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

October 7, 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 1.01 Entry Into a Material Definitive Agreement.

On October 7, 2022, Cabaletta Bio, Inc. (the "Company") entered into an Exclusive License Agreement (the "Agreement") with Nanjing IASO Biotherapeutics Co., Ltd. ("IASO"). Pursuant to the Agreement, the Company received an exclusive, worldwide license under certain IASO intellectual property to use a novel clinical-stage anti-CD19 binder to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of any autoimmune or alloimmune indications in humans. As partial consideration for the exclusive license, IASO will receive an upfront payment of $2.5 million. IASO is also eligible to receive up to mid double digit millions in milestone payments based upon the achievement of specified pre-clinical, development and regulatory milestones, and up to an additional low triple digit millions in milestone payments based upon achievement of specified sales milestones, for a total consideration, inclusive of the upfront payment, of up to $162 million, along with tiered mid-single digit royalties on future net sales for licensed products that may result from the Agreement. IASO has the right of first negotiation if the Company desires to grant a third party an exclusive license to develop, manufacture, commercialize or otherwise exploit the licensed products in the Greater China region. Pursuant to the Agreement, each of IASO and the Company have agreed, subject to certain exceptions, to refrain from engaging in certain competitive activities with respect to certain programs. The Company also may sublicense through multiple tiers the rights granted to it by IASO under the Agreement at any time and, however, it must pay IASO a low double-digit percentage of any revenue obtained from sublicenses or options to third parties, subject to certain customary exclusions. The Agreement will continue on a country-by-country, licensed product-by-licensed product basis until the expiration of the royalty term as identified in the Agreement, unless earlier terminated. Each of the Company and IASO may terminate the Agreement for a material, uncured breach or insolvency of the other party. The Company may also terminate the Agreement at will upon advance written notice and in the event IASO rejects the Agreement due to bankruptcy-related matters. IASO may also terminate the Agreement if the Company fails to achieve certain specified diligence milestones in a timely manner and/or if the Company commences any patent challenges with respect to the patents and patent applications relating to the licensed sequence, in each case upon advance written notice.

The foregoing description of the terms of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement which will be filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022.

Item 7.01 Regulation FD Disclosure.

On October 11, 2022, 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 October 11, 2022, IASO issued a press release announcing the exclusive license granted to the Company (the "IASO Press Release"). A copy of the IASO 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 Form8-K 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 October 11, 2022, the Company issued a press release announcingCABA-201, a newly designed product candidate, which is a fully-human CD19 chimeric antigen receptor containing a 4-1BB co-stimulatory domain. The Company has obtained an exclusive, worldwide license for the CD19 binder in CABA-201, in-licensed from IASO pursuant to the Agreement described in Item 1.01. In addition, the Company announced that it has established an exclusive translational research partnership with Professor Georg Schett, a global leader in the application of CD19-targeting cell therapies in autoimmunity, to generate additional translational data and clinical insights from his ongoing clinical studies. A copy of the full text of the press release referenced above is filed as Exhibit 99.3 to this Current Report on Form 8-K and is incorporated herein by reference into this Item 8.01 of this Current Report on Form 8-K.

On October 7, 2022 the U.S. Food and Drug Administration granted Orphan Drug Designation for MuSK-CAART, or muscle-specific kinase ("MuSK") chimeric autoantibody receptor T ("MuSK-CAART") cells, for the treatment of MuSK myasthenia gravis.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Cabaletta Bio, Inc. Corporate Presentation, dated October 11, 2022, furnished herewith.
99.2	Press Release issued by IASO on October 11, 2022, furnished herewith.
99.3	Press Release issued by the registrant on October 11, 2022.
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: October 11, 2022

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

Exhibit 99.1

Cabaletta Bio®

Corporate Presentation

OCTOBER 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 and CARTA technologies and CABA™ platform; 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 timing of our planned submission of an investigational new drug application (IND) for CABA-201 to the FDA; statements regarding regulatory filings regarding its development programs; the progress and results of our DesCAARTes™ Phase 1 trial, including the significance and impact around the clinical and translational data updates from cohorts A1 through A4 of our DesCAARTes™ Phase 1 trial; the significance and impact around the 28-day safety for cohort A5 and clinical and translational data for cohort A4 announced at the 31st European Association of Dermatology and Venereology Congress; the therapeutic potential and clinical benefits of our product candidates; the expectation that Cabaletta Bio 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; Cabaletta's plans to implement a pre-treatment regimen and the potential ability to enhance *in vivo* DSG3-CAART exposure; our ability to advance dose escalation in the DesCAARTes™ Phase 1 trial at the current dose ranges for the current cohorts and any projected potential dose ranges for future cohorts, and to optimize our targeted cell therapy; 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 planned clinical 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 DSG3-CAART for the treatment of pemphigus vulgaris and 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 the second quarter of 2024. 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, Cabaletta's 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 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

Recent expansion into CD19-CAR T complements & leverages deep cell therapy experience in autoimmunity

CARTA: Newly-designed CABA-201 (4-1BB CD19-CAR T) on track for 1H23 IND submission

- Builds on recent academic clinical data[1] demonstrating that CD19-CAR T may potentially reset the immune system in patients with SLE
  - Exclusive translational research partnership with lead investigator on the academic study[1] will inform CABA-201 clinical development
- Exclusive global license for clinically-evaluated, fully human CD19 binder with favorable clinical tolerability profile in ~20 oncology patients
  - Similar construct design to CD19-CAR T used in the academic SLE study, including 4-1BB costimulatory domain[1,2]
- Potential to cure many common autoimmune diseases such as SLE, RA, myositis and systemic sclerosis[3]

CAART: Advancing clinical studies to increase CAART activity & explore additional indications

- DesCAARTes™ trial in mPV ongoing: Enrolling in combination sub-study (pre-treatment with IVIg & cyclophosphamide)
  - 1 month safety and persistence data anticipated in 1Q23[4]
- MusCAARTes™ trial in MuSK myasthenia gravis: On track to initiate in 4Q22; received FDA Fast Track Designation
  - Higher starting cell dose and early implementation of combination strategy based on learnings from DesCAARTes™ trial

Cash runway extended through 2Q24 with $96.8M at the end of 2Q22

- Initial CABA-201 clinical data[5] as well as 6-month combination data from DesCAARTes™ & MusCAARTes™ 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; RA – Rheumatoid arthritis; mPV – Mucosal pemphigus vulgaris

1. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.
2. 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.
3. Mullin, Emily. "How a 'Living Drug' Could Treat Autoimmune Disease." WIRED, 16 Sept 2022.
4. Assumes no dose-limiting toxicities are observed in the cohort, uninterrupted enrollment and no delays due to COVID-19 resurgence occur in the trial.
5. Pending clearance of CABA-201 IND by the FDA.

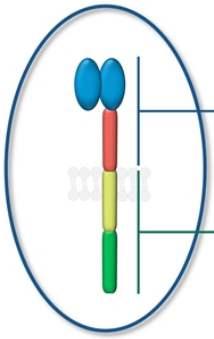
One CABA™ platform, two strategies to address autoimmune diseases

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]*



Fully Human Anti-CD19 Targeting Domain

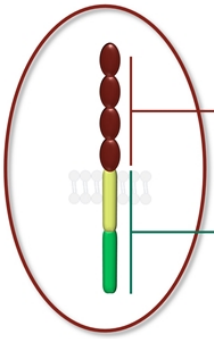
4-1BB Costimulatory Domain & CD3-Zeta Signaling Domain

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*[2]



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. 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 B-cell mediated 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]

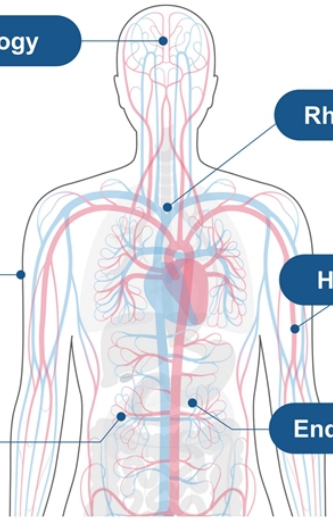
Rheumatology
- Systemic Lupus Erythematosus[3,4,5,6]
- Rheumatoid Arthritis[2,3,4]
- Myositis[5]
- Systemic sclerosis[6]
- ANCA-Associated Vasculitis[3,4,5]

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]

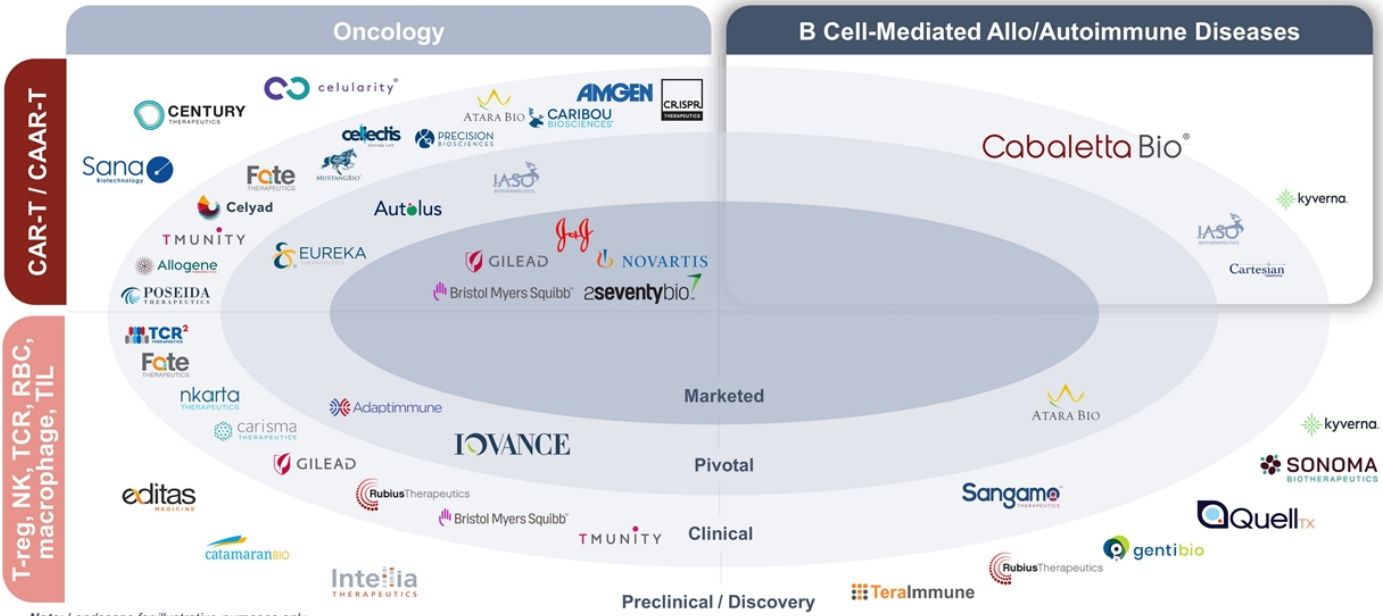


** Illustrative list of diseases where biologic opportunity for cure or treatment with CAART or CARTA approach may be possible.*

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).

Cabaletta: Advancing targeted cell therapy to autoimmunity

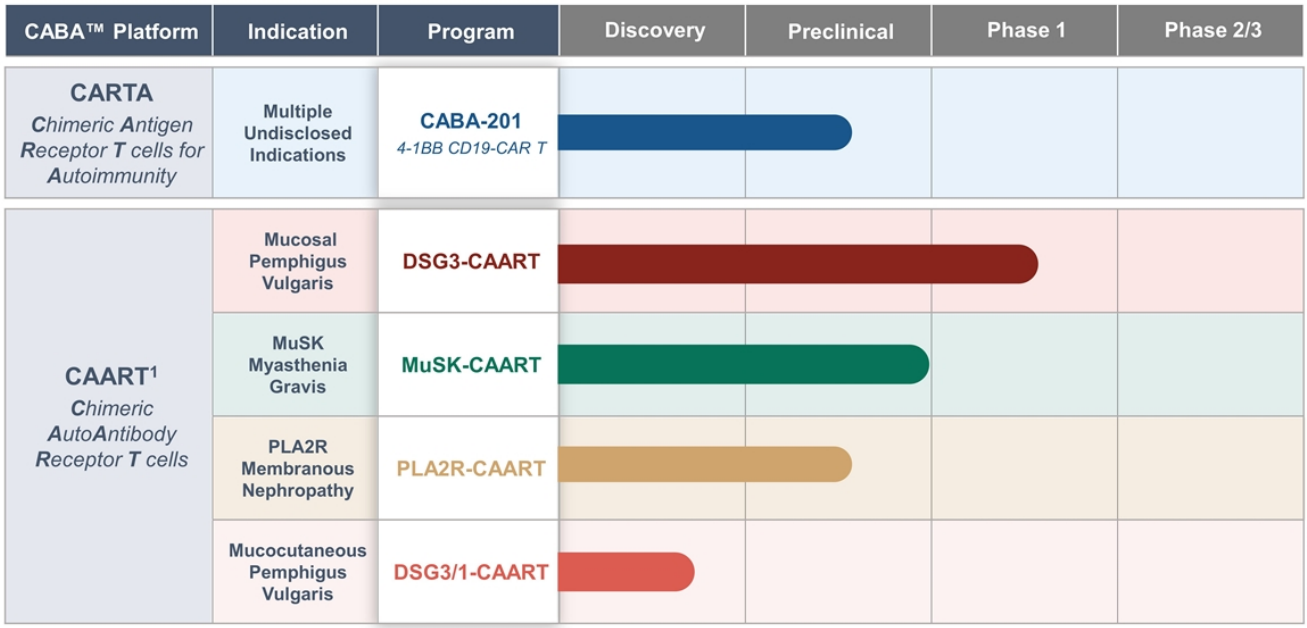
Foundational CAR T technology clinically validated in treating B cell-mediated cancers and SLE[1]



***Note**: Landscape for illustrative purposes only.*

1. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.

Pipeline targeting autoimmune diseases where cure is possible



1. Additional disease targets in discovery stage in our CAART pipeline portfolio include hemophilia and two undisclosed indications.

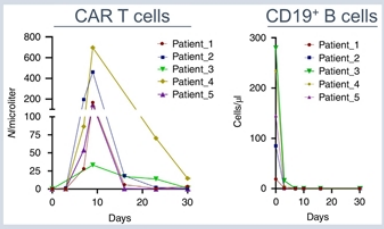
Cabaletta Bio®

Academic clinical data: Immune system reset in 5/5 SLE patients[1]

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

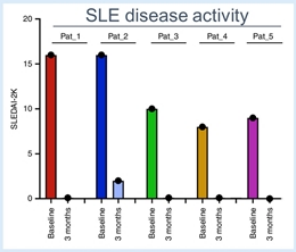
5/5 refractory SLE patients treated with 4-1BB CD19-CAR T[2] resulting in rapid, deep and transient depletion of CD19⁺ B cells[1]

- All 5 patients with moderate to severe disease
- Preconditioning with standard Flu/Cy regimen[2]
- Dose of $1x10^6$ CD19-CAR T cells/kg
- CD19 binder: 4-1BB costimulatory domain & FMC63 scFv



Clinical & serologic responses by 3 mo. after 4-1BB CD19-CAR T therapy with promising safety profile[1]

- Anti-dsDNA antibodies undetectable in 5/5
  - All SLE-associated antibodies reduced
  - Complement levels normalized
- No – or only mild – CRS observed
  - Grade 1 fever in 3/5 patients
- No neurotoxicity / ICANS



Repopulation of healthy B cells[1]

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

Durable clinical responses[1]

- 5-17 months of follow up
- Responses maintained with no need for SLE-associated medications

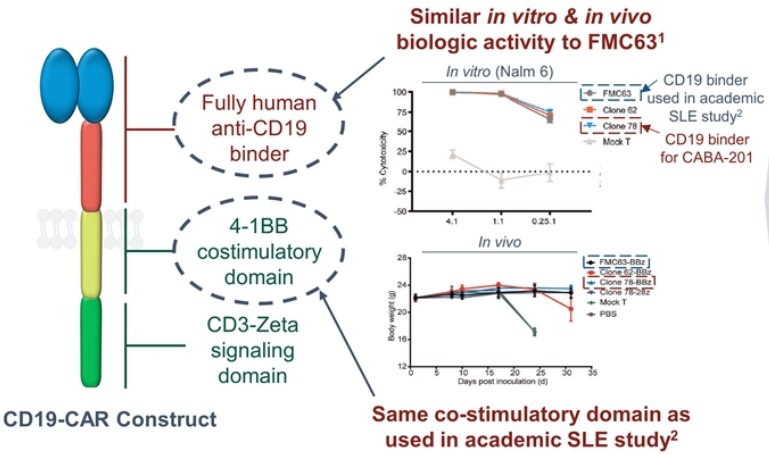
SLE – Systemic lupus erythematosus; scFv – Single chain variable fragment; SLEDAI-2K – Systemic Lupus Erythematosus Disease Activity Index 2000; CRS – Cytokine release syndrome; ICANS – Immune effector cell-associated neurotoxicity syndrome

1. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.
2. The construct utilized in this study has a similar design to CABA-201, sharing the 4-1BB costimulatory domain, but is a different construct.
3. Fludarabine (Flu) 25 $mg/m^2/d$ intravenously day -5 to day -3; Cyclophosphamide (Cy) 1,000 $mg/m^2/d$ intravenously on day -3

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 SLE study[2])

CABA-201



Clinical Data for Licensed CD19 Binder[3]

Fully human binder
Evaluated within dual-CAR combined with CD22 binder with standard Flu/Cy preconditioning

Evaluated in ~20 patients to date[3]
Under evaluation in patients with B cell leukemia and lymphoma in IIT in China

Promising tolerability data to date[3]
Used in oncology patients with high target cell burden

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

CABA-201

Accelerating development of CABA-201 for autoimmune diseases

Differentiated asset, exclusive translational insights & track record of timely CAART clinical implementation

1 Cabaletta is uniquely positioned to efficiently advance CABA-201 in autoimmune diseases

- Expertise in conducting complex, interdisciplinary autoimmune-focused cell therapy clinical trials
- Positive regulatory interactions to support cell trials in autoimmune diseases since 2018
  - 2 INDs cleared within routine 30-day period; multiple clinical protocol modifications, Fast Track designations granted
- Successful manufacturing track record with novel cell therapy products with academic and industry partners
- Deep understanding of autoimmunity allows potential application across broad range of diseases

2 Clinically-evaluated binder & translational research partnership support CABA-201 development

- CABA-201 leverages similar design to 4-1BB-containing CD19-CAR T in seminal academic SLE study[1]
- Exclusive research partnership with lead investigator for SLE study provides early and actionable insights

IND submission for CABA-201 anticipated in first half of 2023

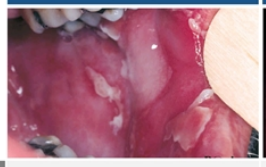
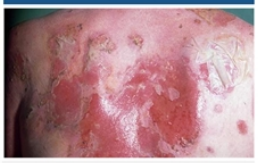
SLE – Systemic lupus erythematosus

1. Mackensen, Andreas, et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nature Medicine (2022): 1-9.

Cabaletta Bio®

Overview of pemphigus vulgaris

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**

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

DesCAARTes™ Phase 1 study of DSG3-CAART[1]

Orphan Drug Designation

Fast Track Designation

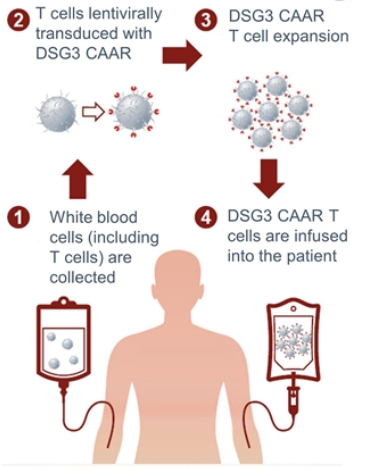
Evaluating DSG3-CAART as monotherapy & in combination with cyclophosphamide and IVIg

Major Inclusion Criteria

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

Major Exclusion Criteria

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



Adjunctive immunosuppressants are stopped; prednisone tapered to low dose prior to infusion

Part A Cohorts[1]	Subjects per Cohort	Dose*
A1 – A6m[2,3]	3 (+3)	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 per Cohort	Dose*
Combo[3,4]	3 (+3)	2.5B

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 reflects a cell dose of 2.5 billion cells in addition to pre-treatment with intravenous immunoglobulin (IVIg) and cyclophosphamide prior to DSG3-CAART infusion.
4. Combination cohort has been prioritized relative to A6m based on emerging data in cohorts A4 and A5. This is subject to the finalization of the protocol.

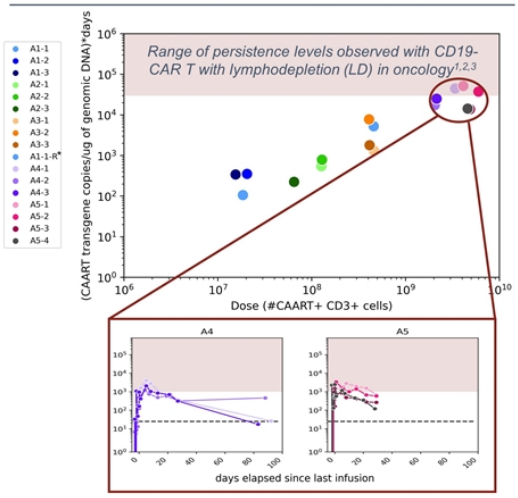
* *20M, 100M, 500M, 2.5B, 5.0B to 7.5B and 10B to 15B refers to the number of DSG3-CAART cells infused for patients in dosing cohorts A1 to A6m (M – millions; B – billions).*

DSG3-CAART

Dose-dependent persistence flattens; aim to increase CAART exposure

Combination sub-study prioritized to address possible cytokine & autoantibody effects on CAART activity

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



Combination sub-study cohort

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

- Dose-dependent increase in CAART persistence leveled off with cohort A5
- CY reduces 'cytokine sink,' potentially enhancing CAART activation & proliferation
- Potential reduction in anti-DSG3 autoantibodies that may inhibit or reduce activity
- CY & IVIg likely to provide transient improvement in first few months after infusion[4,5,6,7,8]
  - Up to 9 mo post-infusion may be required to assess DSG3-CAART clinical effect

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

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

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. Fleischli, Mary E., Rachel H. Valek, and Amit G. Pandya. "Pulse intravenous cyclophosphamide therapy in pemphigus." Archives of dermatology 135.1 (1999): 57-61.
8. 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.

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

MuSK-CAART

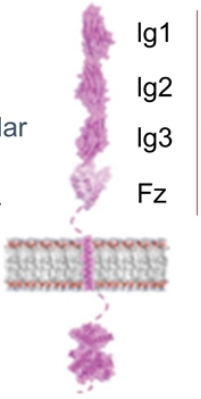
High unmet need in MuSK myasthenia gravis; a valuable CAAR target

All known extracellular domains are included in the CAAR design

MuSK has similar modular structure and size as DSG3, but circulating anti-MuSK ab titers may be ~90% lower than anti-DSG3 ab in PV[4,5,6]

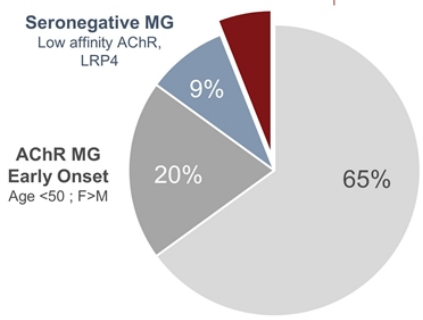
Similarities to pemphigus support clinical potential of CAAR T in MuSK MG

1. IgG4-dominant disease, similar to PV
2. Autoantibody titers drop after rituximab[1,2]
3. Pathogenic B cells are incompletely eliminated by rituximab and persist during relapse[3]



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).
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.

MuSK-CAART

MusCAARTes™ study of MuSK-CAART

Strategy for upcoming trial informed by learnings from DesCAARTes™ study

Orphan Drug Designation

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

25x higher than DesCAARTes™ starting dose

1

Combination cohorts based on DesCAARTes™ study

2

Part	Cohort	# Subjects
A – Dose Escalation[1] Increasing dose levels with 2 (+4) design *(A1 – 500M; A2 – 2.5B; A3[2] – 7.5B)*	A1-A3	2 (+4) per cohort
A – Adaptive Combination Cohorts[1] Combination cohorts, starting at A2 CAART dose *(A4[2] – 2.5B + Cyclophosphamide)*	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: CAAR T expansion/persistence, effect on serum anti-MuSK antibody titer, use of concomitant systemic medications, effect on clinical symptoms, manufacturing success rate

** 500M, 2.5B, 7.5B refers to the number of MuSK-CAART cells infused for patients in dosing cohorts A1 to A3 (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.

2. Cohorts A3 and A4 will be enrolled concurrently after cohort A2 is well-tolerated with a preference for enrollment into A4.

CAART

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; cross reference not required for MuSK-CAART IND.

Cabaletta Bio®

Cabaletta Bio leadership

LEADERSHIP TEAM

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

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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

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Jay Siegel, M.D.
Drew Weissman, M.D., Ph.D.

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

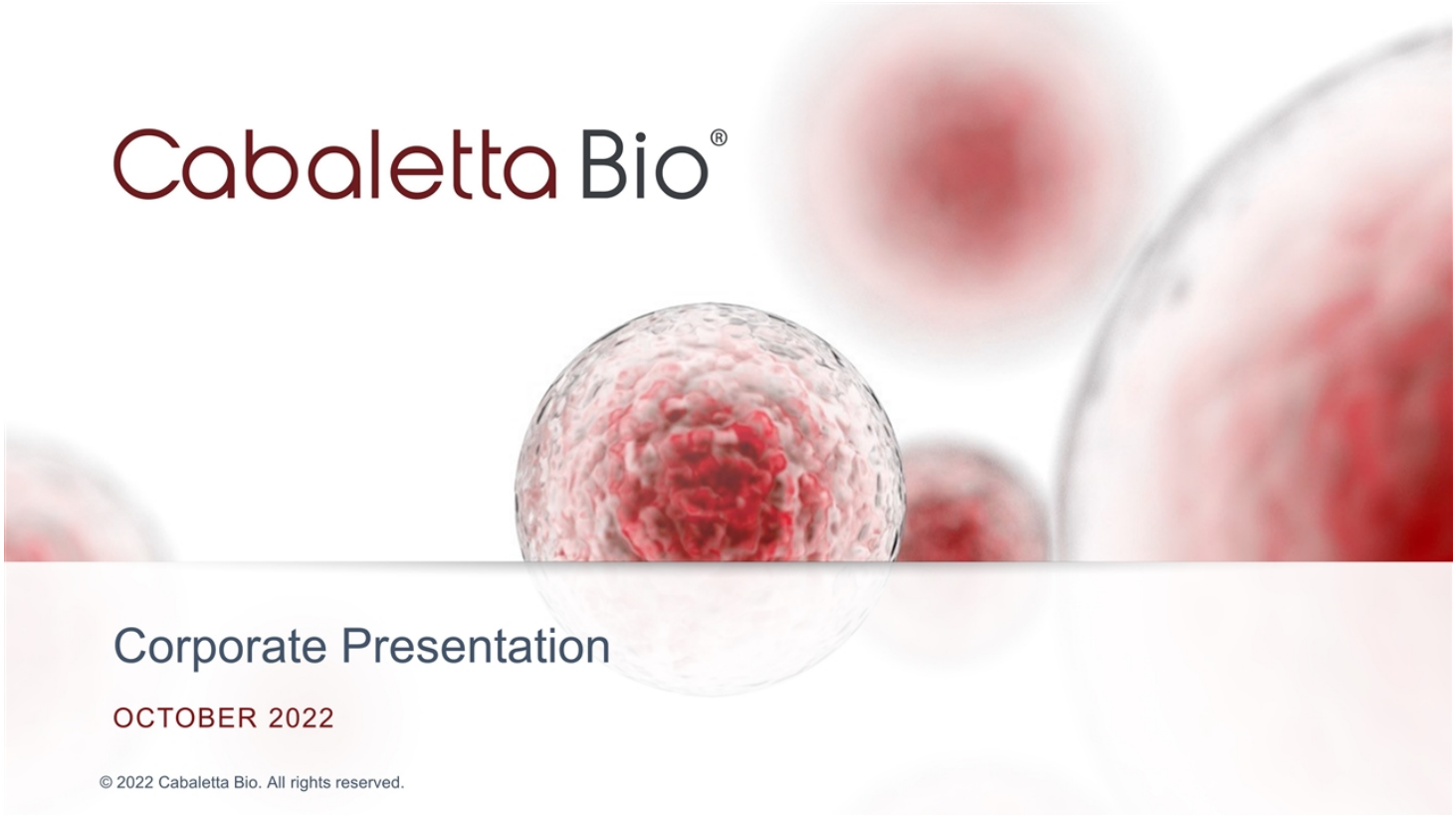
Multiple potential clinical catalysts anticipated in next 12-18 months[1]

	Anticipated Timing	Anticipated Milestone
CABA-201 *4-1BB CD19-CAR T*	1H 2023	IND filing
	1H 2024[2]	Initial clinical data[2]
DSG3-CAART *Mucosal-dominant pemphigus vulgaris*	1Q 2023	1-month safety & persistence data for combination cohort in DesCAARTes™ trial
	3Q 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 extended through 2Q 2024 with $96.8M at the end of 2Q 2022

1. Assumes no dose-limiting toxicities are observed in any cohort, uninterrupted enrollment and no delays due to COVID-19 resurgence occur in the trial.
2. Pending clearance of CABA-201 IND by the FDA.

Cabaletta Bio®



Corporate Presentation

OCTOBER 2022

Cabaletta Bio®

Cabaletta Bio and IASO Biotherapeutics Announce Exclusive Worldwide License Agreement for Clinically Validated CD19 Binder

PHILADELPHIA, Pennsylvania and SAN JOSE, California, NANJING and SHANGHAI, China — October 11, 2022 — IASO Biotherapeutics ("IASO Bio"), a clinical-stage biopharmaceutical company engaged in discovering, developing, and manufacturing innovative medicines and 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 companies entered into an agreement pursuant to which Cabaletta obtained from IASO Bio an exclusive, worldwide license to develop, manufacture and commercialize a clinically validated fully-human CD19 binder for use in product that is designed to modify T cells in treatment of autoimmune diseases. IASO Bio is entitled to receive up to approximately $162 million in aggregate payments, including an upfront payment and potential development and sales milestone payments across up to two products, as well as royalties. IASO Bio has the right of first negotiation to develop and commercialize Cabaletta's products using the licensed sequence in the Greater China region.

Clinically, CD19-targeted chimeric antigen receptor(CAR)-T cell therapies have been shown to induce deep and durable B cell depletion resulting in efficacy in treating B-cell malignancies, supporting the promise of this transformative approach in patients with B cell-mediated autoimmune diseases. Existing approaches to address such diseases are often limited by either modest effects, leading to resistant and uncontrolled disease, or significant treatment-related morbidity and mortality.

"Our collaboration with IASO Bio allows Cabaletta to utilize a CD19 binder inCABA-201, our newly designed, CD19-targeting CAR T product candidate. The CD19 binder has been clinically evaluated with safety data that we believe support clinical development in patients with autoimmune diseases," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "We are excited to progress CABA-201 forward in our effort to develop therapies that deliver deep, durable and potentially curative responses for patients with autoimmune diseases."

"We are very pleased to enter a collaboration with Cabaletta," said Wen (Maxwell) Wang, M.D., Ph.D., CEO of IASO Bio. "The potential of our fully-human CD19 sequence generated by our own fully human antibody discovery platform to provide durable response and superior safety for cancer patients has been validated in clinical trials of our in-house developed fully human CD19/CD22 dual-targeted CAR T-cell therapy CT120 that has been evaluated in approximately 20 patients with promising tolerability data to date. CT120 has obtained two IND clearance for non-Hodgkin's lymphoma (NHL) and acute lymphoblastic leukemia (ALL) in China, and FDA Orphan Drug Designation (ODD) for ALL. The company retains the global rights of CT120 and is advancing its development in China. We are excited to help maximize the value of CD19 sequence with Cabaletta to potentially benefit patients with a broad range of autoimmune diseases."

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 – encompassing chimeric antigen receptor T cells for autoimmunity (CARTA: CABA-201, a 4-1BB-containing CD19-CAR T) and Cabaletta Bio's proprietary chimeric autoantibody receptor T cells (CAART: multiple candidates including DSG3-CAART for mucosal pemphigus vulgaris, MuSK-CAART for MuSK myasthenia gravis) – provides multiple opportunities to treat broad and challenging autoimmune diseases. Cabaletta Bio's headquarters are located in Philadelphia, PA. For more information, visit www.cabalettabio.com and follow us on LinkedIn and Twitter.

About IASO Biotherapeutics

IASO Bio is an innovative biopharmaceutical company specializing in the development and manufacture of cellular therapeutics and antibody drugs. The company is expanding into autoimmune diseases and solid tumors with the development of cell-based drugs and antibody drugs as the cornerstone of innovation. It offers a complete platform from early discovery, registration, and clinical development to commercial production. IASO Bio owns many technology platforms, including a fully human antibody discovery platform, a high-throughput CAR-T drug preference platform, a general CAR technology platform, a production technology platform, and a clinical translational research platform. It has more than 10 products at different stages of development, including Equecabtagene Autoleucel (CT103A), fully human BCMA chimeric antigen receptor autologous T cell injection, which received NDA acceptance of the China NMPA for the treatment of elapsed/refractory multiple myeloma (R/R MM). Equecabtagene Autoleucel also received Breakthrough Therapy Designation by the NMPA in February 2021 and Orphan Drug Designation (ODD) by the U.S. FDA in February 2022. In addition to multiple myeloma, the NMPA has received IND application of Equecabtagene Autoleucel for the new expanded indication of Neuromyelitis Optica Spectrum Disorder (NMOSD). Additionally, its product CT120 (fully human CD19/CD22 dual-target CAR-T cell injection) has entered the clinical research stage for the treatment of CD19/CD22-positive relapsed/refractory B-cell non-Hodgkin lymphoma (B-NHL) and relapsed/refractory acute B-lymphoblastic leukemia (B-ALL) and granted FDA Orphan Drug Designation (ODD).

Leveraging its strong management team, rich product pipeline, cutting-edge R&D, and business model, and with the introduction of innovative drugs that truly solve clinical pain points and open new treatment paths, IASO Bio is becoming one of the industry's most influential and innovative pharmaceutical companies. For more information, please visit www.iasobio.com or www.linkedin.com/company/iasobiotherapeutics.

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 exclusive license agreement with IASO Bio; the company's business plans and objectives; and the expectation that Cabaletta Bio may improve outcomes for patients suffering from autoimmune diseases.

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: Cabaletta'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 the impact of public health epidemics affecting countries or regions in which Cabaletta has operations or does business, such as COVID-19; risks related to Cabaletta's ability to protect and maintain its intellectual property position; 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 or commercialized; and the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Cabaletta's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Cabaletta's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in Cabaletta's other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Cabaletta undertakes no duty to update this information unless required by law.

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Cabaletta Bio®

Cabaletta Bio Announces CABA-201, a Newly Designed CD19-Targeting CAR T Cell Therapy Engineered to Address a Broad Range of Autoimmune Diseases

- *Company has obtained exclusive worldwide license for a fully human CD19 binder with clinical tolerability data that support potential clinical development in autoimmune diseases*
- *CABA-201 Investigational New Drug (IND) application planned for the first half of 2023 with initial clinical data expected by the first half of 2024, pending IND clearance*
- *Clinical development plans being informed by exclusive translational research partnership with Georg Schett, M.D., senior author of the* Nature Medicine *publication reporting clinical and serologic disease remission and potential immune system reset in CD19-CAR T treated refractory systemic lupus erythematosus (SLE) patients and a global leader in the application of CD19-targeting cell therapies in autoimmunity*

PHILADELPHIA, Oct. 11, 2022 — 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 CABA-201, a newly designed, fully human CD19 chimeric antigen receptor (CAR) containing a 4-1BB co-stimulatory domain. Cabaletta has obtained an exclusive, worldwide license for the CD19 binder in CABA-201. The CD19 binder is integrated into a dual targeting CAR T therapy that has been evaluated in approximately 20 cancer patients to date in an investigator-initiated trial. We believe tolerability data generated in these patients support clinical development in patients with autoimmune diseases. In addition, Cabaletta has established an exclusive translational research partnership with Dr. Georg Schett, a pioneer and global leader in the application of CD19-targeting cell therapies in autoimmunity. The collaboration is focused on generation of additional translational data to gain deeper understanding of the immunologic mechanisms of response and clinical insights from ongoing and continued clinical studies in multiple autoimmune disease indications. The construct utilized in these studies has a similar design to CABA-201, sharing the 4-1BB costimulatory domain and the binding region on the CD19 antigen with a fully human binder. With the addition of CABA-201 to its cell therapy pipeline, Cabaletta can potentially address a broad range of autoimmune diseases in indications such as SLE, rheumatoid arthritis, myositis and systemic sclerosis, among others where B cells contribute to disease pathogenesis.

"On the heels of the seminal publication in *Nature Medicine* last month reporting initial clinical activity and tolerability data from a 4-1BB-containing CD19-CAR T in patients with SLE who experienced durable drug-free clinical and serologic remission with the one-time therapy, we are excited to announce our new pipeline candidate, CABA-201. We believe CABA-201 is favorably designed for patients with autoimmune diseases given its fully human CD19 binder and 4-1BB co-stimulatory domain. Our exclusive translational research partnership with Professor Schett, which is designed to leverage the deep experience and expertise of Cabaletta scientists in autoimmune cell therapy, has the potential to provide us with important and timely insights into patients enrolled in his breakthrough clinical studies," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "We have a sufficient cash runway that will allow us to advance CABA-201 in parallel with the DesCAARTes™ and MusCAARTes™ trials employing our chimeric autoantibody receptor (CAAR) technology, with the potential to generate important clinical data readouts for each program. Accelerated by our team's proven experience in developing cell therapies for patients with autoimmune diseases in logistically complex trials, our next anticipated milestones for CABA-201 are an IND submission in the first half of 2023, and pending FDA clearance of the IND, initial clinical data by the first half of 2024. We believe CABA-201 has the potential to transform treatment of several common autoimmune diseases by providing clinical and serologic remission and a potential to reset the immune system, furthering our mission to develop therapies that deliver deep, durable, and potentially curative responses for patients with autoimmune diseases."

Data published by Professor Schett and his colleagues in *Nature Medicine* on September 15, 2022, demonstrate that a CD19-CAR T cell therapy with a 4-1BB co-stimulatory domain following lymphodepletion with fludarabine and cyclophosphamide induced persistent and deep clinical responses in five out of five patients with severe, refractory SLE, with up to 17 months of follow up. The safety profile demonstrated only mild cytokine release syndrome (CRS), with grade 1 CRS observed in three out of five patients, and no neurotoxicity (immune effector cell-associated neurotoxicity syndrome, or ICANS) of any grade observed. New B cells repopulated within five months of CD19-CAR T infusion in all patients, with no evidence of disease recurrence or autoantibodies following repopulation.

"There is significant unmet need in SLE and other autoimmune diseases, where we believe there is strong potential for CD19-targeting cell therapies to provide meaningful responses for patients. The team at Cabaletta has deep expertise in translational research relating to cell therapy in autoimmune patients, which will be complementary to my team's efforts. Together, through our exclusive translational research partnership, we can more efficiently address questions critical to advancing CD19-targeting cell therapy strategies for patients," stated Georg Schett, M.D., Professor and Head of the Department of Internal Medicine 3, and Vice President of Research, Friedrich-Alexander University, Erlangen-Nürnberg, Erlangen, Germany.

CABA-201 includes a fully human CD19 binder that was exclusivelyin-licensed from Nanjing IASO Biotherapeutics, Co., Ltd. (IASO Bio), which currently utilizes the binder in its CT120 product candidate, a 4-1BB-containing tandem CD19xCD22-CAR T cell therapy that has been evaluated in approximately 20 patients with promising tolerability data in an investigator-initiated trial. CT120 is currently in a Phase I clinical trial in China for non-Hodgkin's Lymphoma.

Transaction Terms with IASO Bio

Under the terms of the agreement, Cabaletta will receive an exclusive, worldwide license to IASO Bio's CD19 binder for use in autoimmune and alloimmune indications in humans. IASO Bio is eligible to receive up to $162 million in aggregate payments, including an upfront payment and payment upon the achievement of specified development and commercial milestones, along with tiered mid-single digit royalties on future net sales for products that may result from this collaboration agreement.

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 – encompassing chimeric antigen receptor T cells for autoimmunity (CARTA: CABA-201, a 4-1BB-containing CD19-CAR T) and Cabaletta Bio's proprietary chimeric autoantibody receptor T cells (CAART: multiple candidates including DSG3-CAART for mucosal pemphigus vulgaris, MuSK-CAART for MuSK myasthenia gravis) – provides multiple opportunities to treat broad and challenging autoimmune diseases. Cabaletta Bio's headquarters are located in Philadelphia, PA. For more information, visit www.cabalettabio.com and follow us on LinkedIn and Twitter.

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; the timing of our planned submission of an investigational new drug application (IND) for CABA-201 to the FDA and generation of initial clinical data forCABA-201; statements regarding regulatory filings regarding its development programs; the expectation that Cabaletta Bio may improve outcomes for patients suffering from mPV, MG, or other autoimmune diseases; the progress and results of its DesCAARTes™ Phase 1 trial, including Cabaletta's ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the trial; plans to initiate patient dosing in an open-label Phase 1 clinical trial to evaluate MuSK-CAART safety and tolerability in MuSK MG patients in 2022; the ability to accelerate Cabaletta's pipeline and develop meaningful therapies for patients, including in collaboration with academic and industry partners; and the anticipated contribution of the members of Cabaletta's executives to the company's operations and progress.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: 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 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 the impact of public health epidemics affecting countries or regions in which Cabaletta has operations or does business, such as COVID-19; risks related to Cabaletta's ability to protect and maintain its intellectual property position; 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 or commercialized; and the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Cabaletta's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Cabaletta's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in Cabaletta's other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Cabaletta undertakes no duty to update this information unless required by law.

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