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: February 25, 2021
(Date of earliest event reported)

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

Delaware	**001-37985**	**20-3828755**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 February 25, 2021, AnaptysBio, Inc. ("AnaptysBio") issued a press release announcing its financial results for the three months and year ended December 31, 2020. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02, 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 Item 2.02 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 its financial results for the three months and year ended December 31, 2020, dated February 25, 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 hereunto duly authorized.

AnaptysBio, Inc.

Date: February 25, 2021

By: /s/ Dennis Mulroy

Name: Dennis Mulroy

Title: Chief Financial Officer

AnaptysBio Announces Fourth Quarter and Full Year 2020 Financial Results and Provides Pipeline Updates

- Positive topline data from GALLOP Phase 2 clinical trial of imsidolimab in moderate to severe generalized pustular psoriasis (GPP) announced in October 2020, with Phase 3 trial initiation anticipated in mid-2021
- Topline data from POPLAR Phase 2 imsidolimab clinical trial in palmoplantar pustulosis (PPP) anticipated in Q1 2021
- Expansion of imsidolimab program into four additional dermatological inflammatory Phase 2 clinical trials, including EGFRi-mediated skin toxicities, ichthyosis, hidradenitis suppurativa and acne, with top-line data readouts from Phase 2 trials anticipated through 2021 and 2022
- Advancement of ANB030 into a healthy volunteer Phase 1 trial with top-line data anticipated in mid-2021 and initiation of Phase 2 clinical trials in alopecia areata and vitiligo in Q4 2021
- Amended strategic immuno-oncology collaboration with GlaxoSmithKline (GSK) to increase dostarlimab royalties to 8-25% of global sales, add 1% Zejula™ royalty effective January 2021 and receive additional $60 million cash in Q4 2020
- $75MM in cash milestones anticipated from dostarlimab regulatory milestones under GSK collaboration over upcoming 18 months, including US BLA and EU MAA approval for dMMR endometrial cancer anticipated in H1 2021 and acceptance of US BLA for pan-dMMR tumors in Q1 2021

SAN DIEGO, February 25, 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 reported operating results for the fourth quarter and year ended December 31, 2020 and provided pipeline updates.

“We made progress in advancing AnaptysBio’s pipeline during 2020 and look forward to multiple clinical readouts from our wholly-owned programs in 2021. Imsidolimab will continue to be our key focus going forward as we anticipate GPP Phase 3 initiation and Phase 2 topline readouts from five other immune-dermatology indications through 2021 and 2022. We also anticipate commercial launch of dostarlimab this year and meaningful milestone and royalty revenue to AnaptysBio under our GSK partnership,” said Hamza Suria, president and chief executive officer of AnaptysBio. “Our strategy is to continue advancing first-in-class immunology-focused therapeutic antibodies through key clinical data catalysts using a capital-efficient business model.”

Imsidolimab (Anti-IL-36 Receptor) Program

- In July, we announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for imsidolimab, our proprietary anti-interleukin-36 receptor (IL-36R) antibody, for the treatment of patients with GPP.
- In October, we announced positive topline data from an interim analysis of our imsidolimab GALLOP Phase 2 trial in GPP. Six of 8 patients achieved the primary endpoint of disease improvement upon Day 29, while erythema with skin pustules, which clinically defines GPP, decreased by 94% on Day 29 relative to baseline. We plan to report 16-week data from the GALLOP trial at a medical conference in 2021.
- We anticipate initiation of a Phase 3 trial for imsidolimab in GPP during mid-2021 following completion of protocol alignment, and review of 16-week data from the Phase 2 GALLOP trial, with the FDA.
- We are also conducting a randomized, placebo-controlled, multi-dose Phase 2 trial in 59 patients with palmoplantar pustulosis, or PPP, also known as the POPLAR trial, with topline data anticipated in Q1 2021.
- We have expanded our imsidolimab program into third and fourth new clinical indications, EGFRi-mediated skin toxicities and ichthyosis, with interim top-line data from Phase 2 trials anticipated at the end of 2021 and in 2022, respectively, and we are also expanding the imsidolimab program into fifth and sixth

new clinical indications, hidradenitis suppurativa and acne, with initiation of Phase 2 trials in these indications anticipated in Q2 2021.

- We initiated a worldwide registry of GPP and PPP patients, named RADIANCE, in Q1 2021, to improve understanding of the patient journey and support enrollment of future trials.

ANB030 (Anti-PD-1 Agonist) Program

- We anticipate topline data from our ongoing Phase 1 healthy volunteer clinical trial of ANB030, our wholly-owned PD-1 agonist antibody, designed to assess the safety, pharmacokinetics and pharmacodynamics of ANB030 in single and multiple ascending dose cohorts in mid-2021.

- Preclinical translational data using ANB030 was presented in March 2020 at the Festival of Biologics Meeting.

- We anticipate initiating Phase 2 trials of ANB030 in alopecia areata and vitiligo in Q4 2021.

ANB032 (Anti-BTLA Modulator) Program

- We filed a Clinical Trial Notification ("CTN") in Australia for ANB032, our wholly-owned BTLA modulator antibody, during the first quarter of 2021 and anticipate initiating a healthy volunteer Phase 1 trial in the first half of 2021 upon clearance of the CTN.

- We presented preclinical data regarding ANB032 at the 2020 Federation of Clinical Immunology Societies (FOCIS) Virtual Annual Meeting in October 2020.

Etokimab (ANB020 Anti-IL-33) Program

- We discontinued further development of etokimab, our anti-IL-33 antibody previously referred to as ANB020, following review of topline week 16 data from the approximately 100-patient ECLIPSE trial in chronic rhinosinusitis with nasal polyps (CRSwNP), where patients dosed with etokimab every four (q4w) or eight weeks (q8w) failed to achieve statistically significant over placebo on either co-primary endpoint.

Dostarlimab (Anti-PD-1 Antagonist) Program Partnered with GSK

- In October 2020, we amended our immuno-oncology collaboration with GSK resulting in increased financial consideration to AnaptysBio. Royalties due to AnaptysBio for dostarlimab were increased to 8-25% of global net sales, where AnaptysBio will receive 8% of annual global net sales below $1 billion, and 12-25% of net sales above $1 billion. The $1.1 billion in cash milestone payments due under the collaboration agreement remain unchanged, and AnaptysBio anticipates receiving $75 million in such cash milestones over the next 18 months as dostarlimab obtains FDA and EMA regulatory approval for the first two indications. An additional $165 million in sales milestones is anticipated by AnaptysBio upon achievement of certain dostarlimab annual sales revenues. GSK also agreed, starting January 1, 2021, to pay AnaptysBio a 1% royalty on all of GSK's global net sales of Zejula. In addition, GSK paid AnaptysBio a one-time cash payment of $60 million in Q4 2020. In exchange, AnaptysBio provided GSK with freedom to conduct development and commercialization of Zejula in combination with third-party molecules and settled the dispute between AnaptysBio and GSK.

- US BLA and European Union EMA approvals for dostarlimab are anticipated for endometrial cancer in H1 2021, which will result in $20 million and $10 million milestone payments, respectively. The FDA recently accepted a subsequent US BLA for dostarlimab in pan-deficient mismatch repair tumors and we anticipate receiving a $10 million payment from GSK in Q1 2021 as a result of this milestone.

Board of Directors

- In January 2021, the Company appointed Dr. Magda Marquet to its board of directors. She is the co-founder of AltheaDx, a commercial stage, precision medicine company, and co-founded Althea Technologies and as its co-CEO led the company to become a highly profitable, commercial company. Prior to starting Althea Technologies, Dr. Marquet held several positions in pharmaceutical development in companies such as Vical and Amylin Pharmaceuticals. She currently serves on the Board of Directors of Arcturus Therapeutics, Micronoma, Matrisys Biosciences and ProciseDx.

Fourth Quarter Financial Results

- Cash, cash equivalents and investments totaled $411.2 million as of December 31, 2020 compared to $428.5 million as of December 31, 2019, for a net decrease of $17.3 million. The decrease relates primarily to cash used for operating activities partially offset by an increase in collaboration revenue of $67.0 million.

- Collaboration revenue was $60.0 million and $75.0 million for the three and twelve months ended December 31, 2020, which related to milestone payments for successful BLA and MAA filings for dostarlimab and the $60.0 million amendment related payment from GSK, compared to $3.0 million and $8.0 million for the three and twelve months ended December 31, 2019.

- Research and development expenses were $21.6 million and $80.0 million for the three and twelve months ended December 31, 2020, compared to $21.4 million and $99.3 million for the three and twelve months ended December 31, 2019. The annual decrease was due primarily to reduced outside services for manufacturing and clinical activities based on the timing of projects.

- General and administrative expenses were $5.1 million and $18.9 million for the three and twelve months ended December 31, 2020, compared to $3.8 million and $16.1 million for the three and twelve months ended December 31, 2019. The increase was due primarily to increased legal and insurance expenses.

- Net income was $33.6 million for the three months ended December 31, 2020, or a net income per share of $1.23 and a net loss of $19.9 million for the twelve months ended December 31, 2020, or a net loss per share of $0.73, compared to a net loss of $20.3 million and $97.3 million for the three and twelve months ended December 31, 2019, or a net loss per share of $0.75 and $3.60.

Financial Guidance

AnaptysBio expects its net cash burn in 2021 will be close to $100 million. We anticipate that our cash, cash equivalents and anticipated revenues will fund our current operating plan at least into 2024.

About AnaptysBio

AnaptysBio is 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. The Company's proprietary anti-inflammatory pipeline includes its anti-IL-36R antibody imsidolimab, previously referred to as ANB019, for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, palmoplantar pustulosis, or PPP, EGFRi, ichthyosis, hidradenitis suppurativa and acne; its anti-PD-1 agonist program, 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 GlaxoSmithKline, including an anti-PD-1 antagonist antibody (dostarlimab GSK4057190A), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889A) 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 trial in PPP, imsidolimab's Phase 2 clinical trials in EGFRi, ichthyosis, hidradenitis suppurativa, and acne, and ANB030's Phase 1 healthy volunteer clinical trial; the timing of initiation of imsidolimab's Phase 2 clinical trials in hidradenitis suppurativa and acne; the timing of initiation of imsidolimab's Phase 3 clinical trial in GPP; the timing of initiation of ANB032's Phase 1 healthy volunteer clinical trial; the milestones and royalty payments to be received under the GSK collaboration; and our projected 2021 cash burn and cash runway. 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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AnaptysBio, Inc.
Consolidated Balance Sheets
(in thousands, except par value)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 250,456	$ 171,017
Short-term investments	143,197	203,210
Prepaid expenses and other current assets	2,908	3,506
Total current assets	396,561	377,733
Property and equipment, net	1,783	1,618
Long-term investments	17,546	54,305
Other long-term assets	602	1,481
Restricted cash	60	60
Total assets	$ 416,552	$ 435,197
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,217	$ 16,237
Accrued expenses	15,262	11,052
Notes payable, current portion	—	1,375
Other current liabilities	342	871
Total current liabilities	19,821	29,535
Other long-term liabilities	—	654
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at December 31, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 27,356 shares and 27,255 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	27	27
Additional paid in capital	660,665	648,669
Accumulated other comprehensive (loss) income	(4)	338
Accumulated deficit	(263,957)	(244,026)
Total stockholders' equity	396,731	405,008
Total liabilities and stockholders' equity	$ 416,552	$ 435,197

AnaptysBio, Inc.
Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Collaboration revenue	$ 60,000	$ 3,000	$ 75,000	$ 8,000
Operating expenses:				
Research and development	21,567	21,426	80,025	99,338
General and administrative	5,088	3,832	18,854	16,094
Total operating expenses	26,655	25,258	98,879	115,432
Income (loss) from operations	33,345	(22,258)	(23,879)	(107,432)
Other income (expense), net:				
Interest expense	—	(200)	—	(1,041)
Interest income	376	2,282	3,959	10,984
Other (expense) income, net	(75)	(109)	(11)	1
Total other income (expense), net	301	1,973	3,948	9,944
Income (loss) before income taxes	33,646	(20,285)	(19,931)	(97,488)
Provision for income taxes	—	22	—	152
Net income (loss)	33,646	(20,263)	(19,931)	(97,336)
Other comprehensive (loss) income:				
Unrealized (loss) income on available for sale securities, net of tax of $0, ($36), $0, and $153, respectively	(263)	(142)	(342)	561
Comprehensive income (loss)	$ 33,383	$ (20,405)	$ (20,273)	$ (96,775)
Net income (loss) per common share:				
Basic	$ 1.23	$ (0.75)	$ (0.73)	$ (3.60)
Diluted	$ 1.20	$ (0.75)	$ (0.73)	$ (3.60)
Weighted-average number of shares outstanding:				
Basic	27,349	27,154	27,302	27,059
Diluted	27,938	27,154	27,302	27,059