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 3, 2022
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 3, 2022, 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.

The information contained in Item 7.01 of this Current Report onForm 8-K, including Exhibit 99.1 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Cabaletta Bio, Inc. Corporate Presentation, dated March 3, 2022, 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.

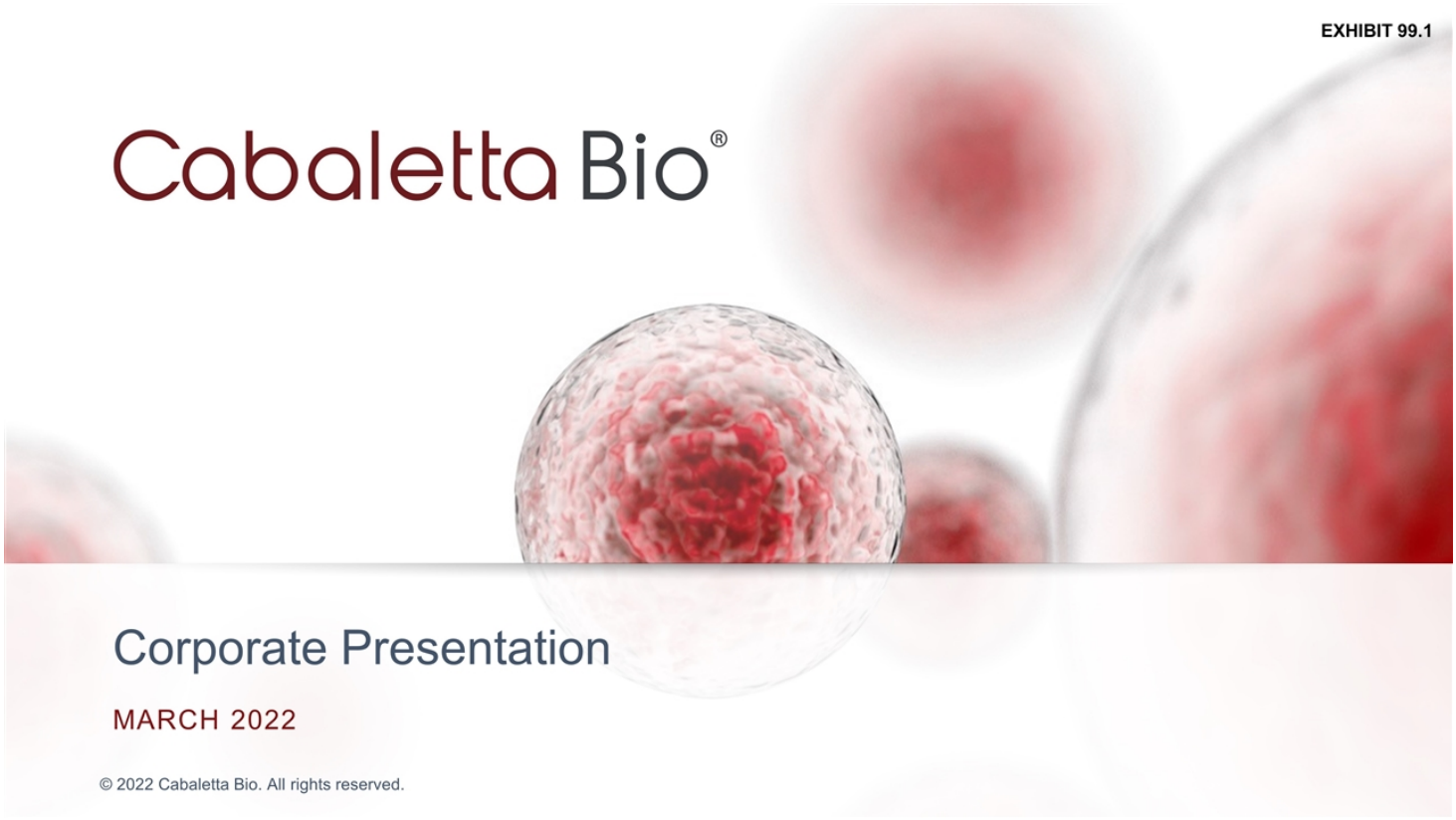
CABALETTA BIO, INC.

Date: March 3, 2022

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

EXHIBIT 99.1

Cabaletta Bio®



Corporate Presentation

MARCH 2022

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 technology and CABA™ platform; the progress and results of our DesCAARTes™ Phase 1 trial, including our ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the trial; the expected announcement of additional biologic activity data for the third and fourth dose cohorts in mid-2022 as well as the 28-day safety data for the fifth dose cohort in mid-2022; the therapeutic potential and clinical benefits of our product candidates; our ability to successfully complete our preclinical and clinical studies for our product candidates, including our ongoing Phase 1 DesCAARTes™ trial, our planned clinical trial of MuSK-CAART and other discovery programs; our ability to obtain and maintain regulatory approval of our product candidates, including our expectations regarding the intended incentives conferred by Fast Track Designation for MuSK-CAART to improve activities of daily living and muscle strength in patients with MuSK antibody-positive myasthenia gravis; 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 through at least the first quarter of 2023. 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 and clinical trials of DSG3-CAART and MuSK-CAART, 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, 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 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 overview

Developing highly specific CAAR T products to treat B cell-mediated autoimmune diseases

- Targeting diseases with a biologic opportunity for deep and durable, perhaps curative, responses
- Leveraging a clinically validated CAR T product design and manufacturing process through Penn alliance

DesCAARTes™ trial in patients with mucosal pemphigus vulgaris (mPV) ongoing

- No DLTs observed in first 4 dose cohorts (20M, 100M, 500M & 2.5B cells)
  - Without lymphodepletion and in patients with circulating anti-DSG3 antibodies
- No clear evidence of biologic activity observed in the first 2 low dose cohorts (20M and 100M) as of 12/12/21
  - Using doses that are <2% of the currently planned maximum dose
- Dose dependent increase in DSG3-CAART persistence was observed in 3rd cohort during 28 days post infusion
  - Dose escalation plan includes up to 375x fold dose increase (20M to 7.5B) across 5 cohorts

Cell therapy pipeline[1] targeting diseases that affect over 80,000 U.S. patients

- MuSK-CAART for MuSK myasthenia gravis – IND cleared by FDA, ongoing preparations for trial initiation in 2022
  - FDA Fast Track Designation granted in Feb 2022 to improve ADL[2] and muscle strength in patients with MuSK MG
- PLA2R-CAART pre-IND interaction with FDA completed in 4Q21 for PLA2R positive primary membranous nephropathy patients

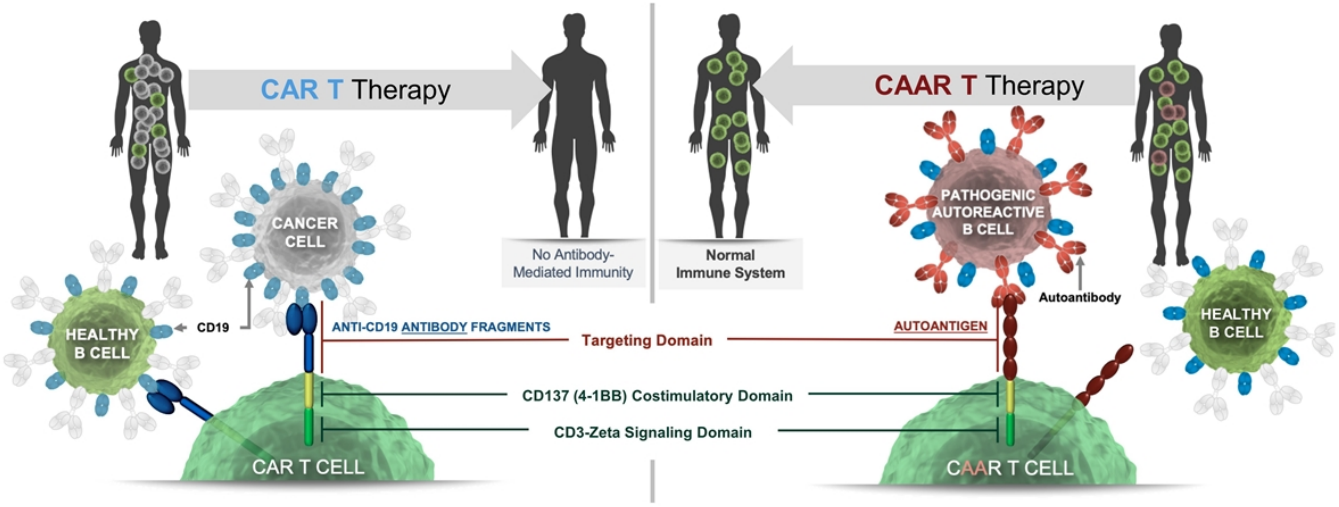
Cash runway through at least 1Q23 with $119.3M in cash and investments at the end of 3Q21

** 20M, 100M, 500M, and 2.5B and 5.0B to 7.5B refers to the number of DSG3-CAART cells infused for patients in dosing cohorts 1 to 5 (M – millions; B – billions).*

1. Includes five disclosed product candidates and two undisclosed pipeline disease targets in our pipeline.
2. Activities of Daily Living

Our scientific platform leverages clinically validated CAR T technology

CAAR T product candidates are designed for selective and specific elimination of the pathogenic B cells



Chimeric **A**ntigen **R**eceptor **T** cell

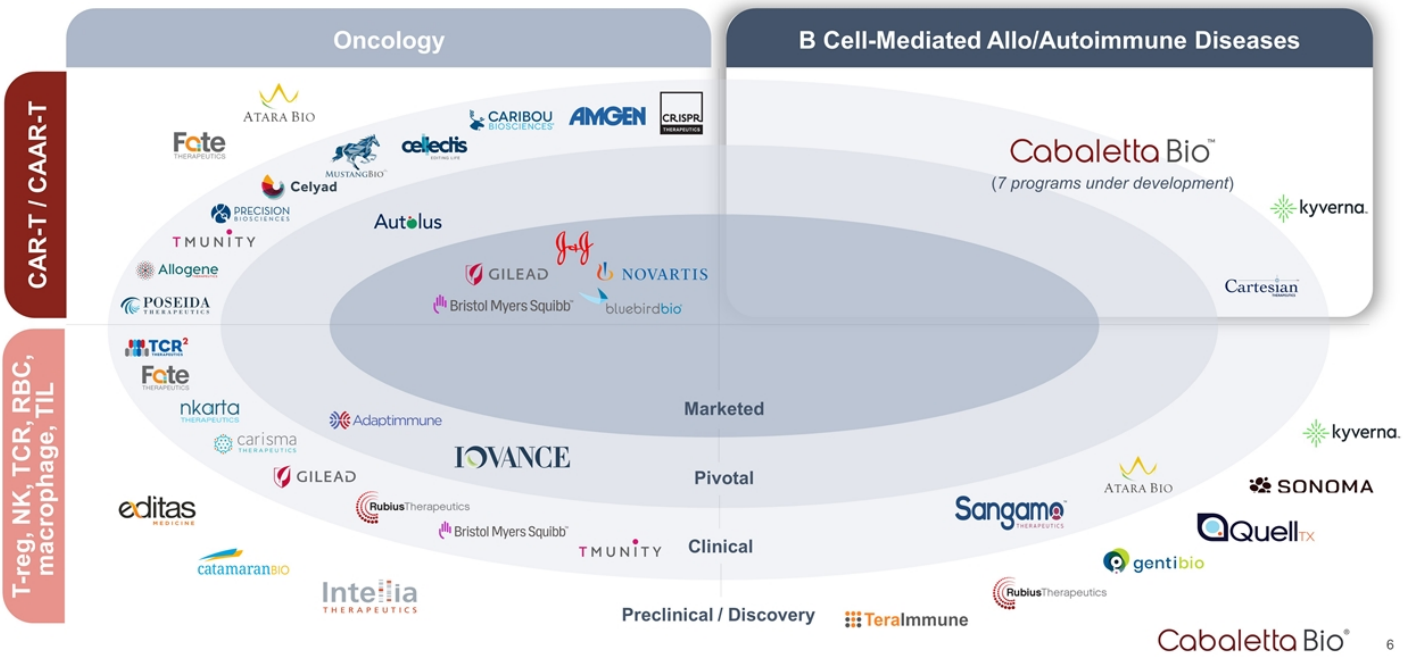
Kymriah

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

CABA CAAR T

Cabaletta: Advancing targeted cell therapy to autoimmunity

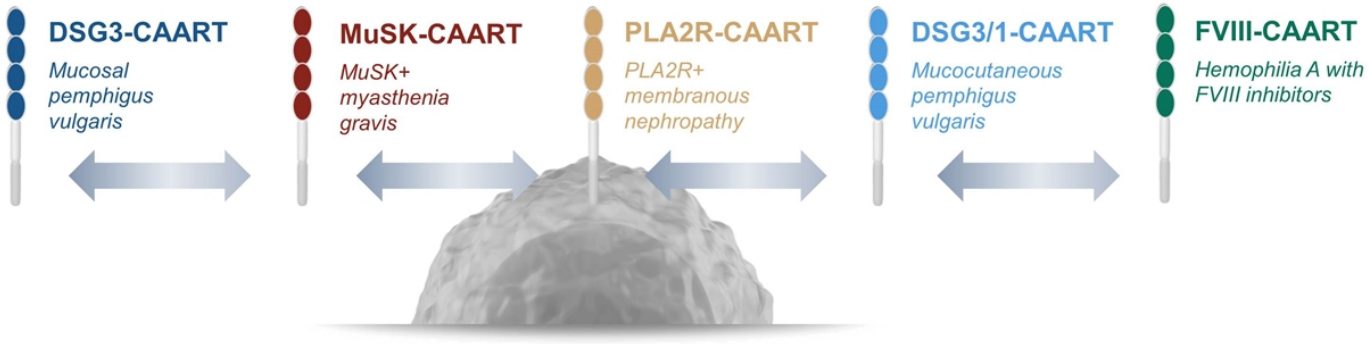
Foundational CAR T technology clinically validated in treating B cell-mediated cancers



Modular platform with “plug-and-play” architecture

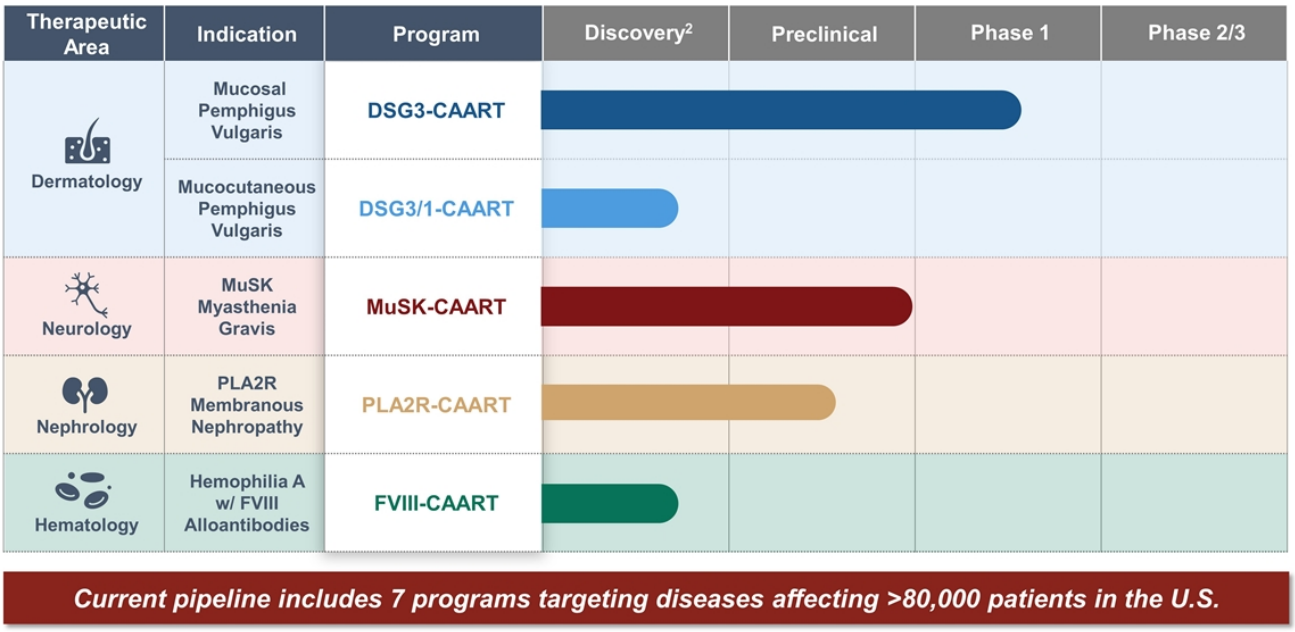
CABA™ platform designed to enable a portfolio of programs targeting B cell-mediated diseases

Swapping the extracellular domain, or autoantigen, creates **new product candidates**



Clinically validated engineered T cell platform is the foundational technology

Pipeline[1] includes multiple disease targets where cure is possible



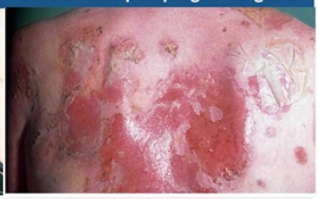
Current pipeline includes 7 programs targeting diseases affecting >80,000 patients in the U.S.

1. Two additional undisclosed disease targets currently in discovery stage are not shown in our pipeline portfolio.
2. In our discovery stage, we perform epitope mapping and optimize CAAR construct and design.

Cabaletta Bio®

Overview of pemphigus vulgaris

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

	Mucosal PV[1] 25% of U.S. pemphigus vulgaris	Mucocutaneous PV[2] 75% of U.S. pemphigus vulgaris
		
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
US Disease Prevalence	**3,250 to 4,750**	**9,750 to 14,250**

Current Treatment Landscape

Broad immunosuppression[3,6]

- Modestly effective
- Poorly tolerated

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

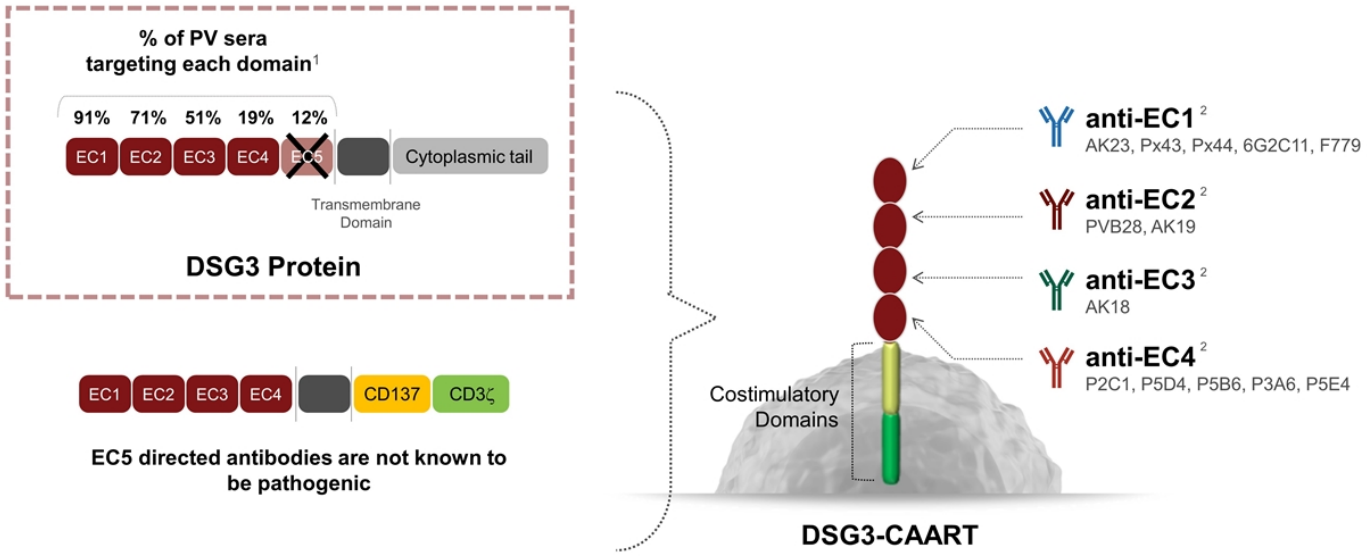
- Response: ~40% of patients achieved a 16-week period with no lesions or medicines during 1 yr[4,5]
- 22% annual serious adverse event (SAE) rate[4]
  - 4-9%[3,4,5] annual risk of severe infection in PV
- Real world data indicate:
  - *Transient* remission ~ 70% CROT[6]:
    - ~30% relapse in 1 year[6]
    - >50% relapse within 2 years[6]
  - ~30% never achieve CROT[6]
  - ~1.9% lifetime risk of fatal infection[7]

CROT = 8+ weeks without lesions while off systemic therapy

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 is designed to bind all known pathogenic autoantibodies

Inclusion of all disease-relevant epitopes enables a ‘one-size-fits-all’ approach for patients with mPV



1. Ohyama, Bungo, et al. "Epitope spreading is rarely found in pemphigus vulgaris by large-scale longitudinal study using desmoglein 2–based swapped molecules." Journal of investigative dermatology 132.4 (2012): 1158-1168.
2. Antibodies that target the specific extracellular domain are shown below each extracellular domain.

DesCAARTes™ study of DSG3-CAART

Phase 1 trial in patients with mPV evaluating up to 375x dose range (20M up to 7.5B cells)

Orphan Drug Designation

Fast Track Designation

Open-label study to determine the maximum tolerated dose & fractionation of DSG3-CAART

Major Inclusion Criteria

- Age: ≥18
- Inadequately managed by standard immunosuppressive therapies
- Confirmed diagnosis
- Active disease
- Anti-DSG3 antibody positive

Major Exclusion Criteria

- Rituximab recently administered
- Prednisone > 0.25 mg/kg/day
- Other autoimmune disorder requiring immunosuppressive therapies
- Recent investigational treatment
- ALC < 1,000 at screening

SCREENING → MANUFACTURING → TREATMENT → MONITORING (UP TO 4 WEEKS) → Next Patient

Part	Cohort	# Subjects
A – Dose Escalation (up to 375x dose increase) Fractionated infusion at increasing dose levels	A1-A5	3 (+3) per cohort
B – Dose Consolidation Consolidating selected dose fractions into a single infusion	B1-B2	3 (+3) per cohort
C – Expansion[1] Expanded subject enrollment at final selected dose	C	~12
	Total	**~33 (+18)**

Study Endpoint & Objectives

Primary Endpoint: Adverse Events, including Dose Limiting Toxicity (DLT)

- DLTs include any grade 3 or 4 CRS or neurotoxicity, or any Grade 2 CRS or neurotoxicity that failed to improve to ≤ Grade 1 or baseline within 7 days

Secondary Objectives: DSG3 ELISA level changes, CAAR T expansion/persistence, change in PDAI, change in ODSS, use of systemic medications, rate of/time to/duration of remission, manufacturing success rate

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.

DesCAARTes™ clinical trial assessments & timeframes

Safety assessed acutely, at 28 days & at 3 months, with data on biologic activity within 6 months

Day 28 safety data

Infusion of DSG3-CAART in context of circulating soluble DSG3 antibody

Other safety measures

- CRS / neurotoxicity
- Other adverse events

Primary safety endpoint at 3 months

Potential for disease flare during planned steroid taper +/- discontinuation of immuno-suppressive medications for mPV

Early evaluations of efficacy include[1]:

- Persistence of DSG3-CAART detected via qPCR
- Change in level of DSG3 antibodies (targeting persistent reduction)
- Change in mPV therapy and absence of new systemic rescue therapy
- Change in disease activity based on clinically validated scales
  - e.g. PDAI, ODSS

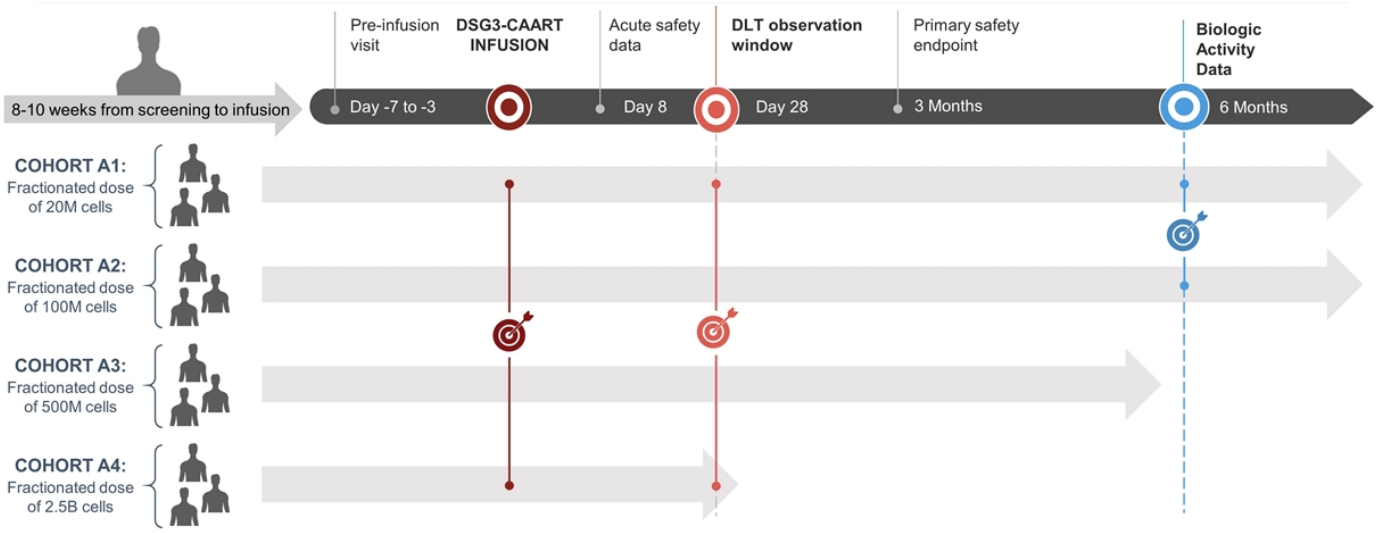
Data expected within 6 months of completion for each cohort

** Clearance of 28-day observation window without DLTs required to initiate next dosing cohort.*

1. This information represents data that we believe can be used to inform potential efficacy endpoints in future clinical development.
2. Spindler, Volker, et al. "Mechanisms causing loss of keratinocyte cohesion in pemphigus." Journal of Investigative Dermatology 138.1 (2018): 32-37.

No DLTs observed to date in first 4 cohorts of DesCAARTes™ trial

Dose-dependent increase in DSG3-CAART persistence observed in Cohort A3 vs. Cohorts A1 and A2

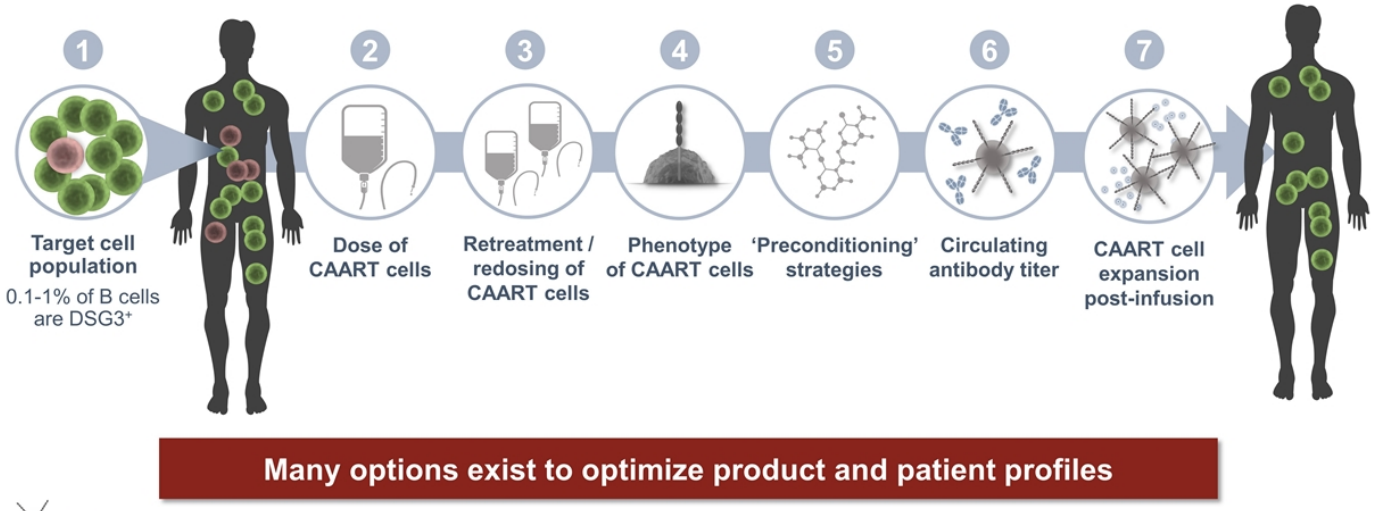


Safety data observed to date has enabled progression to cohort A5 (5.0-7.5B cells); additional clinical data for cohorts A3 and A4 expected to be provided at a scientific meeting in mid-2022

** 20M, 100M, 500M, 2.5B and 5.0B to 7.5B refers to the number of DSG3-CAART cells infused for patients in dosing cohorts 1 to 5 (M – millions; B – billions)*

Optimizing product and patient profiles – many options to consider

Range of strategies to consider for targeted cell therapy approaches in patients with autoimmune diseases



Many options exist to optimize product and patient profiles

CAART cell

Pathogenic autoreactive B cell

Healthy B cell

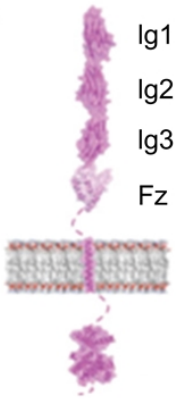
Cabaletta Bio®

High unmet need in MuSK myasthenia gravis; a valuable CAAR target

All known extracellular domains can be included in the CAAR design

Similarities to pemphigus support clinical potential of CAAR T in MuSK MG

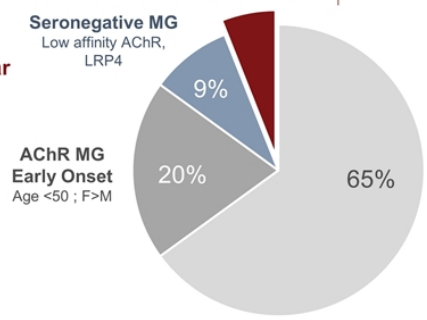
1. Autoantibody titers drop after rituximab[1,2]
2. Pathogenic B cells are incompletely eliminated by rituximab and persist during relapse[3]



MuSK has similar modular structure and size as DSG3

MuSK MG
6.0 - 7.5%

- Typically more severe
- Limited treatment options
- Early onset – 7:1 females

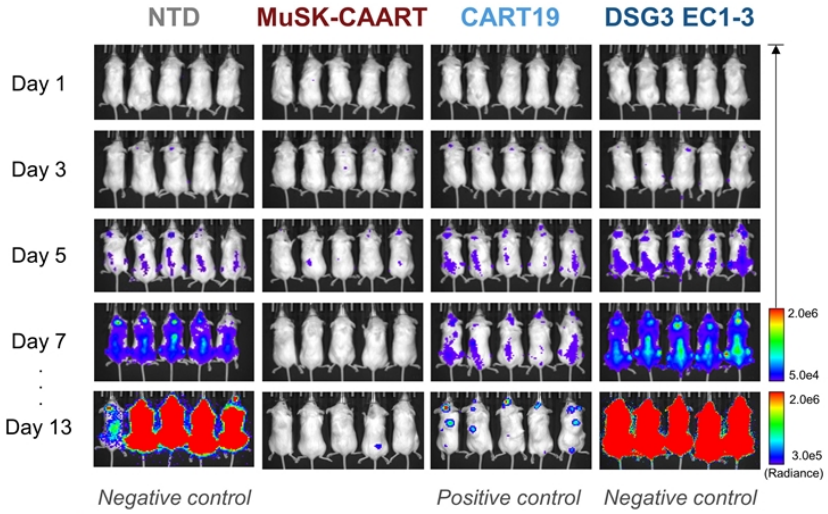


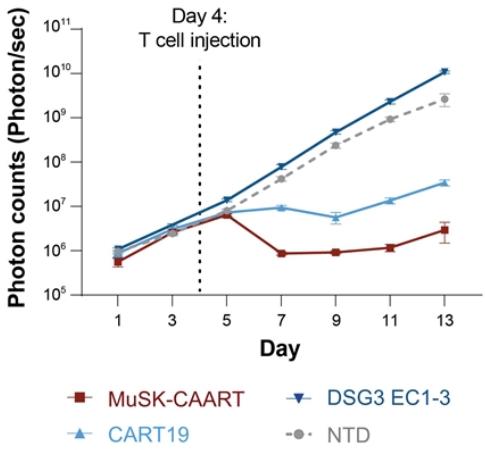
Total US MG Prevalence: 50,000 to 80,000 patients

1. Hain, Berit, et al. "Successful treatment of MuSK antibody–positive myasthenia gravis with rituximab." Muscle & Nerve: Official Journal of the American Association of Electrodiagnostic Medicine 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).

MuSK-CAART demonstrated specific *in vivo* target engagement[1]

MuSK-CAART eliminated anti-MuSK target cells[2] in an animal model where CART19 cells were a positive control





MuSK-CAART IND open and planning to initiate first-in-human MuSK-CAART trial in 2022

1. https://cabalettabio.com/technology/posters-publications.
2. Target cells represent a B cell tumor line (CD19 positive) that has been modified to express the anti-MuSK antibody.

MusCAARTes™ study of MuSK-CAART

Strategy for upcoming trial evaluating MuSK-CAART informed by progression of DesCAARTes™ study

Fast Track Designation

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

Major Inclusion Criteria

- Age: ≥18
- MG severity Class I-IVa
- MGC ≥ 4
- Anti-MuSK antibody positive
- Negative anti-AChR antibody test

Major Exclusion Criteria

- Prednisone > 0.25-0.5 mg/kg/day
- Other autoimmune disorder requiring immunosuppressive therapies

SCREENING → MANUFACTURING → TREATMENT (SINGLE INFUSION) → MONITORING (2-4 WEEKS) → Next Patient

2 *Single dose rather than fractionation*

Part	Cohort	# Subjects
A – Dose Escalation Increasing dose levels to determine maximum tolerated dose *(A1 – 100M; A2 – 500M; A3 – 2.5B; A4 – 5 to 7.5B)*	A1-A4	2 (+4) per cohort
B – Expansion Expanded subject enrollment at final selected dose	B	~12
	Total	**~20 (+16)**

1 *Higher starting dose*

3 *versus 3 (+3) design in DesCAARTes™ trial*

Study Endpoint & Objectives

Primary Endpoint: Adverse Events, including DLT

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

* *100M, 500M, 2.5B and 5.0B to 7.5B refers to the number of MuSK-CAART cells infused for patients in dosing cohorts 1 to 4 (M – millions; B – billions).*

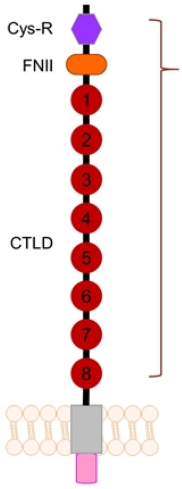
Cabaletta Bio®

Preclinical stage CAART program in membranous nephropathy

Primary MN is an immune-mediated kidney disease with anti-PLA2R antibodies in ~75% of patients

Accumulating evidence of a correlation between PLA2R antibodies and disease activity, remission and relapse in primary MN

1. PLA2R autoantibody levels routinely used as diagnostic and prognostic markers
2. Autoantibody titer shown to rise rapidly before clinical manifestations
3. Co-localization of antigen & PLA2R antibodies at site of damage in kidney



PLA2R+ MN is attractive for CAAR development

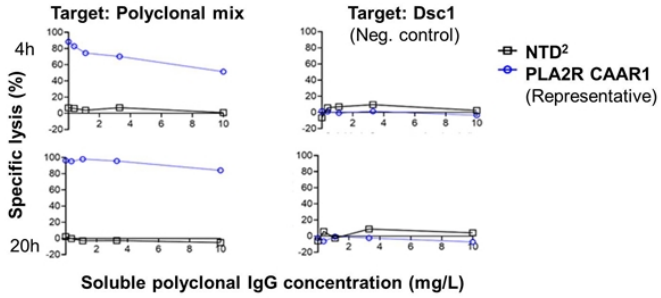
- Epitopes are well-defined
- IgG4-dominant disease, similar to PV and MuSK MG
- Eligible US population
  - prevalence of ~4,000-8,000;
  - incidence of ~700-1,400 / yr

PLA2R-CAART showed *in vitro* antigen-specific cytotoxicity[1]

PLA2R CAARs demonstrated activity in the presence of physiologic levels of anti-PLA2R autoantibodies

PLA2R-CAAR

- **Candidate CAAR contains targets that bind >95% of anti-PLA2R autoantibodies**
- **Demonstrated no off-target binding interactions in membrane protein array**



Pre-IND interaction with FDA on PLA2R-CAART completed in 4Q21

1. As presented at the ASN Kidney Week 2021.
2. NTD = non transduced T cell control against the same target cells.

Cabaletta Bio®

Manufacturing strategy

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

1. Penn-sponsored CD19 CAR IND CMC data has been cross-referenced in DSG3-CAART IND to provide additional data reflecting alignment.

Cabaletta Bio®

Cabaletta Bio leadership

LEADERSHIP TEAM

Steven Nichtberger, M.D.
President, CEO & Chairman
MERCK
tengion
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Multiple potential data catalysts with possible pipeline read-through

DesCAARTes™ trial ongoing: Currently enrolling patients in 5th cohort (5.0-7.5B cells)

- Represents 375x dose range from 1st trial cohort, delivered via only 2 fractionated doses
- DesCAARTes™ clinical data updates expected to be provided at scientific meetings throughout 2022-2023
  - Biologic activity data for Cohorts A3 and A4 (500M and 2.5B) in mid-2022[1]
  - 28-day safety data for Cohort A5 in mid-2022[1]

MuSK-CAART: Plan to initiate first-in-human trial in 2022; received FDA Fast Track Designation

Expanding network of academic & industry partners

WuXi AppTec, ARTISANBIO, Penn, Yale, Stanford Medicine, OxfordBioMedica, Children's Hospital of Philadelphia, UC Davis, Iowa

** 20M, 100M, 500M, 2.5B and 5.0B to 7.5B refers to the number of DSG3-CAART cells infused for patients in dosing cohorts 1 to 5 (M – millions; B – billions).*

1. Assumes no dose-limiting toxicities are observed during cohort, uninterrupted enrollment and no delays due to COVID-19 resurgence occur in the trial.

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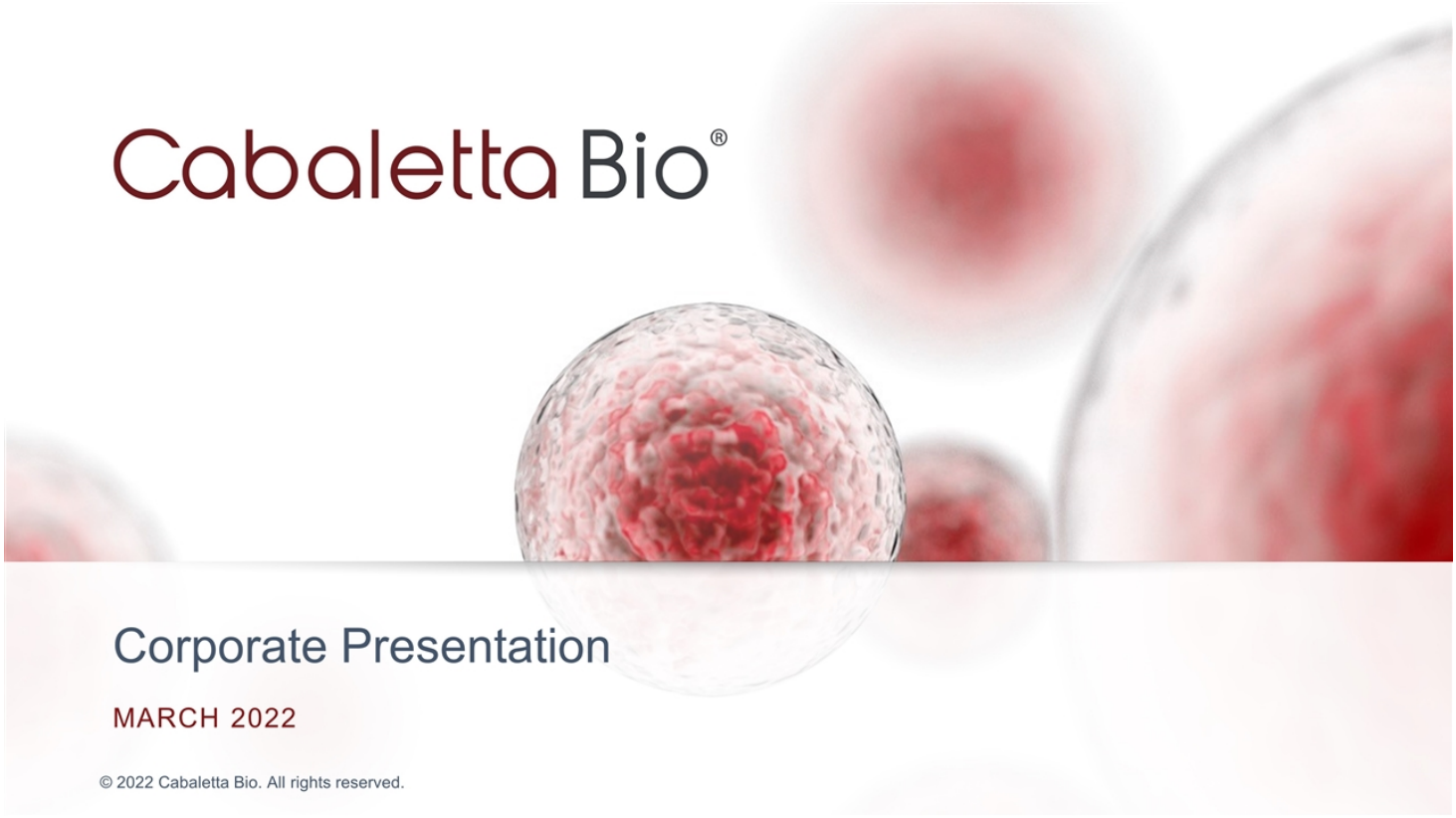
Cabaletta Bio®



Corporate Presentation

MARCH 2022