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

March 31, 2023
Date of Report (Date of earliest event reported)

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 7.01 Regulation FD Disclosure.

On March 31, 2023, Cabaletta Bio, Inc. (the "Company") posted to the "Investors & Media" section of the Company's website at *www.cabalettabio.com* an updated corporate presentation providing a corporate overview and updated development plan (the "Corporate Presentation"). A copy of the Corporate Presentation is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

On March 31, 2023, the Company issued a Press Release announcing that the Company's Investigational New Drug ("IND") application for CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy, has been cleared by the U.S. Food and Drug Administration (the "FDA") (the "Press Release"). A copy of the Press Release is attached hereto as Exhibit 99.2 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On March 31, 2023, the Company issued the Press Release announcing that the Company's IND application for CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy, has been cleared by the FDA. The Company plans to initiate a Phase 1/2 clinical trial of CABA-201 for the treatment of systemic lupus erythematosus ("SLE") in patients with active lupus nephritis (LN) or active SLE without renal involvement.

SLE is a chronic, potentially severe, autoimmune disease, most commonly impacting young women between the ages of 15 and 40 with higher frequency and more severity in people of color, where the immune system attacks healthy tissue throughout the body. It is characterized by abnormal B cell function and autoantibody production resulting in a range of clinical manifestations including end organ damage and an increased risk of death. It affects an estimated 160,000-320,000 patients in the U.S. in total. LN is the most common end-organ manifestation of SLE, affecting approximately 40% of SLE patients. Among these patients, the risk of end-stage renal disease is approximately 17% and the risk of death is approximately 12%, each within 10 years of diagnosis.

CABA-201 is designed to be given as a one-time infusion, with the potential to transiently, but fully, eliminate B cells, thus enabling an "immune system reset" and durable remission in patients with SLE. The Phase 1/2 clinical trial is an open-label dose evaluation study designed to evaluate CABA-201 in SLE subjects with active LN or active SLE without renal involvement. Subjects will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to CABA-201 infusion. This represents the first trial that employs the Company's CARTA (Chimeric Antigen Receptor T cells for Autoimmunity) strategy. The Company expects to generate 3-month clinical data on efficacy endpoints and tolerability for patients dosed with CABA-201 by the first half of 2024.

Forward Looking Statements

The information under this Item 8.01 contains "forward-looking statements" of the Company within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, express or implied statements regarding expectations regarding: the Company's ability to grow its autoimmune-focused pipeline; the Company's business plans and objectives; the Company's expectations around the potential success and therapeutic benefits of CABA-201, including its belief that CABA-201 may enable an "immune system reset" and provide deep and durable remission in patients with SLE and potentially for patients diagnosed with other autoimmune diseases; the Company's plans to initiate a Phase 1/2 clinical trial of CABA-201 in patients with SLE, including its anticipated progress, clinical trial design, ability to leverage its experience in autoimmune cell therapy and lupus product development; the Company's planned initial clinical data read-out in the first half of 2024; and the Company's ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner in its Phase 1/2 clinical trial of CABA-201. Any forward-looking statements in this Item 8.01 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: the risk that signs of biologic activity or persistence may not inform long-term results; the Company's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of 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 Company's ability to protect and maintain its intellectual property position; risks related to fostering and maintaining successful relationships with the Company's collaboration and manufacturing partners; 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 the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in the Company's other and subsequent filings with the Securities and Exchange Commission. All information in this Item 8.01 is as of the date of this Current Report on Form 8-K, and the Company undertakes no duty to update this information unless required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Cabaletta Bio, Inc. Corporate Presentation, dated March 31, 2023, furnished herewith.
99.2	Press Release issued by the registrant on March 31, 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.

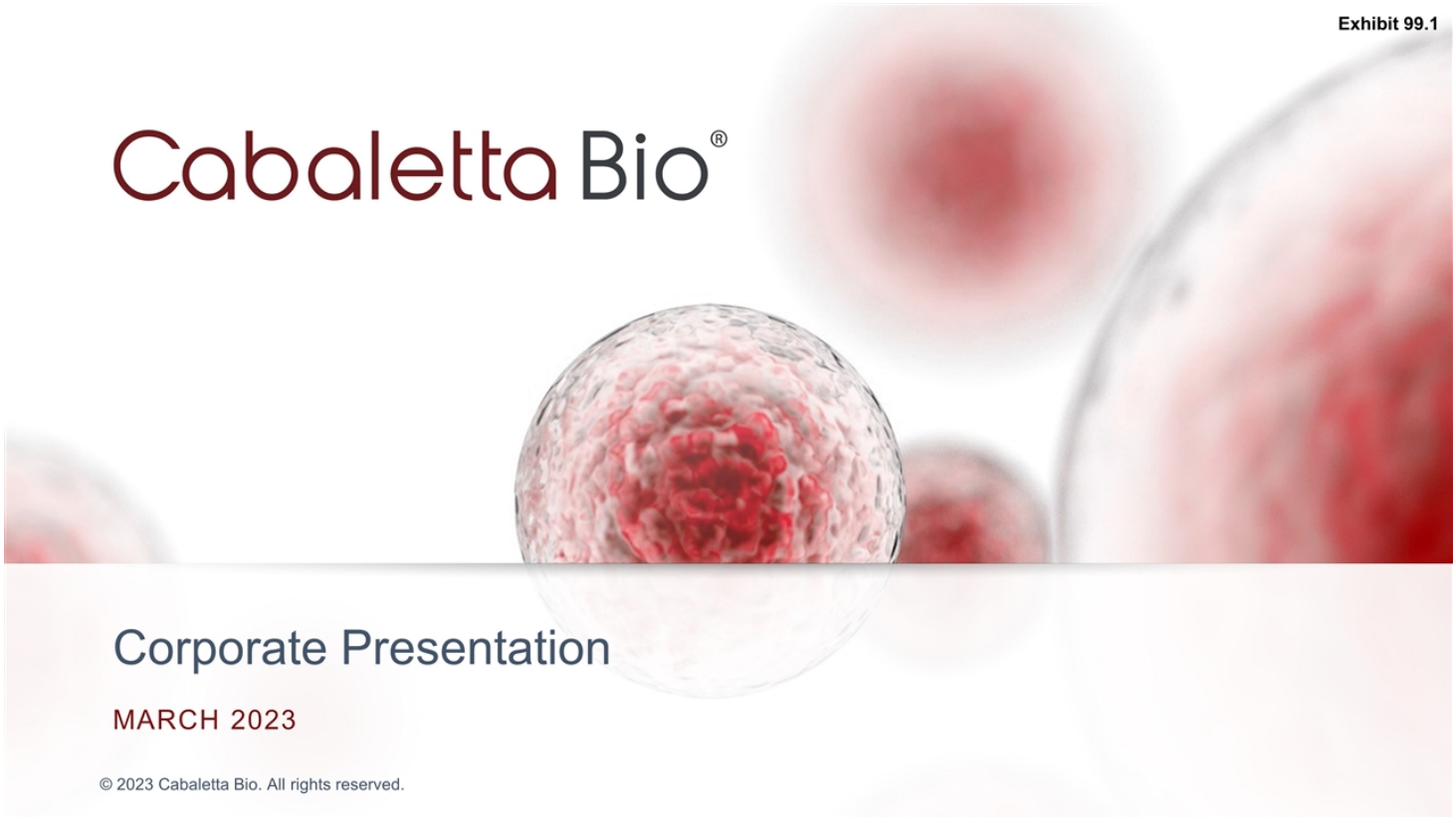
CABALETTA BIO, INC.

Date: March 31, 2023

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

Exhibit 99.1

Cabaletta Bio®



Corporate Presentation

MARCH 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 Systemic Lupus Erythematosus ("SLE") and potentially for patients diagnosed with other autoimmune disease; our plans to initiate 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; our planned initial clinical data read-out in the first half of 2024; our ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner in our Phase 1/2 clinical trial 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 and the potential ability to enhance in vivoDSG3-CAART exposure; the therapeutic potential and clinical benefits of our product candidates; the expectation that Cabaletta may improve outcomes for patients suffering from mucosal pemphigus vulgaris, myasthenia gravis, or other autoimmune diseases; our ability to escalate dosing as high as 10 to 15 billion cells in cohort A6m, initiate dosing in a combination cohort or otherwise; our ability to implement a pre-treatment regimen and the potential ability to enhance *in vivo* DSG3-CAART exposure; 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 CABA-201, our ongoing Phase 1 DesCAARTes™ trial, and our ongoing Phase 1 MusCAARTes™ trial of MuSK-CAART, 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 first 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 employed in the recent *Nature Medicine* publication 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

CABA-201 IND cleared for SLE +/- nephritis within 6 months of in-licensing binder for product candidate

CARTA Strategy | CABA-201 (4-1BB CD19-CAR T) IND cleared for Phase 1/2 study in SLE

- **CABA-201 has been specifically engineered for patients with autoimmune diseases**
  - *Same 4-1BB costimulatory domain and similar CD19 binder affinity[1] as used in the academic SLE[2] & myositis studies[3]*
  - *Fully human CD19 binder in CABA-201 clinically evaluated in ~20 oncology patients with safety profile appropriate for study in autoimmunity*
- **Efficient Phase 1/2 clinical trial design – including initial dose and dosing intervals between patients**
  - *Clinical trial informed by CABA-201 binder clinical safety data, prior autoimmune cell therapy INDs and exclusive translational partnership*
  - *CABA-201 will be evaluated in SLE patients with lupus nephritis (LN) and in SLE patients without renal involvement*
- **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 in mucosal pemphigus vulgaris – 1 month safety & persistence data anticipated 1H23[4]**
  - *Enrolling in combination sub-study using pre-treatment with IVIg & cyclophosphamide*
- **MusCAARTes™ trial in MuSK myasthenia gravis – leveraging insights from autoimmune experience with DSG3-CAART**
  - *Initiated in 4Q22; received FDA Fast Track Designation & Orphan Drug Designation*

Initial CABA-201 clinical data & 6-mo combination data from CAART trials expected by 1H24[4]

CAART – Chimeric AutoAntibody Receptor T cells; CARTA – Chimeric Antigen Receptor T cells for Autoimmunity; IND – Investigational New Drug; SLE – Systemic lupus erythematosus

1. 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.
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).

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

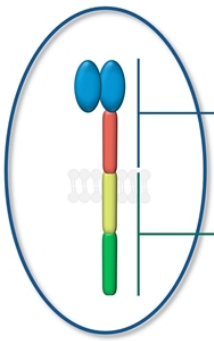
One CABA™ platform, two strategies to address autoimmune diseases

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

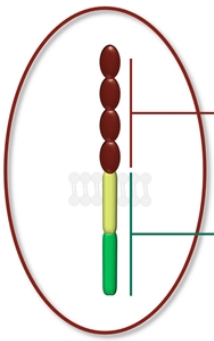
4-1BB Costimulatory Domain & CD3-Zeta Signaling Domain

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]
- Chronic Inflammatory Demyelinating Polyneuropathy[1,2]
- Anti-NMDAR Encephalitis[3,6]
- Lambert-Eaton Syndrome[5]

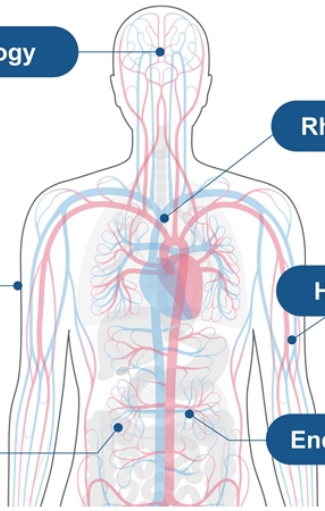
Rheumatology
- **Systemic Lupus Erythematosus**[3,4,5,6]
- Rheumatoid Arthritis[2,3,4]
- **Myositis**[5]
- **Systemic sclerosis**[6]
- ANCA-Associated Vasculitis[3,4,5]

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]

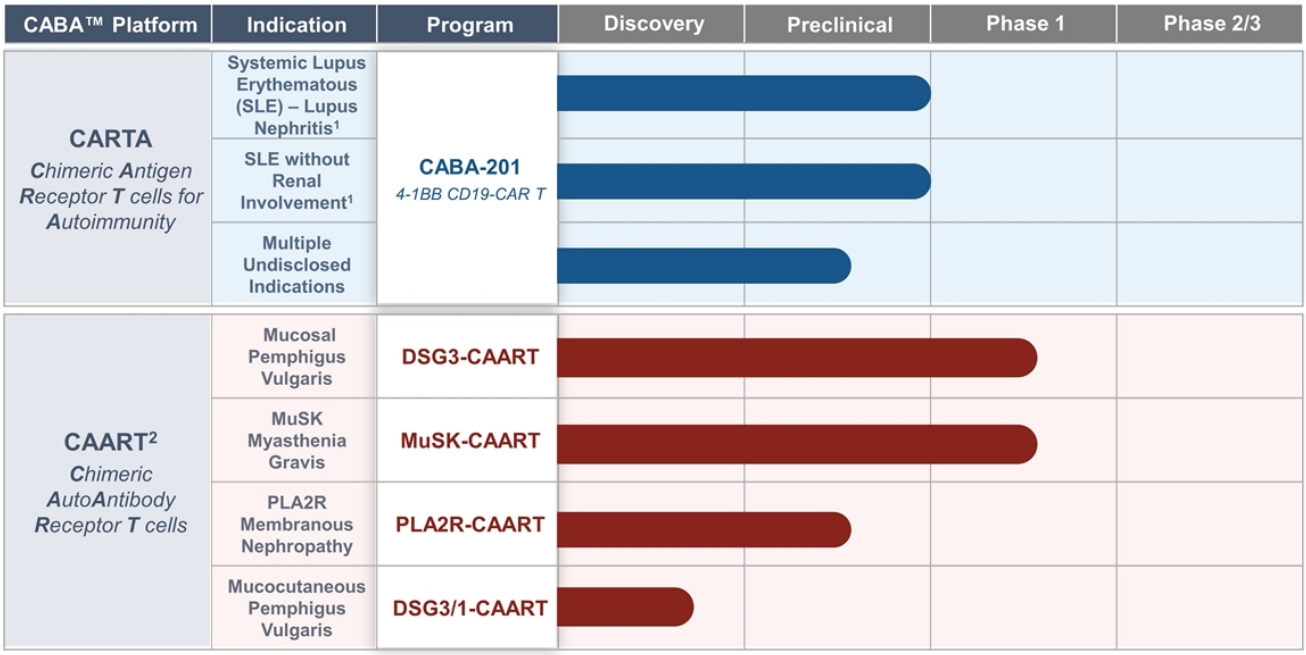
Endocrinology
- Type 1 Diabetes[3,6]
- Graves' Disease[3,5]
- Hashimoto's Disease[5]



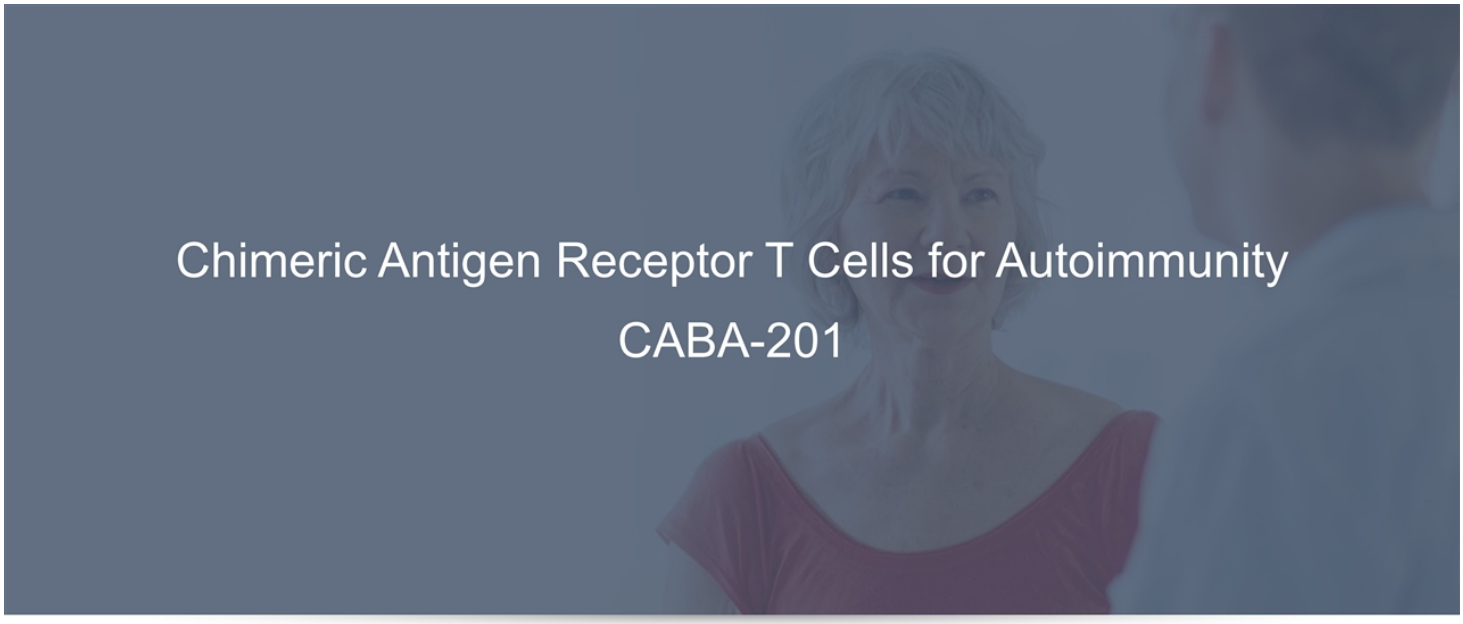
- *Illustrative list of autoimmune diseases where B cells may play a role in initiating or maintaining disease, and where biologic opportunity for cure or treatment with CAART or CARTA approach may be possible.*
- *Diseases **in bold** represent where clinical studies are underway or plan to be initiated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



1. Being evaluated in a single clinical trial for CABA-201.
2. Additional CAART disease targets in discovery stage include two undisclosed indications.



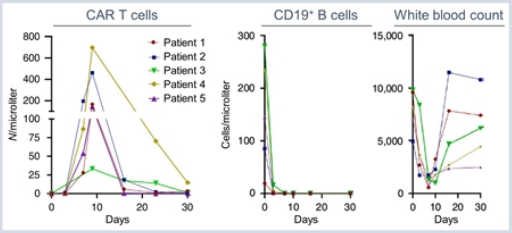
Cabaletta Bio®

Academic data: Immune system reset in SLE & myositis patients[1,2]

Exclusive translational research partnership with lead investigator informing our CD19 clinical strategy

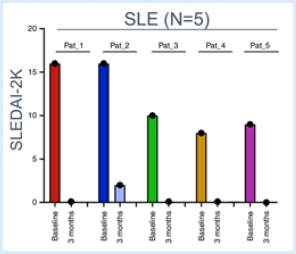
4-1BB CD19-CAR T[3] resulted in rapid, deep & transient CD19+ B cell depletion

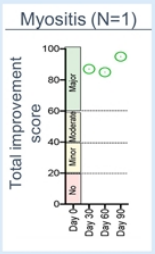
- 1x10^6 cells/kg preceded by standard Flu/Cy regimen
- CD19 binder (FMC63 scFv) & 4-1BB costim domain[3]



Clinical & serologic responses within 3 mo. of CD19-CAR T therapy in refractory patients with SLE[1] & patient with myositis[2]

Rapid & robust improvement in clinical disease activity





Normalization of serum markers of disease

5/5 SLE patients

- Anti-dsDNA Abs undetectable
- Complement levels normalized

Myositis patient (anti-synthetase syndrome):

- Creatinine kinase dropped to normal

Promising safety data[1,2]

- Grade 1 CRS (fever) in 4/6 patients
- No ICANS of any grade

Repopulation of healthy B cells[1,2]

- New B cells in 6/6 patients in 2-5 months
- Limited decline in vaccination titers

Durable clinical responses[1,2]

- 5-17 months of follow up
- Off other immunosuppressive medications

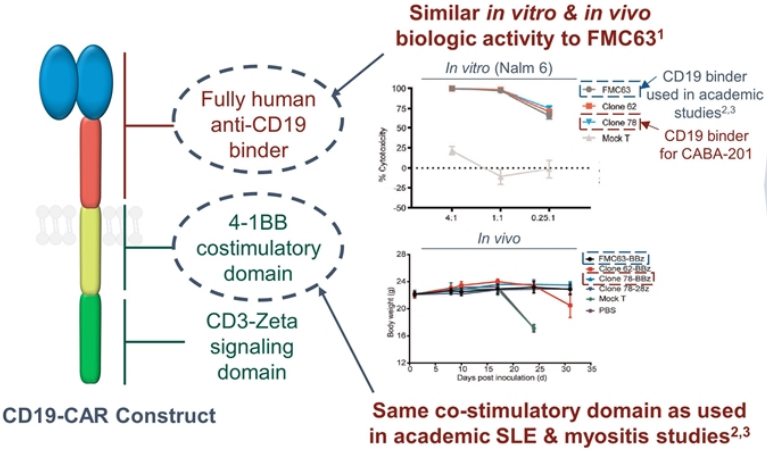
SLE – Systemic lupus erythematosus; ASyS – Anti-synthetase syndrome; scFv – Single chain variable fragment; SLEDAI-2K – Systemic Lupus Erythematosus Disease Activity Index 2000; CRS – Cytokine release syndrome; ICANS – Immune effector cell-associated neurotoxicity syndrome; Anti-dsDNA Abs – Anti-double-stranded deoxyribonucleic acid antibodies

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. The construct utilized in this study 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] (binder used in academic studies[2,3])

CABA-201



Clinical data reported by Iaso using licensed CD19 binder[4]

- **Fully human binder**
  Evaluated within dual-CAR combined with CD22 binder with standard Flu/Cy preconditioning
- **Data reported in ~20 patients to date[4]**
  B cell leukemia and lymphoma in IIT in China
- **Safety data supports autoimmune development[4]**

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

1. 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.
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).
4. Evaluated as part of CT120, a dual-CD19xCD22 CAR T product candidate under development by Nanjing IASO Biotherapeutics, Co., Ltd. (IASO Bio).

CABA-201

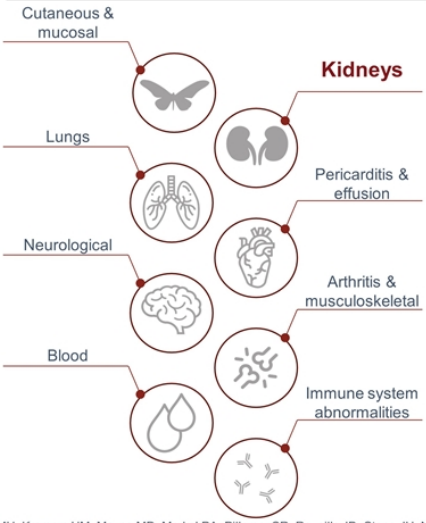
SLE & Lupus Nephritis: unmet clinical need

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

SLE is a chronic autoimmune disease that affects ~160-320k[1], typically young U.S. patients - and over 3 million people worldwide[2]

- Widespread, chronic inflammation and tissue damage which can affect virtually any organ system
- Potential for life-threatening complications
- Disproportionately affects
  - young women
  - people of color[3,4]

Potential SLE Manifestations



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]**

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

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

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

Phase 1/2 Study of CABA-201

Open Label, Dose Evaluation to evaluate CABA-201 in subjects with
1) SLE with active LN or 2) SLE without renal involvement

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

Part A key secondary objectives include CABA-201 effects on:
- SLE clinical disease activity, and
- SLE serology, as well as
- Pharmacokinetics / pharmacodynamics

Efficient Study Design

1. **Initial dose to be evaluated[1]**
2. **Patient dosing intervals**

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
- Previous CAR T therapy

Timely IND clearance supports anticipated milestone to generate 3-month clinical efficacy endpoint and tolerability data for patients dosed with CABA-201 by 1H24

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 infusion.

Accelerating development of CABA-201 for autoimmune diseases

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

Efficient clinical trial design for CABA-201 facilitates rapid and broad development program

1. **Product – Candidate with 4-1BB co-stim domain; similar binding activity to academic CD-19 CAR T**[1,2,3]
   - 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 complicated cell therapy programs in autoimmune patients
     - Novel insights on clinical designs from prior FDA discussions and three 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 provided early and actionable insights**
   - Scientific and clinical data sharing has already impacted our clinical strategy and design

SLE – Systemic lupus erythematosus

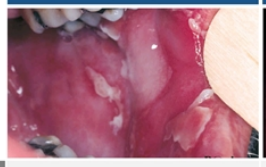
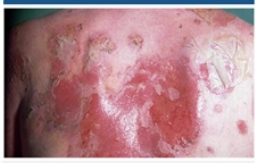
1. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human anti-CD19 chimeric antigen receptors for T-cell therapy." Journal of Cellular Physiology 236.8 (2021): 5832-5847.
2. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus."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

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]

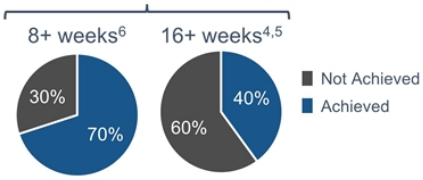
Modestly effective & poorly tolerated

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

Monotherapy DSG3-CAART demonstrates favorable tolerability to date, but persistence plateaus

DesCAARTes™ study of DSG3-CAART

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

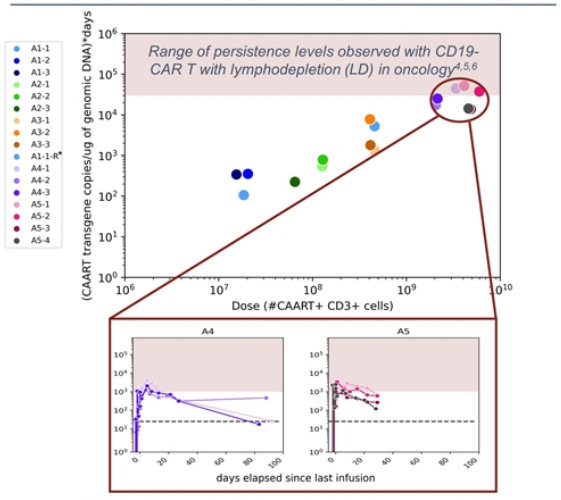
Part A Cohorts[1]	Subjects	Dose*
A1 – A6m[2,3]	3 (+3) per cohort	20M to 15B

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

Combination Sub-study	Subjects	Dose*
IVIG / Cyclophosphamide[3]	3 (+3) per cohort	2.5B

DSG3-CAART Persistence to 29d in Cohorts A1-A5



* *A1-1-R refers to a subject in cohort A1 who was retreated at the cohort A3 dose (500M).*

1. FDA has requested, and the Company has agreed, that we will share data from part A to inform a discussion on the optimal design of part C. According to FDA advice, the submission of part A data is not gating to planned enrollment in part B.
2. Cohort A6m reflects a two-dose regimen of 5.0 to 7.5 billion cells, 3 weeks apart, for a total of 10 to 15 billion cells, which is designed to prolong exposure time of DSG3-CAART *in vivo*.
3. Combination cohort has been prioritized relative to A6m based on emerging data in cohorts A4 and A5.
4. Mueller, Karen Thudium, et al. "Cellular kinetics of CTL019 in relapsed/refractory B-cell acute lymphoblastic leukemia and chronic lymphocytic leukemia." Blood. 130.21 (2017): 2317-2325.
5. Schuster SJ, Bishop MR, Tam CS, et al. Tisagenlecleucel in Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma. N Engl J Med. 2019;380(1):45-56. doi:10.1056/NEJMoa1804980.
6. The range of persistence observed with anti-CD19 CART therapy in oncology has not been confirmed to be necessary or sufficient for clinical responses in patients with mPV.

* *20M, 100M, 500M, 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).*

DSG3-CAART

Combination sub-study prioritized to increase CAART exposure

Combination strategy designed to enhance cytokine and/or diminish autoantibody effects on CAART activity

Combination sub-study cohort

A4 dose (2.5x10^9 cells) + cyclophosphamide (CY) & IVIg

- Dose-dependent increase in CAART persistence as monotherapy plateaued with Cohort A5
  - no clear pattern in antibody levels and disease activity observed in cohort A5 dose
- CY + IVIg preconditioning regimen may:
  - reduce anti-DSG3 autoantibodies, addressing a potential efficacy barrier
  - reduce 'cytokine sink,' potentially enhancing CAART activation & proliferation
  - provide transient improvement in first few months after infusion[1,2,3,4,5]
    - which may require 6-9 months to determine DSG3-CAART clinical effect

Cohort A6m | *2x A5 dose (1-1.5x10^{10} cells) – lower priority*

- Two infusions at the A5 dose level 3 weeks apart
  - To potentially increase the duration of maximal exposure to DSG3-CAART

1. Amagai, Masayuki, et al. "A randomized double-blind trial of intravenous immunoglobulin for pemphigus." Journal of the American Academy of Dermatology 60.4 (2009): 595-603.
2. Arnold, D. F., et al. "An 'n-of-1'placebo-controlled crossover trial of IVIg as adjuvant therapy in refractory pemphigus vulgaris." British Journal of Dermatology 160.5 (2009): 1098-1102.
3. Zhang, Wenjing, et al. "Short-Term Intravenous Infusion of Cyclophosphamide in the Treatment of Refractory Pemphigus Vulgaris: A Retrospective Study." Dermatology 237.2 (2021): 185-190.
4. Fleischli, Mary E., Rachel H. Valek, and Amit G. Pandya. "Pulse intravenous cyclophosphamide therapy in pemphigus." Archives of dermatology 135.1 (1999): 57-61.
5. Lolis, Margarita, et al. "Effect of IVIg with or without cytotoxic drugs on pemphigus intercellular antibodies." Journal of the American Academy of Dermatology 64.3 (2011): 484-489.

MuSK-CAART

High unmet need in MuSK myasthenia gravis

Strategy for first-in-human trial informed by learnings 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[1] OxfordBioMedica WuXi AppTec	• 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. CDMOs shown are currently contracted for select CAART product candidates.

Cabaletta Bio leadership

LEADERSHIP TEAM

Steven Nichtberger, M.D.
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

Anup Marda
Chief Financial Officer

Bristol-Myers Squibb

Martha O'Connor
Chief HR Officer

Bristol-Myers Squibb
accentureconsulting

BOARD OF DIRECTORS

Steven Nichtberger, M.D.
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Scott Brun, M.D.
Richard Henriques, M.B.A.
Mark Simon, M.B.A.

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Carl June, M.D.
Iain McInnes, Ph.D., FRCP, FRSE, FMedSci
Michael C. Milone, M.D., Ph.D.
Co-Founder and Co-Chair
Georg Schett, M.D.
Jay Siegel, M.D.
Drew Weissman, M.D., Ph.D.

Track record of operational success employing novel cell therapies in autoimmunity across preclinical, clinical, manufacturing & regulatory domains

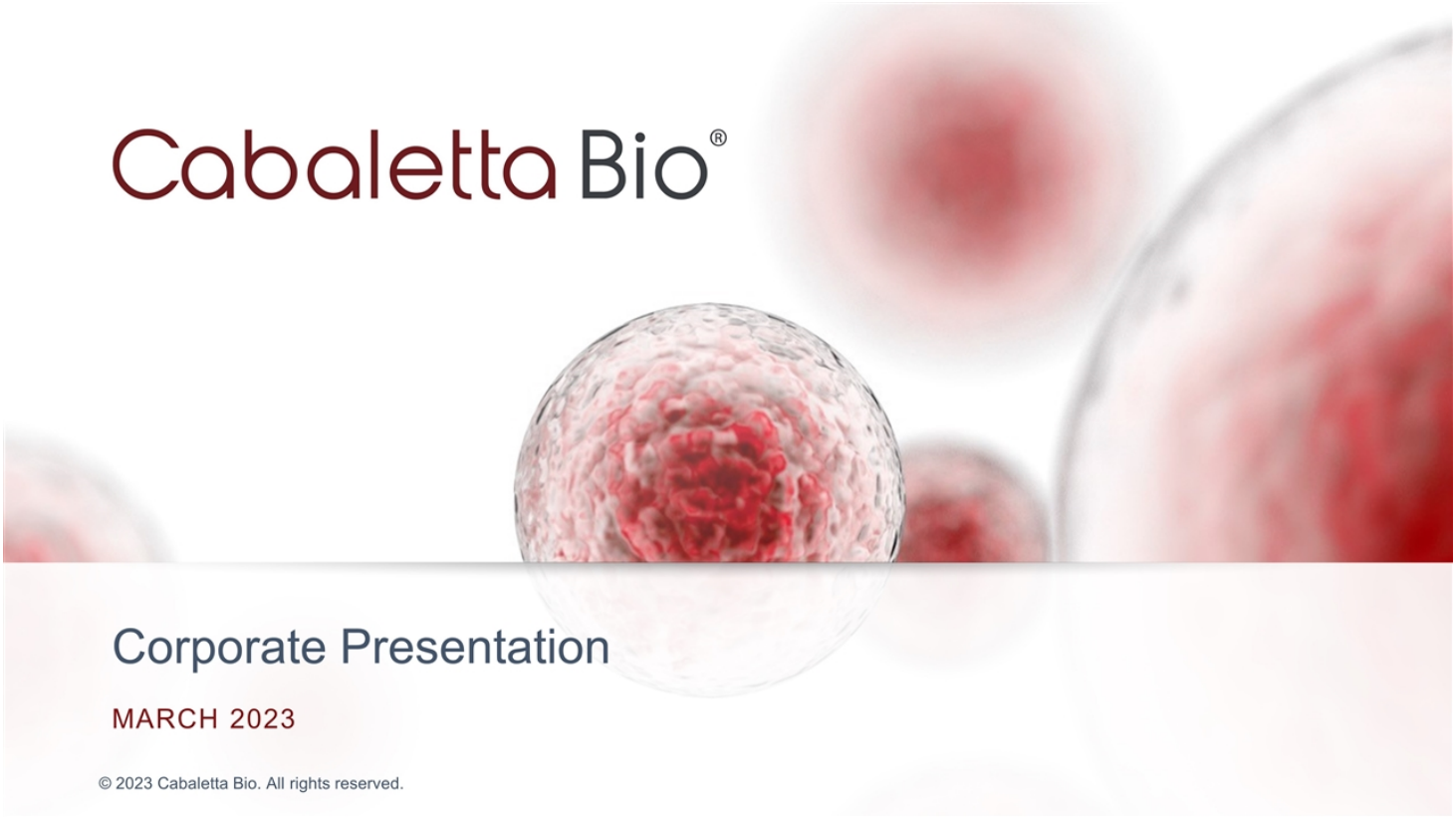
Multiple potential clinical catalysts anticipated in next 12-18 months[1]

	Expected Timing	Expected Milestone
CABA-201 *4-1BB CD19-CAR T*	1H 2023	IND clearance ✓
	1H 2024	Initial clinical data
DSG3-CAART *Mucosal-dominant pemphigus vulgaris*	1H 2023	1-month safety & persistence data for combination cohort in DesCAARTes™ trial
	2H 2023	6-month data for combination cohort
MuSK-CAART *MuSK-associated myasthenia gravis*	4Q 2022	Initiate first-in-human MusCAARTes™ trial ✓
	1H 2024	6-month data for combination cohort

Cash runway into 1Q25

1. Assumes no dose-limiting toxicities are observed in any cohort and uninterrupted enrollment occurs in the trials.

Cabaletta Bio®



Corporate Presentation

MARCH 2023

Exhibit 99.2

Cabaletta Bio®

Cabaletta Bio Receives FDA Clearance of IND Application for CABA-201 for Treatment of Systemic Lupus Erythematosus

- IND application cleared within 6 months of in-licensing CABA-201 binder

- CABA-201 data package and experience from prior autoimmune cell therapy INDs informed Phase 1/2 clinical trial design, including the initial dose to be evaluated and the patient dosing intervals

PHILADELPHIA, March 31, 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 that the Company's Investigational New Drug (IND) application for CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy, has been cleared by the U.S. Food and Drug Administration (FDA). The Company plans to initiate a Phase 1/2 clinical trial of CABA-201 for the treatment of systemic lupus erythematosus (SLE) in patients with active lupus nephritis (LN) or active SLE without renal involvement.

"We believe the clearance of this IND application within 6 months of licensing the binder for CABA-201 is an important milestone for patients with autoimmune disease. The efficient clinical trial design was informed by the data package we submitted, including clinical safety data with the CABA-201 binder, our experience from prior autoimmune cell therapy IND applications and our exclusive translational research partnership with the senior author of the *Nature Medicine* paper, which demonstrated 5/5 durable remissions throughout the follow-up period up to 17 months in patients with refractory SLE," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "The Phase 1/2 clinical trial will begin in patients with either active LN or SLE without renal involvement. Based on its similarity to the product used in the *Nature Medicine* paper, we believe CABA-201 has the potential to provide deep and durable responses for patients with SLE and possibly other autoimmune diseases where B cells play a role to initiate or sustain disease pathology. By achieving a timely IND clearance, we believe we are well positioned to generate 3-month clinical data on efficacy endpoints and tolerability for patients dosed with CABA-201 by the first half of 2024."

SLE is a chronic, potentially severe, autoimmune disease, most commonly impacting young women between the ages of 15 and 40 with higher frequency and more severity in people of color, where the immune system attacks healthy tissue throughout the body. It is characterized by abnormal B cell function and autoantibody production resulting in a range of clinical manifestations including end organ damage and an increased risk of death. It affects an estimated 160,000-320,000 patients in the U.S. in total. LN is the most common end-organ manifestation of SLE, affecting approximately 40% of SLE patients. Among these patients, the risk of end-stage renal disease is approximately 17% and the risk of death is approximately 12%, each within 10 years of diagnosis.

CABA-201 is designed to be given as a one-time infusion, with the potential to transiently, but fully, eliminate B cells, thus enabling an "immune system reset" and durable remission in patients with SLE. The Phase 1/2 clinical trial is an open-label dose evaluation study designed to evaluate CABA-201 in SLE subjects with active LN or active SLE without renal involvement. Subjects will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to CABA-201 infusion. This represents the first trial that employs Cabaletta's CARTA (Chimeric Antigen Receptor T cells for Autoimmunity) strategy.

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 lupus nephritis and systemic lupus erythematosus without renal involvement, 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 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 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 Professor Georg Schett and the exclusive license agreement with IASO Bio; the Company's business plans and objectives; Cabaletta Bio's expectations around the potential success and therapeutic benefits of CABA-201, including its belief that CABA-201 may enable an "immune system reset" and provide deep and durable responses for patients with SLE and potentially for patients diagnosed with other autoimmune disease; the Company's plans to initiate a Phase 1/2 clinical trial of CABA-201 in patients with SLE, including its anticipated progress, clinical trial design, ability to leverage its experience in autoimmune cell therapy and lupus product development; the Company's planned initial clinical data read-out in the first half of 2024; Cabaletta's ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner in its Phase 1/2 clinical trial of CABA-201; and 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.

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: 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* publication 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 and 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:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com

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