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: April 27, 2022
(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 April 27, 2022, AnaptysBio, Inc. issued a press release announcing ANB032 (anti-BTLA agonist) top-line phase 1 data. 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 ANB032 (anti-BTLA agonist) top-line phase 1 data, dated April 27, 2022.
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: April 27, 2022

By: /s/Dennis Mulroy

Name: Dennis Mulroy

Title: Chief Financial Officer

AnaptysBio Announces Positive ANB032 (anti-BTLA agonist) Top-Line Phase 1 Data and Provides Pipeline Updates

- ANB032, our wholly owned anti-BTLA agonist antibody, demonstrated favorable safety, tolerability and a rapid and sustained pharmacokinetic and pharmacodynamic profile that supports advancement of ANB032 into subsequent patient trials
- ANB032 IND filing in an initial proof-of-concept Phase 2 trial is anticipated in the second half of 2022
- Imsidolimab (anti-IL-36R Ab) top-line data from the Phase 2 trial in moderate-to-severe hidradenitis suppurativa is anticipated in the third quarter of 2022

SAN DIEGO, April 27, 2022 - 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 positive top-line data from a Phase 1 trial of ANB032, its investigational wholly owned anti-BTLA agonist antibody. Top-line data demonstrated favorable safety, tolerability, and a rapid and sustained pharmacokinetic and pharmacodynamic profile that supports advancement of ANB032 into subsequent patient trials.

AnaptysBio has a strategic portfolio review ongoing while continuing to execute on the development of its three wholly owned clinical stage antibody programs:

- Imsidolimab (anti-IL-36R Ab) top-line data from the GEMINI-1 Phase 3 trial in GPP is anticipated in the fourth quarter of 2023
- Imsidolimab top-line data from the HARP Phase 2 trial in moderate-to-severe hidradenitis suppurativa is anticipated in the third quarter of 2022
- Rosnilimab (anti-PD-1 agonist Ab) top-line data from the AZURE Phase 2 trial in moderate-to-severe alopecia areata is anticipated in the first half of 2023
- ANB032 (anti-BTLA agonist Ab) IND filing of a Phase 2 clinical trial is anticipated in the second half of 2022

“We are pleased to report promising results for ANB032 in this Phase 1 trial, as we continue to execute across our three wholly owned clinical stage antibody programs,” said Dr. Paul F. Lizzul, chief medical officer of AnaptysBio. “We believe ANB032’s mechanism is broadly applicable to T and B cell driven inflammatory diseases and look forward to further clinical development with this important immune checkpoint modulator.”

A total of 96 subjects were enrolled in the randomized, double-blind, placebo-controlled healthy volunteer Phase 1 trial, where single ascending dose (SAD) cohorts received subcutaneous or intravenous single doses of ANB032 or placebo, while multiple ascending dose (MAD) cohorts received four weekly subcutaneous doses of ANB032 or placebo.

ANB032 was generally well-tolerated, no dose limiting toxicities were observed and there were no discontinuations due to adverse events, other than one patient quarantined for potential COVID infection. No serious adverse events (SAEs) were reported. Most adverse events were considered to be mild-to-moderate, of short duration, resolved without sequelae and occurred sporadically in a dose-independent manner. Three severe adverse events (2 blood creatine phosphokinase (CPK) increase and 1 aspartate

aminotransferase (AST) increase), none of which were treatment-related, were reported in two subjects in the lowest dose MAD cohort. Three subjects had mild-to-moderate single injection site reactions (ecchymosis; erythema; and pain) of short duration.

Pharmacokinetic analyses demonstrated a favorable profile for ANB032 including an approximate two-week half-life for subcutaneous and intravenous routes of administration. Full BTLA receptor occupancy was observed rapidly within hours and was maintained for greater than 30 days following IV or subcutaneous ANB032 dosing.

ANB032 pharmacodynamic activity resulted in reduction of cell surface BTLA expression on T cells and B cells following dosing. A portion of the cell surface BTLA was shed from the cells as soluble BTLA (sBTLA), while the residual approximately 60% of baseline BTLA on T cells and B cells remained occupied by ANB032. The duration of reduced BTLA expression correlated with receptor occupancy in a dose-dependent manner and was maintained for greater than 30 days following IV or subcutaneous ANB032 dosing.

“ANB032 demonstrated rapid and sustained target engagement on both T cells and B cells. Importantly, reduction of cell surface BTLA expression and the shedding of a portion of the cell surface BTLA as soluble BTLA, which was previously demonstrated to occur with ANB032 treatment in animal models of inflammation where robust efficacy was observed, confirmed the pharmacodynamic activity of ANB032 in humans,” said Dr. Martin Dahl, SVP Discovery Biology of AnaptysBio. “Based upon these data, we believe ANB032’s in vivo mechanism has the potential to broadly treat T and B-cell driven human inflammatory diseases.”

About ANB032
ANB032, a wholly owned anti-BTLA agonist antibody developed by AnaptysBio, demonstrated favorable safety, tolerability and a rapid and sustained pharmacokinetic and pharmacodynamic profile in a Phase 1 healthy volunteer trial. ANB032 is anticipated to down-modulate the activity of T cells, B cells and BTLA expressing myeloid dendritic cells via several potential mechanisms: direct BTLA agonistic activity, stabilization of the interaction of BTLA and HVEM in cis which prevents pro-inflammatory signaling mediated by HVEM ligands such as LIGHT, and abrogation of pro-inflammatory HVEM signaling mediated by BTLA in trans. Genetic studies have demonstrated that BTLA pathway mutations increase human susceptibility to multiple autoimmune diseases and insufficient BTLA signaling can lead to dysregulated T or B cell responses.

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, and moderate-to-severe hidradenitis suppurativa; rosnilimab, its anti-PD-1 agonist program, previously referred to as ANB030, for the treatment of moderate-to-severe alopecia areata; and its anti-BTLA agonist 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).

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 top-line data for our Phase 2 clinical trial of imsidolimab in moderate-to-severe hidradenitis suppurativa, our Phase 3 clinical trial of imsidolimab in GPP and our Phase 2 clinical trial of rosnilimab in moderate-to-severe alopecia areata; the timing of an IND filing for ANB032; and the potential of ANB032 to treat T and/or B cell-mediated human inflammatory diseases. 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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