

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: August 8, 2019

(Date of earliest event reported)

ANAPTYSBIO, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-37985

(Commission File Number)

20-3828755

(IRS Employer Identification No.)

10421 Pacific Center Court, Suite 200

San Diego, CA

(Address of Principal Executive Offices)

92121

(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 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))

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 2.02 Results of Operations and Financial Condition.

On August 8, 2019, AnaptysBio, Inc. (“*AnaptysBio*”) issued a press release announcing its financial results for the six months ended June 30, 2019. A copy of the press release is attached as Exhibit 99.01 to this Current Report on Form 8-K.

The information in this Item 2.02, including Exhibit 99.01 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 Item 2.02 and in the accompanying Exhibit 99.01 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.

99.01 [Press release issued by AnaptysBio, Inc. regarding its financial results for the three and six months ended June 30, 2019, dated August 8, 2019.](#)

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 hereunto duly authorized.

AnaptysBio, Inc.

Date: August 8, 2019

By: /s/ Dominic Piscitelli

Name: Dominic Piscitelli

Title: Chief Financial Officer

AnaptysBio Announces Second Quarter 2019 Financial Results and Provides Pipeline Updates

- Multiple Top-line Phase 2 Clinical Efficacy Readouts from Wholly-owned Pipeline Anticipated in 2019
- Etokimab Phase 2b Eosinophilic Asthma Trial Initiation Anticipated in 4Q19
- IND Filing for Company's Third Wholly-Owned Program, ANB030, an anti-PD-1 Agonist, Expected in 4Q19
- Recognized \$5.0 million milestone for advancement of dostarlimab, an anti-PD-1 antagonist antibody partnered with GSK, into Phase 3 for a second indication

SAN DIEGO, Aug. 8, 2019 - AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation, today reported operating results for the second quarter ended June 30, 2019 and provided pipeline updates.

“In the first half of 2019, we’ve made significant progress across our entire clinical and preclinical pipeline toward achieving our mission of bringing novel treatments to patients with severe inflammatory diseases,” said Hamza Suria, president and chief executive officer of AnaptysBio. “With multiple data readouts from our etokimab and ANB019 clinical trials, and an IND planned for ANB030, the remainder of 2019 is set to be an important period for AnaptysBio.”

Etokimab (ANB020 Anti-IL-33) Program

- In June 2019, AnaptysBio presented full data from its Phase 2a proof-of-concept clinical trial of etokimab in adult patients with severe eosinophilic asthma at the 2019 European Academy of Allergy and Clinical Immunology (EAACI) Congress. Data showed that a single dose of etokimab resulted in rapid and sustained lung function improvement as measured using Forced Expiratory Volume in One Second, or FEV1, patient reported outcomes associated with asthma symptoms, as measured using the Asthma Control Questionnaire 5, and biomarker levels as measured using blood eosinophils. The Company believes these data support continued development of etokimab in eosinophilic asthma and plans to initiate a multi-dose Phase 2b randomized, double-blinded, placebo-controlled trial in 300-400 eosinophilic asthma patients in the fourth quarter of 2019.
- The Company is also conducting its ATLAS trial, a Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in approximately 300 adult patients with moderate-to-severe atopic dermatitis. The study is designed to assess different dose levels and dosing frequencies of subcutaneously-administered etokimab, with top-line data expected in the fourth quarter of 2019.
- AnaptysBio is conducting a randomized, placebo-controlled Phase 2 trial in approximately 100 adult patients with chronic rhinosinusitis with nasal polyps, also referred to as the ECLIPSE trial. Patients are being treated with two multi-dosing frequencies of subcutaneously-administered etokimab or placebo, each in combination with mometasone furoate nasal spray as background therapy. The Company anticipates interim top-line data from the ECLIPSE trial in the fourth quarter of 2019.

ANB019 (Anti-IL-36 Receptor) Program

- The Company is conducting a single arm, open-label Phase 2 trial of ANB019 in up to 10 patients with generalized pustular psoriasis, or GPP, also known as the GALLOP trial, with interim top-line data expected in mid-2019.
 - The Company is conducting a randomized, placebo-controlled, multi-dose Phase 2 trial in 50 patients with palmoplantar pustulosis, or PPP, also known as the POPLAR trial, with top-line data anticipated in the first half of 2020.
-

ANB030 (Anti-PD-1 Agonist) Program

- ANB030 is a wholly-owned antibody that binds PD-1 in an agonistic manner, leading to reduced T cell activity and anti-inflammatory effects *in vivo*. Genetic mutations in the PD-1 pathway are associated with increased susceptibility to various inflammatory conditions and we believe ANB030 has the potential to suppress inflammatory diseases by restoring insufficient PD-1-mediated negative signaling on activated T cells. The Company plans to focus future clinical development of ANB030 on certain autoimmune diseases where PD-1 checkpoint receptor function may be under-represented and anticipates filing an Investigational New Drug Application (IND) in the fourth quarter of 2019. Preclinical data from the ANB030 was presented in June at the 2019 FOCIS Annual Meeting.

Second Quarter Financial Results

- Cash, cash equivalents and investments totaled \$467.9 million as of June 30, 2019 compared to \$500.2 million as of December 31, 2018, for a decrease of \$32.3 million. The decrease relates primarily to cash used for operating activities.
- Collaboration revenue was \$5.0 million for the three and six months ended June 30, 2019, which related to a milestone for initiation of a Phase 3 trial in a second indication for dostarlimab, the anti-PD-1 antagonist antibody partnered with TESARO, a GlaxoSmithKline (GSK) company, compared to no revenue for the three and six months ended June 30, 2018.
- Research and development expenses were \$27.4 million and \$48.0 million for the three and six months ended June 30, 2019, compared to \$10.6 million and \$22.4 million for the three and six months ended June 30, 2018. The increase was due primarily to continued advancement of the Company's etokimab and ANB019 clinical programs and additional personnel-related expenses, including share-based compensation.
- General and administrative expenses were \$4.3 million and \$8.4 million for the three and six months ended June 30, 2019, compared to \$3.8 million and \$7.8 million for the three and six months ended June 30, 2018. The increase was due primarily to additional personnel-related expenses, including share-based compensation.
- Net loss was \$24.0 million and \$46.0 million for the three and six months ended June 30, 2019, or a net loss per share of \$0.89 and \$1.70, compared to a net loss of \$13.6 million and \$28.7 million for the three and six months ended June 30, 2018, or a net loss per share of \$0.57 and \$1.20.

Financial Guidance

AnaptysBio expects that its cash, cash equivalents and investments will fund its current operating plan at least through the end of 2020.

About Etokimab

Etokimab, previously referred to as ANB020, is an antibody that potently binds and inhibits the activity of interleukin-33, or IL-33, a pro-inflammatory cytokine that multiple studies have indicated is a central mediator of atopic diseases, which AnaptysBio believes is broadly applicable to the treatment of atopic inflammatory disorders, such as atopic dermatitis, eosinophilic asthma, chronic rhinosinusitis with nasal polyps, or CRSwNP, and potentially other allergic conditions. Following completion of a healthy volunteer Phase 1 trial of etokimab, AnaptysBio continued clinical development of etokimab into a Phase 2a trial for moderate-to-severe adult atopic dermatitis and a placebo-controlled Phase 2a trial in severe adult eosinophilic asthma patients. AnaptysBio is conducting its ATLAS trial, a randomized, double-blinded, placebo-controlled multi-dose Phase 2b clinical trial of etokimab in approximately 300 moderate-to-severe adult atopic dermatitis patients where top-line data is anticipated in the fourth quarter of 2019. The Company is conducting its ECLIPSE trial, a randomized, double-blinded, placebo-controlled Phase 2 trial of etokimab in approximately 100 adult patients with CRSwNP with interim top-line data anticipated in the fourth quarter of 2019. AnaptysBio also plans to initiate a randomized, double-blinded, placebo-controlled, multi-dose Phase 2b trial of etokimab in patients with eosinophilic asthma in the fourth quarter of 2019.

About ANB019

ANB019 is an antibody that inhibits the function of the interleukin-36-receptor, or IL-36R, which AnaptysBio plans to initially develop as a potential first-in-class therapy for patients suffering from generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP. AnaptysBio has previously presented data from a Phase 1 clinical trial, which demonstrated favorable safety, pharmacokinetics and pharmacodynamic properties that supported advancement of ANB019 into Phase 2 studies. AnaptysBio is conducting its GALLOP trial, a Phase 2 study of ANB019 in GPP where interim top-line data is anticipated in mid-2019, and its POPLAR trial, a Phase 2 study in PPP where top-line data is anticipated in the first half of 2020.

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 its anti-IL-33 antibody etokimab, previously referred to as ANB020, for the treatment of moderate-to-severe atopic dermatitis, eosinophilic asthma, and adult chronic rhinosinusitis with nasal polyps, or CRSwNP; its anti-IL-36R antibody ANB019 for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP; and its PD-1 agonist program, ANB030, and other novel anti-inflammatory checkpoint receptor modulator antibodies for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated. 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 partnership with TESARO, a GSK company, including an anti-PD-1 antagonist antibody (dostarlimab (TSR-042)), an anti-TIM-3 antagonist antibody (TSR-022) and an anti-LAG-3 antagonist antibody (TSR-033), and an inflammation partnership with Celgene, 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 etokimab's Phase 2b clinical trial in moderate-to-severe adult atopic dermatitis patients, etokimab's Phase 2 clinical trial in adult patients with chronic rhinosinusitis with nasal polyps and ANB019's Phase 2 clinical trials in GPP and PPP, the timing of and our ability to launch a Phase 2b clinical trial of etokimab in eosinophilic asthma patients, and the timing of an IND filing for ANB030, a new wholly-owned anti-inflammatory antibody program. 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.

Contact:

Dominic Piscitelli

AnaptysBio, Inc.

858.362.6348

dpiscitelli@anaptysbio.com

ANAPTYSBIO, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value data)

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 146,552	\$ 113,596
Receivable from collaborative partners	5,000	—
Australian tax incentive receivable	—	174
Short-term investments	275,664	313,486
Prepaid expenses and other current assets	3,772	6,960
Total current assets	<u>430,988</u>	<u>434,216</u>
Property and equipment, net	1,481	1,445
Long-term investments	45,707	73,128
Other long-term assets	1,913	148
Restricted cash	60	60
Total assets	<u>\$ 480,149</u>	<u>\$ 508,997</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 10,921	\$ 5,443
Accrued expenses	14,102	8,761
Notes payable, current portion	4,781	7,574
Other current liabilities	819	58
Total current liabilities	<u>30,623</u>	<u>21,836</u>
Other long-term liabilities	1,105	796
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at June 30, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.001 par value, 500,000 shares authorized, 27,045 shares and 26,922 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	27	27
Additional paid in capital	640,550	633,251
Accumulated other comprehensive income (loss)	574	(223)
Accumulated deficit	(192,730)	(146,690)
Total stockholders' equity	<u>448,421</u>	<u>486,365</u>
Total liabilities and stockholders' equity	<u>\$ 480,149</u>	<u>\$ 508,997</u>

ANAPTYSBIO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	\$ 5,000	\$ —	\$ 5,000	\$ —
Operating expenses:				
Research and development	27,350	10,583	47,981	22,393
General and administrative	4,307	3,832	8,448	7,779
Total operating expenses	31,657	14,415	56,429	30,172
Loss from operations	(26,657)	(14,415)	(51,429)	(30,172)
Other income (expense), net:				
Interest expense	(281)	(436)	(601)	(887)
Interest income	2,957	1,297	5,945	2,482
Other income (expense), net	(41)	(64)	(34)	(127)
Total other income (expense), net	2,635	797	5,310	1,468
Loss before income taxes	(24,022)	(13,618)	(46,119)	(28,704)
Provision for income taxes	60	—	79	—
Net loss	(23,962)	(13,618)	(46,040)	(28,704)
Other comprehensive income (loss):				
Unrealized income (loss) on available for sale securities, net of tax of \$99, \$0, \$214 and \$0, respectively	370	124	797	(250)
Other comprehensive income (loss), net of tax	\$ 370	\$ 124	\$ 797	\$ (250)
Net loss per common share:				
Basic and diluted	\$ (0.89)	\$ (0.57)	\$ (1.70)	\$ (1.20)
Weighted-average number of shares outstanding:				
Basic and diluted	27,026	23,932	27,004	23,867