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

FORM 8-K

CURRENT REPORT PURSUANT TO
SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: October 9, 2023
(Date of earliest event reported)

ANAPTYSBIO, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-37985**	**20-3828755**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10770 Wateridge Circle, Suite 210,
San Diego, CA 92121
(Address of Principal Executive Offices, and Zip Code)

(858) 362-6295
(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 (see General Instruction A.2. below):

☐Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐Pre-commencement communication 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 $0.001 per share	ANAB	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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.

On October 9, 2023, AnaptysBio, Inc. issued a press release announcing positive top-line phase 3 clinical trial results of Imsidolimab (IL-36R) in Generalized Pustular Psoriasis (GPP). A copy of the press release is attached as Exhibit 99.1 to this report and incorporated herein by reference.

The information within this report, including Exhibit 99.1 to this Current Report on Form 8-K, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this report and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document filed by AnaptysBio with the Securities and Exchange Commission, whether made before or after the date of this Current Report on Form 8-K, regardless of any general incorporation language in such filing (or any reference to this Current Report on Form 8-K generally), except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Exhibit Title or Description
99.1	Press release issued by AnaptysBio, Inc. regarding Imsidolimab top-line phase 3 data, dated October 9, 2023.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document).

SIGNATURES

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

AnaptysBio, Inc.

Date: October 10, 2023

By: /s/ Dennis Mulroy

Name: Dennis Mulroy

Title: Chief Financial Officer

Anaptys Announces Positive Top-Line Phase 3 Clinical Trial Results of Imsidolimab (IL-36R) in Generalized Pustular Psoriasis (GPP)

- 53.3% of patients who received a single dose of 750mg IV imsidolimab achieved GPPPGA 0/1 (clear or almost clear) at Week 4 (primary endpoint), compared to 13.3% of patients on placebo (p=0.0131)
- Demonstrated favorable safety and tolerability with no SAEs, low incidence and no increase of infections vs. placebo and no cases of DRESS or Guillain-Barre in imsidolimab-treated patients
- Only one of 30 (3.3%) imsidolimab-treated patients had detectable ADA, which were non-neutralizing
- Plan to present comprehensive data from GEMINI-1 and top-line GEMINI-2 results at a medical meeting in H2 2024
- Intend to out-license imsidolimab in 2024

SAN DIEGO, Oct. 9, 2023 — AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced positive top-line results from its global Phase 3 GEMINI-1 trial evaluating the safety and efficacy of imsidolimab (IL-36R mAb) in patients with generalized pustular psoriasis (GPP) flares. Investigational imsidolimab met its primary endpoint in the study population achieving rapid clearance of pustulation, erythema and scaling through Week 4 after a single dose of 750mg IV imsidolimab. Top-line data also demonstrate a favorable safety and tolerability profile.

“The success of the GEMINI-1 trial highlights Anaptys’ commitment to patients and our ability to internally discover and develop differentiated antibodies,” said Daniel Faga, president and chief executive officer of Anaptys. “Moving forward, we intend to out-license imsidolimab with this compelling and competitive dataset to bring this therapy to patients living with this highly morbid condition and reallocate the potential proceeds of a transaction to further invest in the broad development of our best-in-class immune cell modulators, including our checkpoint agonists, in autoimmune and inflammatory diseases.”

Imsidolimab is an IgG4 antibody that inhibits the function of the interleukin-36 receptor (IL-36R), a signaling pathway within the immune system shown to be involved in the pathogenesis of inflammatory diseases, including GPP. The registration-enabling GEMINI-1 trial in GPP, which recruited 45 patients, is the first randomized, double-blind, placebo-controlled trial to use the composite endpoint of Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) at Week 4 as its primary assessment. The GPPPGA assessment, representing a stringent and comprehensive characterization of disease severity, required satisfying an overall clinical response score of 0/1 (clear or almost clear) collectively across each GPP disease attribute, including pustulation, erythema and scaling.

“GPP is an unpredictable and potentially life-threatening skin disease with systemic symptoms,” said Professor Hervé Bachelez, M.D., Ph.D., Hôpital Saint-Louis, Paris, one of the world’s leading experts on GPP. “Achieving positive top-line results utilizing the GPPPGA composite endpoint in this well conducted, randomized controlled, global trial, along with a compelling safety profile, represents the potential for a single dose of imsidolimab to predictably provide relief for patients living with this burdensome disease.”

Imsidolimab Met Primary Endpoint Achieving Rapid Clearance of GPP Through Week 4 After a Single Dose

53.3% of patients who received a single dose of 750mg IV imsidolimab achieved GPPPGA 0/1 (clear or almost clear) at Week 4 (primary endpoint), compared to 13.3% of patients on placebo (p=0.0131).

Additionally, 66.7% (10/15) of placebo patients exited GEMINI-1 early, crossed-over to GEMINI-2 and were eligible to receive rescue therapy with a single dose of 750mg IV imsidolimab.

Imsidolimab Was Well Tolerated Through End of Study

- All AEs reported in imsidolimab-treated patients were mild or moderate and balanced across imsidolimab-treated vs. placebo patients
- No SAEs or severe AEs reported in imsidolimab-treated patients
- No cases reported of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or Guillain-Barre syndrome (GBS)
- Low incidence and no elevation of infections vs. placebo
- No infusion reactions reported
- One of 30 (3.3%) imsidolimab-treated patients had detectable anti-drug antibodies, which were non-neutralizing

Anaptys plans to present comprehensive data from GEMINI-1 and top-line GEMINI-2 results at a medical meeting in H2 2024. Furthermore, the company anticipates filing a biologics license application (BLA) with the U.S. Food and Drug Administration (FDA) by Q3 2024.

“We are excited that these top-line results from the Phase 3 GEMINI-1 trial support that a single infusion of imsidolimab is efficacious and well tolerated,” said Paul Lizzul, M.D., Ph.D., chief medical officer of Anaptys. “We would like to thank the patients, investigators and study personnel for their participation in this trial. We look forward to engaging with FDA and plan to submit a BLA by Q3 2024.”

GEMINI-1 Trial Design and Patient Demographics

Anaptys’ Phase 3 registration-enabling GEMINI-1 clinical trial was a four week, double-blind, placebo-controlled, randomized study to evaluate the efficacy and safety of imsidolimab (IL-36R) in patients with GPP, irrespective of mutational status.

A total of 45 patients, 15 patients per arm, were enrolled across diverse global regions ranging from the U.S., EU, MENA, and Asia. Patients were randomized 1:1:1 to receive a single infusion of 750mg IV imsidolimab, 300mg IV imsidolimab or placebo at Day 0. Placebo patients who were worsening or not improved after Day 8 were eligible for rescue therapy and crossover into the GEMINI-2 Phase 3 trial where they received a single infusion of 750mg IV imsidolimab.

GEMINI-2 Trial Design

Patients who were rescued or completed the GEMINI-1 trial are subsequently being enrolled in GEMINI-2, the second Phase 3 trial for imsidolimab in GPP, where they are receiving monthly doses of 200mg subcutaneous imsidolimab or placebo depending upon whether they are responders, partial responders or non-responders to treatment under GEMINI-1.

The objective of the ongoing GEMINI-2 trial is to assess the efficacy and safety of imsidolimab for the prevention and/or reduction in severity of recurrent GPP flares when dosed chronically as a monthly subcutaneous dosing over a three-year period.

About imsidolimab (IL-36R) and GPP

Imsidolimab is a fully humanized IgG4 antibody that inhibits the function of the interleukin-36-receptor, or IL-36R, that is being developed for the treatment of GPP.

GPP is a rare, chronic, systemic autoinflammatory disease that is potentially life-threatening, if left untreated.

During a GPP flare, individuals experience the sudden eruption of painful pustules. These pustules appear over large areas of the skin, accompanied by redness, severe itchiness, and dry, cracked, or scaly skin. People with GPP may also experience more general symptoms such as fever, headache, extreme tiredness, or a burning sensation on the skin.

About Anaptys

Anaptys is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. It is developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, its PD-1 agonist, in a Phase 2b trial for the treatment of moderate-to-severe rheumatoid arthritis; and ANB032, its BTLA agonist, in a Phase 2b trial for the treatment of moderate-to-severe atopic dermatitis. Its preclinical immune cell modulator portfolio includes ANB033, an anti-CD122 antagonist antibody for the treatment of autoimmune and inflammatory diseases. In addition, Anaptys has developed two cytokine antagonists available for out-licensing: imsidolimab, an anti-IL-36R antagonist, in Phase 3 for the treatment of generalized pustular psoriasis, or GPP, and etokimab, an anti-IL-33 antagonist for the treatment of respiratory disorders that is Phase 2/3 ready. Anaptys has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immune-oncology, including an anti-PD-1 antagonist antibody (*Jemperli* (dostarlimab-gxly)), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889) and an anti-LAG-3 antagonist antibody (GSK4074386).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the timing of the release of data from the Company’s clinical trials, including imsidolimab’s Phase 3 GEMINI-2 clinical trial in GPP; the timing of GEMINI-1 and GEMINI-2 clinical trial data to be presented at a medical meeting; the timing of a BLA filing for imsidolimab; whether any of the Company’s product candidates will be best in class; the company’s ability to find a licensing partner for imsidolimab or etokimab and the timing of any such transaction. Statements including words such as “plan,” “intend,” “continue,” “expect,” or “ongoing” and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company’s ability to advance its product candidates, obtain regulatory approval of and ultimately

commercialize its product candidates, the timing and results of preclinical and clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to protect intellectual property and other risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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