

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: November 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 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 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 \$0.001 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 (§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 November 8, 2019, AnaptysBio, Inc. (“*AnaptysBio*”) issued a press release announcing its financial results for the nine months ended September 30, 2019. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 7.01 Regulation FD.

On November 8, 2019, AnaptysBio issued a press release announcing that its Etokimab ATLAS Phase 2b clinical trial in moderate-to-severe atopic dermatitis failed to meet its primary endpoint. A copy of the press release is furnished as Exhibit 99.2 to this report and incorporated herein by reference.

The information within this report, including Exhibit 99.1 and Exhibit 99.2 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.

99.1	<u>Press release issued by AnaptysBio, Inc. regarding its financial results for the three and nine months ended September 30, 2019, dated November 8, 2019.</u>
99.2	<u>Press release issued by AnaptysBio, Inc. regarding its Etokimab ATLAS Phase 2b Clinical Trial, dated November 8, 2019.</u>
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 hereunto duly authorized.

AnaptysBio, Inc.

Date: November 8, 2019 By: /s/ Eric Loumeau

Name: Eric Loumeau

Title: Interim Chief Financial Officer and General Counsel

AnaptysBio Announces Third Quarter 2019 Financial Results and Provides Pipeline Updates

- Topline Data From Etokimab ATLAS Phase 2b Clinical Trial in Moderate-to-Severe Atopic Dermatitis Failed to Meet Primary Endpoint
- Reported Positive Topline Data from Interim Analysis of GALLOP Phase 2 Clinical Trial of ANB019 Monotherapy in Moderate-to-Severe Generalized Pustular Psoriasis
- IND Filing for Company's Third Wholly-Owned Program, ANB030, an anti-PD-1 Agonist Antibody, Expected in 4Q19

SAN DIEGO, November 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 third quarter ended September 30, 2019 and provided pipeline updates.

“While we are disappointed with the top-line results of our etokimab ATLAS trial, we intend to re-evaluate our etokimab development strategy following additional data from ATLAS and top-line results from ECLIPSE in the first quarter of 2020,” said Hamza Suria, president and chief executive officer of AnaptysBio. “We look forward to advancing ANB019, ANB030 and additional preclinical programs in our wholly-owned pipeline.”

Etokimab (ANB020 Anti-IL-33) Program

- The Company today announced topline data from its ATLAS trial, a Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in approximately 300 adult patients treated with etokimab in moderate-to-severe atopic dermatitis. Each of the etokimab dosing arms failed to meet the primary endpoint of the trial, which was demonstration of statistically greater improvement in the Eczema Area and Severity Index (EASI) relative placebo at week 16.
- 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 topline data from an interim analysis of the ECLIPSE trial in the first quarter of 2020.
- The Company has decided to postpone the initiation of its planned Phase 2b etokimab clinical trial in eosinophilic asthma, a multi-dose, randomized, double-blinded, placebo-controlled trial in 300-400 patients, until it has the opportunity to analyze the full data set from the ATLAS trial.

ANB019 (Anti-IL-36 Receptor) Program

- In September, AnaptysBio announced positive topline data from an interim analysis of its Phase 2 clinical trial of ANB019 monotherapy in moderate-to-severe generalized pustular psoriasis, or GPP, also known as the GALLOP trial. In this interim analysis, both patients achieved the primary endpoint of disease score improvement at Day 29 and Day 113 without requiring rescue therapy, demonstrated rapid and sustained mJDA score improvement, with reduction of 58% at Day 8 and 63% at Day 113, and showed complete clearance of skin pustules by Day 8 and through Day 113, with CRP levels decreasing to nearly normal. Enrollment is ongoing in the GALLOP study, and the Company anticipates additional clinical data and a regulatory strategy update for the development of ANB019 in GPP during 2020.
- The Company is also 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 topline 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 and initiating a Phase 1 clinical trial in 2020. Preclinical data from the ANB030 was presented in June at the 2019 FOCIS Annual Meeting.

Board of Directors

- In September, the Company appointed Laura J. Hamill to its board of directors. Most recently, Ms. Hamill served as Executive Vice President, Worldwide Commercial Operations, for Gilead Sciences, where she was involved in the strategic direction and long-term planning of the organization. Previously, Ms. Hamill held a number of US and international executive roles at Amgen, culminating with Senior Vice President and General Manager where she led ~\$20B in U.S. commercial operations

Third Quarter Financial Results

- Cash, cash equivalents and investments totaled \$444.4 million as of September 30, 2019 compared to \$500.2 million as of December 31, 2018, for a decrease of \$55.8 million. The decrease relates primarily to cash used for operating activities.
- Collaboration revenue was zero and \$5.0 million for the three and nine months ended September 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 \$5.0 million for the three and nine months ended September 30, 2019.
- Research and development expenses were \$29.9 million and \$77.9 million for the three and nine months ended September 30, 2019, compared to \$17.9 million and \$40.3 million for the three and nine months ended September 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 \$3.8 million and \$12.3 million for the three and nine months ended September 30, 2019, compared to \$4.0 million and \$11.8 million for the three and nine months ended September 30, 2018. The change was due primarily to personnel-related expenses, including share-based compensation.
- Net loss was \$31.0 million and \$77.1 million for the three and nine months ended September 30, 2019, or a net loss per share of \$1.15 and \$2.85, compared to a net loss of \$16.0 million and \$44.7 million for the three and nine months ended September 30, 2018, or a net loss per share of \$0.66 and \$1.86.

Financial Guidance

AnaptysBio expects that its cash, cash equivalents and investments will fund its current operating plan, taking into account the adjustments to etokimab clinical development activities referenced above, at least into 2021. The Company expects to re-evaluate its current operating plan in light of the topline data from the ATLAS trial and to make adjustments as appropriate to manage the Company's available cash resources.

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 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:

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eloumeau@anaptysbio.com

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

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 182,898	\$ 113,596
Australian tax incentive receivable	—	174
Short-term investments	238,104	313,486
Prepaid expenses and other current assets	3,595	6,960
Total current assets	<u>424,597</u>	<u>434,216</u>
Property and equipment, net	1,695	1,445
Long-term investments	23,418	73,128
Other long-term assets	1,735	148
Restricted cash	60	60
Total assets	<u>\$ 451,505</u>	<u>\$ 508,997</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 10,522	\$ 5,443
Accrued expenses	15,286	8,761
Notes payable, current portion	3,077	7,574
Other current liabilities	845	58
Total current liabilities	<u>29,730</u>	<u>21,836</u>
Other long-term liabilities	883	796
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, \$0.001 par value, 500,000 shares authorized, 27,098 shares and 26,922 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	27	27
Additional paid in capital	644,148	633,251
Accumulated other comprehensive income (loss)	480	(223)
Accumulated deficit	(223,763)	(146,690)
Total stockholders' equity	<u>420,892</u>	<u>486,365</u>
Total liabilities and stockholders' equity	<u>\$ 451,505</u>	<u>\$ 508,997</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Collaboration revenue	\$ —	\$ 5,000	\$ 5,000	\$ 5,000
Operating expenses:				
Research and development	29,931	17,883	77,912	40,276
General and administrative	3,814	4,004	12,262	11,783
Total operating expenses	33,745	21,887	90,174	52,059
Loss from operations	(33,745)	(16,887)	(85,174)	(47,059)
Other income (expense), net:				
Interest expense	(240)	(400)	(841)	(1,287)
Interest income	2,757	1,369	8,702	3,851
Other income (expense), net	144	(40)	110	(167)
Total other income (expense), net	2,661	929	7,971	2,397
Loss before income taxes	(31,084)	(15,958)	(77,203)	(44,662)
Provision for income taxes	51	—	130	—
Net loss	(31,033)	(15,958)	(77,073)	(44,662)
Other comprehensive income (loss):				
Unrealized (loss) income on available for sale securities, net of tax of (\$25), \$0, \$189 and \$0, respectively	(94)	136	703	(115)
Comprehensive loss	\$ (31,127)	\$ (15,822)	\$ (76,370)	\$ (44,777)
Net loss per common share:				
Basic and diluted	\$ (1.15)	\$ (0.66)	\$ (2.85)	\$ (1.86)
Weighted-average number of shares outstanding:				
Basic and diluted	27,058	24,146	27,022	23,961

AnaptysBio Reports Etokimab ATLAS Phase 2b Clinical Trial in Moderate-to-Severe Atopic Dermatitis Fails to Meet Primary Endpoint

SAN DIEGO, Nov. 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 announced topline data from its ATLAS trial, a Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in approximately 300 adult patients treated with etokimab in moderate-to-severe atopic dermatitis. Each of the etokimab dosing arms failed to meet the primary endpoint of the trial, which was demonstration of statistically greater improvement in the Eczema Area and Severity Index (EASI) relative placebo at week 16. The Company will be receiving additional data and plans to provide a detailed update in the first quarter of 2020.

As a result of this topline data, the Company has decided to postpone the initiation of its Phase 2b etokimab clinical trial in eosinophilic asthma, a multi-dose, randomized, double-blinded, placebo-controlled trial in 300-400 patients, until it has the opportunity to analyze the full data set from the ATLAS trial. The Company will continue conducting its ECLIPSE trial, a randomized, placebo-controlled Phase 2 trial in approximately 100 adult patients with chronic rhinosinusitis with nasal polyps, with topline data from an interim analysis expected in the first quarter of 2020.

“We are surprised and very disappointed by the topline results of the ATLAS trial,” said Hamza Suria, president and chief executive officer of AnaptysBio. “We would like to thank all involved in the participation and support of the ATLAS study, including the patients, the investigators, their staff and our employees. We look forward to continuing our strategy of advancing our wholly-owned clinical and preclinical pipeline programs.”

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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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