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 4, 2021
(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 2, 2021, AnaptysBio issued a press release announcing an imsidolimab clinical program update. A copy of the press release is furnished 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 exhibits 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 an imsidolimab clinical program update, dated October 2, 2021
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 4, 2021

By: /s/Dennis Mulroy

Name: Dennis Mulroy

Title: Chief Financial Officer

AnaptysBio Presents Updated Data From Imsidolimab Phase 2 GALLOP Trial in Generalized Pustular Psoriasis

- Imsidolimab demonstrated rapid and sustained efficacy with 6 of 8 (75%) generalized pustular psoriasis (GPP) patients achieving the primary endpoint at week 4 and week 16
- Early reduction of erythema with pustules by 60% at week 1 improved to 94% reduction at week 4 and 98% reduction at week 16
- Phase 3 GEMINI-1 clinical trial has been initiated subsequent to FDA end-of-Phase 2 meeting and FDA orphan drug designation for the treatment of GPP
- In addition to GPP, imsidolimab clinical development to focus on moderate-to-severe acne and moderate-to-severe hidradenitis suppurativa, with Phase 2 top-line data anticipated in these indications during the first and second halves of 2022, respectively

SAN DIEGO, October 2nd 2021 - AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on emerging immune control mechanisms applicable to inflammation and immuno-oncology indications, today announced that week 16 data from the GPP GALLOP Phase 2 trial of imsidolimab, its investigational anti-interleukin-36 receptor (IL-36R) therapeutic antibody, was presented at the 2021 European Academy of Dermatology and Venereology (EADV) Congress. The oral presentation, titled “Imsidolimab, an Anti-IL-36 Receptor Monoclonal Antibody, in the Treatment of Generalized Pustular Psoriasis: Results from a Phase 2 Trial”, was presented by Dr. Johann Gudjonsson, professor of Dermatology at the University of Michigan.

“These promising results demonstrate the potential for imsidolimab in the treatment of GPP patients,” said Dr. Johann Gudjonsson. “GPP is a severely debilitating life-threatening dermatological disease in need of novel therapeutic approaches. I look forward to the advancement of imsidolimab in GPP Phase 3 trials.”

“I would like to thank all of the patients, physicians, nurses and clinical research collaborators that helped AnaptysBio conduct the GALLOP clinical trial,” said Dr. Paul Lizzul, chief medical officer of AnaptysBio. “We are pleased to advance development of imsidolimab across GPP, acne and hidradenitis suppurativa going forward.”

Study Data

Key data available to date from the 8 patients enrolled in the GALLOP trial are as follows:

- Six of 8 (75%) patients treated with imsidolimab monotherapy achieved the primary endpoint of response on the clinical global impression (CGI) scale at week 4 and week 16 (Table 1), without requiring rescue medication. Two of 8 (25%) patients were considered to have not met the primary endpoint because they dropped out of the trial prior to Day 29.
- Modified Japanese Dermatology Association severity index total score (mJDA-SI), which incorporates both dermatological and systemic aspects of GPP, decreased on average by 29% at week 1, 54% at week 4 and 58% at week 16. Erythema with pustules, which clinically defines GPP, decreased by 60% at week 1, 94% by week 4 and 98% by week 16. Dermatology Life Quality Index (DLQI), which is a patient-reported measure, achieved a reduction of 6 points at week 4 and 11 points by week 16, each of which exceeded the minimal clinically importance difference (MCID) of 4 points. GPP Physician Global Assessment (GPPPGA) scale was implemented by protocol amendment during the course of the trial and was assessed in 4 of the 8 enrolled patients, where zero (clear) or 1 (almost clear) response was achieved in 2 (50%) patients at week 4 and 3 (75%) patients at week 16.
- Genotypic testing indicated homozygous wild-type IL-36RN, CARD14 and AP1S3 alleles for all 7 tested patients.
- Through week 16, anti-drug antibodies were only detected in one patient, which occurred at week 12 and did not impact imsidolimab pharmacokinetics or efficacy.

Imsidolimab was generally well-tolerated and most treatment-emergent adverse events were mild to moderate in severity and resolved without sequelae.

No infusion or injection site reactions were observed. As previously reported, one patient dropped out of the trial following diagnosis of *Staphylococcal aureus* bacteremia in the first week, which was a serious adverse event deemed to be possibly drug-related. Because the patient was symptomatic prior to dosing and had a prior medical history of bacteremia, a common comorbidity of GPP, the Company does not believe this event is likely attributable to imsidolimab. Another patient dropped out of the study on Day 22 due to investigator reported inadequate efficacy. One patient contracted COVID-19 during the course of the trial, which was mild, unrelated to imsidolimab, and did not lead to study discontinuation.

Endpoint	Baseline	Week 1 Relative to Baseline	Week 4 Relative to Baseline	Week 16 Relative to Baseline
CGI Responders	N/A	7 of 8 patients	6 of 8 patients	6 of 8 patients
mJDA-SI	9	-29%	-54%	-58%
Erythema with Pustules (% body surface area)	24%	-60%	-94%	-98%
DLQI	16	-1	-6	-11

Table 1. Key endpoints at week 1, 4 and 16 relative to baseline.

GALLOP Phase 2 Trial Design

Eight patients were enrolled in the GALLOP trial from 12 sites in the United States and Europe. Patients were washed out of prior therapy and no concomitant therapy was permitted during the trial. Key inclusion criteria include active ongoing GPP disease with a minimum mJDA-SI score of 7 and at least 10% body surface area covered by active pustules and erythema, while key exclusion criteria included concomitant dermatological conditions or infection. Patients were treated with a 750mg intravenous induction dose of imsidolimab at day 1, followed by monthly 100mg subcutaneous doses on days 29, 57 and 85. The primary endpoint of this trial was clinical response on the CGI scale at week 4 and week 16 without rescue therapy. Baseline clinical assessments were conducted for each patient on day 1 prior to imsidolimab dosing. Missing mJDA-SI data points were imputed using last-observation-carry forward (LOCF) methodology.

GEMINI Phase 3 Trial

Following an end-of-Phase 2 meeting with the FDA in Q2 2021 where week 16 data from the GALLOP Phase 2 trial was reviewed, AnaptysBio has initiated a 45-patient GPP Phase 3 trial of imsidolimab, called GEMINI-1, where the primary endpoint is the proportion of patients achieving a GPPPGA score of zero (clear) or 1 (almost clear) at week 4. Patients completing GEMINI-1 will be enrolled in a subsequent GEMINI-2 Phase 3 trial designed to assess 6 months of monthly subcutaneous imsidolimab dosing. Over 50 global clinical sites will be involved in screening GPP patients for enrollment. The Company is also continuing enrollment of a global registry of GPP patients, called RADIANCE, which is intended to improve understanding of the GPP patient journey and support enrollment of GEMINI-1. The FDA has previously granted orphan drug designation for imsidolimab for the treatment of GPP.

Imsidolimab Clinical Development Focus

Going forward, the Company has prioritized clinical development of imsidolimab in GPP where Phase 3 GEMINI-1 has been initiated, moderate-to-severe acne where Phase 2 ACORN top-line data is anticipated in the first half of 2022 and moderate-to-severe hidradenitis suppurativa where Phase 2 HARP top-line data is anticipated in the second half of 2022. The company is discontinuing imsidolimab clinical development for EGFR-mediated skin toxicities and ichthyosis due to evolving clinical landscapes for these indications and slower than anticipated enrollment.

About GPP
GPP is a rare, chronic life-threatening, inflammatory disease with no currently approved therapies in the United States or Europe. Typically diagnosed after age 30, these patients can die from complications of bacteremia, sepsis, acute respiratory distress syndrome and cardiac failure. Most patients are treated off-label with systemic anti-inflammatory agents, including high-dose cyclosporine, methotrexate, corticosteroids, retinoids or biologics, which are often tapered or discontinued due to lack of efficacy or toxicity. GPP is known to be associated with excess signaling through the IL-36 receptor, which can be caused by genetic mutations and environmental factors. Medical claims analyses recently conducted by IQVIA indicate approximately 37,000 unique patients were diagnosed with GPP at least once, and approximately 15,000 unique patients were diagnosed with GPP at least twice, in the United States by a physician between 2017 and 2019 using the International Classification of Diseases 10th Revision (ICD-10) billing code pertaining to GPP (L40.1).

About AnaptysBio
AnaptysBio is a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation. The Company's proprietary anti-inflammatory pipeline includes imsidolimab, its anti-IL-36R antibody, previously referred to as ANB019, for the treatment of dermatological inflammatory diseases, including generalized pustular psoriasis, or GPP, acne and hidradenitis suppurativa; rosnilimab, its anti-PD-1 agonist program, previously referred to as ANB030, for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated; and its BTLA modulator program, ANB032, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. AnaptysBio's antibody pipeline has been developed using its proprietary somatic hypermutation, or SHM platform, which uses in vitro SHM for antibody discovery and is designed to replicate key features of the human immune system to overcome the limitations of competing antibody discovery technologies. AnaptysBio has also developed multiple therapeutic antibodies in an immuno-oncology collaboration with GSK, including an anti-PD-1 antagonist antibody (JEMPERLI (dostarlimab-gxly) GSK4057190), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889) and an anti-LAG-3 antagonist antibody (GSK4074386), and an inflammation collaboration with Bristol-Myers Squibb, including an anti-PD-1 checkpoint agonist antibody (CC-90006) currently in clinical development.

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 our clinical trials, including imsidolimab's Phase 2 clinical trials in acne and hidradenitis suppurativa. Statements including words such as "plan," "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 our 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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