## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 8-K/A

**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)

Delaware (State or other jurisdiction of incorporation)  2929 Arch Street, Suite 600, Philadelphia, PA (Address of principal executive offices)		001-39103 (Commission File Number)	82-1685768 (I.R.S. Employer Identification No.)
			19104 (Zip Code)
	(Registr	(267) 759-3100 ant's telephone number, including area code)	
		Not Applicable	
	(Former nar	ne or former address, if changed since last rep	ort)
	(Former nar appropriate box below if the Form 8-K filing is interprovisions:	ne or former address, if changed since last rep	
	appropriate box below if the Form 8-K filing is in:	ne or former address, if changed since last rep  ended to simultaneously satisfy the filing	obligation of the registrant under any of the
following	appropriate box below if the Form 8-K filing is interprovisions:	ne or former address, if changed since last rep ended to simultaneously satisfy the filing under the Securities Act (17 CFR 230.42.	obligation of the registrant under any of the
following	appropriate box below if the Form 8-K filing is interprovisions:  Written communications pursuant to Rule 425	ne or former address, if changed since last rep ————————————————————————————————————	obligation of the registrant under any of the (5)
following	appropriate box below if the Form 8-K filing is interprovisions:  Written communications pursuant to Rule 425 Soliciting material pursuant to Rule 14a-12 under	ene or former address, if changed since last rep ended to simultaneously satisfy the filing under the Securities Act (17 CFR 230.42. der the Exchange Act (17 CFR 240.14a-12. to Rule 14d-2(b) under the Exchange Act	obligation of the registrant under any of the (5) 2) 2(17 CFR 240.14d-2(b))
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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.  $\Box$ 

#### EXPLANATORY NOTE

This current report on Form 8-K/A (the "Amendment") amends the Current Report on Form8-K filed on March 3, 2022 by Cabaletta Bio, Inc. (the "Company") (the "Original Form 8-K"). Slide 19, entitled MusCAARTes<sup>TM</sup> study of MusK-CAART, was updated to clarify that a total of six subjects will need to have received the final selected dose in Part A of the study. The Amendment is amending and restating the Original Form 8-K in its entirety.

#### Item 7.01 Regulation FD Disclosure.

A copy of the updated Corporate Presentation, which the Company intends to use effective immediately, 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 <u>Cabaletta Bio, Inc. Corporate Presentation, dated March 3, 2022 (corrected), furnished herewith.</u>
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### SIGNATURE

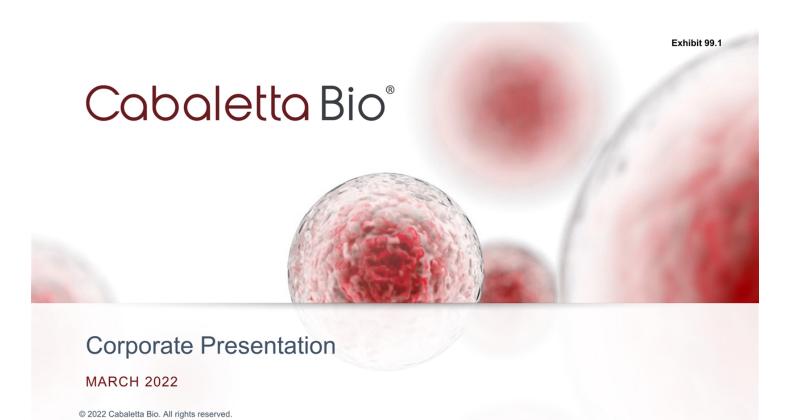
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

#### CABALETTA BIO, INC.

Date: March 14, 2022

By: /s/ Steven Nichtberger

Steven Nichtberger, M.D. President and Chief Executive Officer



## Disclaimer

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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 protect and maintain our intellectual property position, risks related to clinical trials sit 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 or clinical 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 contained herein, whether as a result of any new information, future events, chan

Develop and launch the first curative targeted cellular therapies for patients with autoimmune diseases

## 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 3<sup>rd</sup> 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<sup>1</sup> 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<sup>2</sup> 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

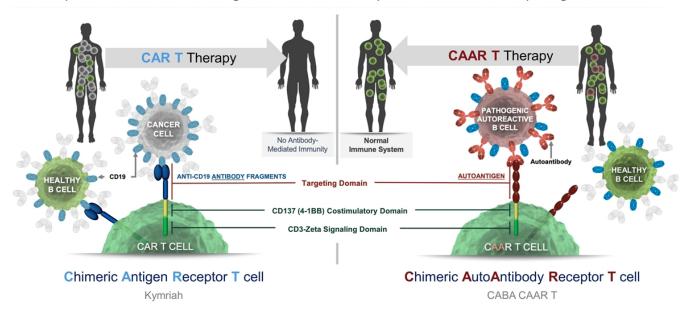
\* 20M, 100M, 500M, and 2.5B and 5.0B to 7.5B refers to the number of DSG3-CAART cells infused for patients in dosing cohorts 1 to 5 (M - millions); B - billions).

1. Includes five disclosed product candidates and two undisclosed pipeline disease targets in our pipeline.

2. Activities of Daily Living

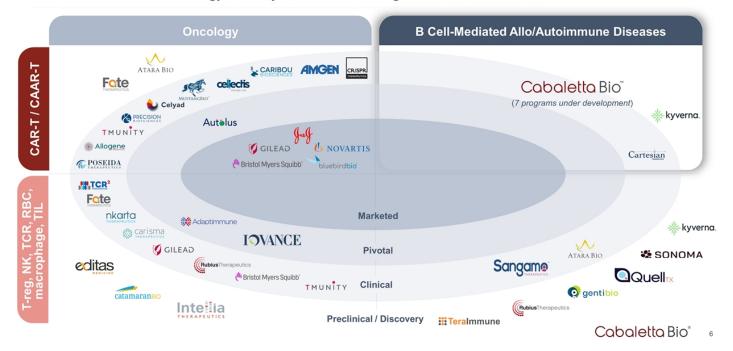
## Our scientific platform leverages clinically validated CAR T technology

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



## Cabaletta: Advancing targeted cell therapy to autoimmunity

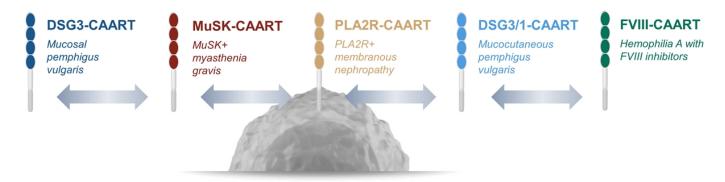
Foundational CAR T technology clinically validated in treating B cell-mediated cancers



## Modular platform with "plug-and-play" architecture

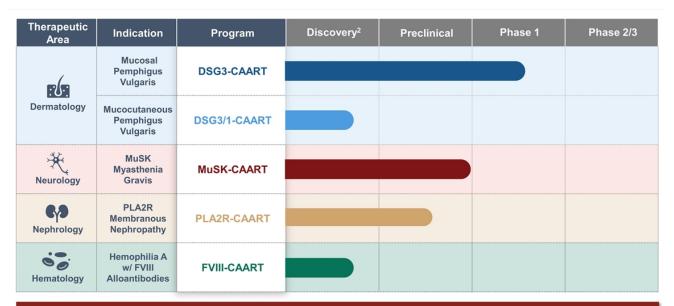
CABA™ platform designed to enable a portfolio of programs targeting B cell-mediated diseases

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



Clinically validated engineered T cell platform is the foundational technology

## Pipeline<sup>1</sup> includes multiple disease targets where cure is possible



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

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

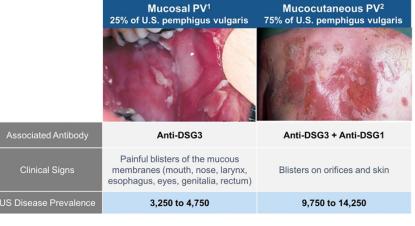


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## Overview of pemphigus vulgaris

Mucosal PV1

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



## **Current Treatment Landscape**

#### Broad immunosuppression<sup>3,6</sup>

- · Modestly effective
- · Poorly tolerated

#### Rituximab plus steroids (~3,500 mg/yr)<sup>4</sup>

- Response: ~40% of patients achieved a 16-week period with no lesions or medicines during 1 yr<sup>4,5</sup>
- 22% annual serious adverse event (SAE) rate<sup>4</sup>
  - 4-9%<sup>3,4,5</sup> annual risk of severe infection in PV
- · Real world data indicate:
  - Transient remission ~ 70% CROT6:
    - ~30% relapse in 1 year<sup>6</sup>
    - >50% relapse within 2 years<sup>6</sup>
  - ~30% never achieve CROT6
  - ~1.9% lifetime risk of fatal infection<sup>7</sup>

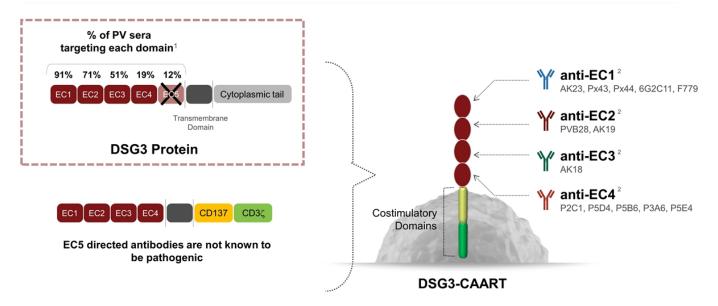
## CROT = 8+ weeks without lesions while off systemic therapy

- Image credit: D@nderm
- 1. Image credit: D@nderm.

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  2. http://www.yrgd.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 Mofetti 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



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.
 Antibodies that target the specific extracellular domain are shown below each extracellular domain.

## DesCAARTes™ study of DSG3-CAART



CORFENING MANUFACTURING



#### 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	(UP TO 4 WEE	Patient 4
Part	Cohort	# Subjects
A – Dose Escalation (up to 375x dose increase) Fractionated infusion at increasing dose levels	A1-A5	3 (+3) per cohort
		0 (+0)

TREATMENT MONITORING Next

B - Dose Consolidation
Consolidating selected dose fractions into a single infusion

C - Expansion¹
Expanded subject enrollment at final selected dose

Total

Per Corton:

3 (+3)
per cohort

C - Expansion¹
Expanded subject enrollment at final selected dose

Total

~33 (+18)

**Study Endpoint & Objectives** 

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

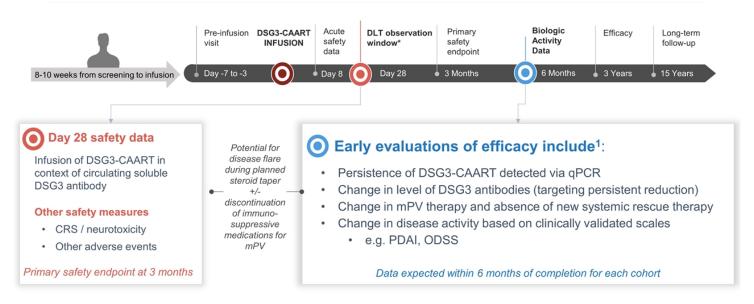
 DLTs include any grade 3 or 4 CRS or neurotoxicity, or any Grade 2 CRS or neurotoxicity that failed to improve to ≤ Grade 1 or baseline within 7 days

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

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<sup>™</sup> clinical trial assessments & timeframes

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

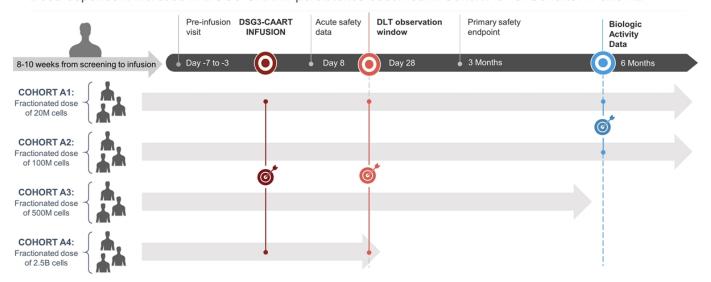


<sup>\*</sup> Clearance of 28-day observation window without DLTs required to initiate next dosing cohort.

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



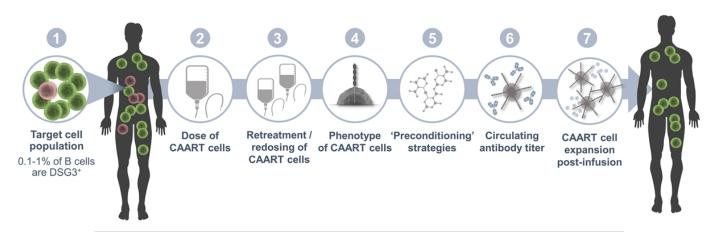
Safety data observed to date has enabled progression to cohort A5 (5.0-7.5B cells); additional clinical data for cohorts A3 and A4 expected to be provided at a scientific meeting in mid-2022

\* 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)

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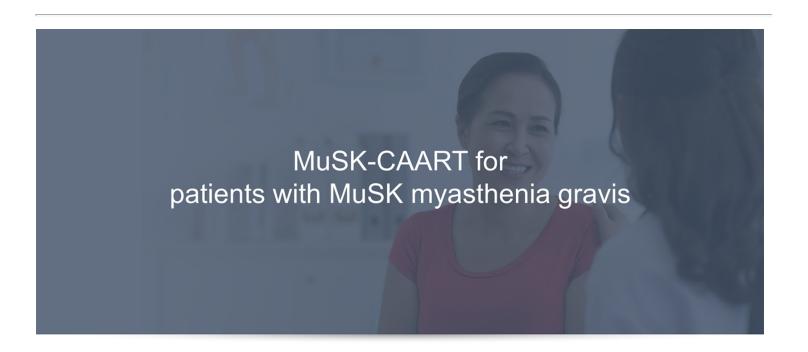
## Optimizing product and patient profiles – many options to consider

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



Many options exist to optimize product and patient profiles

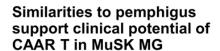




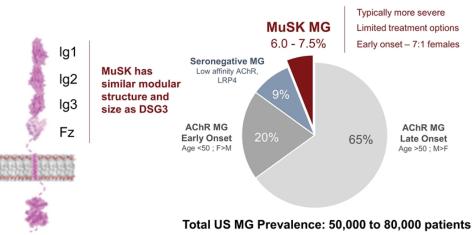
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## High unmet need in MuSK myasthenia gravis; a valuable CAAR target

All known extracellular domains can be included in the CAAR design



- Autoantibody titers drop after rituximab<sup>1,2</sup>
- Pathogenic B cells are incompletely eliminated by rituximab and persist during relapse<sup>3</sup>



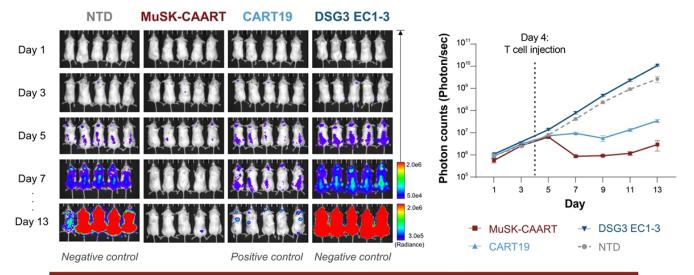
<sup>1.</sup> Hain, Berit, et al. "Successful treatment of MuSK antibody—positive myasthenia gravis with rituximab." Muscle & Nerve: Official Journal of the American Association of Electrodiagnostic Medicine 33.4 (2006): 575-580.

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." JCl insight 5.14 (2020).

## MuSK-CAART demonstrated specific in vivo target engagement<sup>1</sup>

MuSK-CAART eliminated anti-MuSK target cells<sup>2</sup> 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

<sup>1.</sup> 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



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

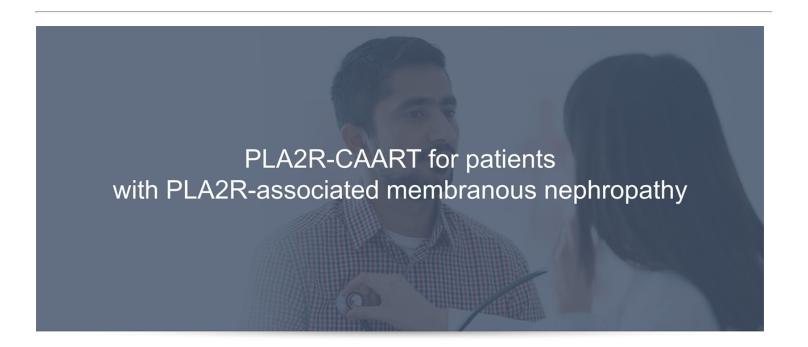


#### Study Endpoint & Objectives

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 A1 to A4 (M – millions; B – billions). 1. A total of 6 subjects will need to have received the final selected dose in Part A of the study



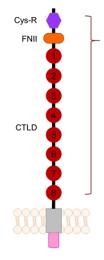
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## Preclinical stage CAART program in membranous nephropathy

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
- 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

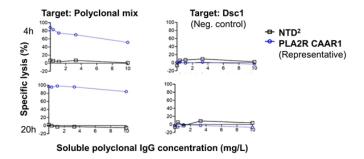
  - prevalence of ~4,000-8,000; incidence of ~700-1,400 / yr

## PLA2R-CAART showed in vitro antigen-specific cytotoxicity1

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

As presented at the ASN Kidney Week 2021.

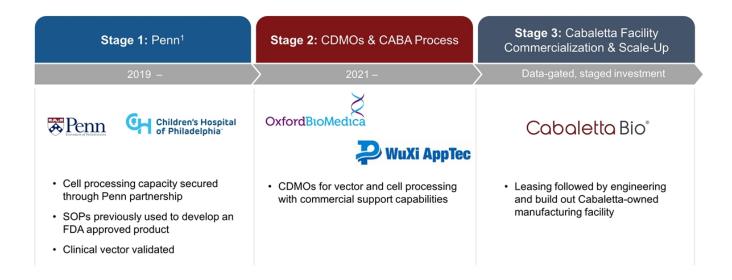
2. NTD = non transduced T cell control against the same target cells



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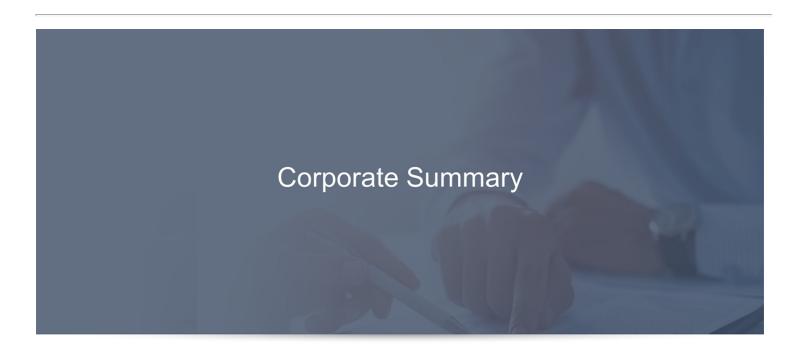
## Manufacturing strategy

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.

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## Cabaletta Bio leadership

Steven Nichtberger, M.D. President, CEO & Chairman





Michael Gerard General Counsel Spark. SANDOZ A Novarti



Samik Basu, M.D. Chief Scientific Officer



Heather Harte-Hall





LEADERSHIP TEAM

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







Anup Marda Chief Financial Officer Bristol-Myers Squibb



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







Martha O'Connor Chief HR Officer



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Arun Das, M.D. Chief Business Officer

Goldman Sachs

## Multiple potential data catalysts with possible pipeline read-through

- **DesCAARTes™** trial ongoing: Currently enrolling patients in 5<sup>th</sup> 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<sup>1</sup>
    - 28-day safety data for Cohort A5 in mid-20221
- MuSK-CAART: Plan to initiate first-in-human trial in 2022; received FDA Fast Track Designation

## **Expanding network of academic & industry partners**















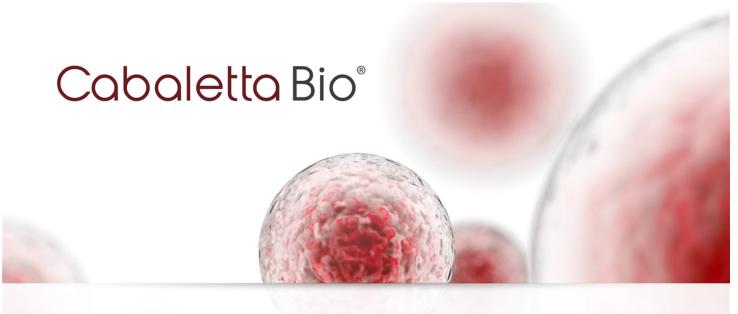


\* 20M, 100M, 500M, 2.5B and 5.0B to 7.5B refers to the number of DSG3-CAART cells infused for patients in dosing cohorts 1 to 5 (M – millions; B – billions)

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

Develop and launch the first curative targeted cellular therapies for patients with autoimmune diseases

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## Corporate Presentation

**MARCH 2022** 

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