
3. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human anti-CD19 CARs for T-cell therapy." Journal of Cellular Physiology 236.8 (2021): 5832-5847.

4. Assumes no dose-limiting toxicities are observed in the cohort and uninterrupted enrollment occur in the trials.

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Corporate Presentation

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