# **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: May 11, 2023 (Date of earliest event reported)

## ANAPTYSBIO, INC.

(Exact Name of Registrant as Specified in Charter)

001-37985

20-3828755

**Delaware** 

(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
(A	10770 Wateridge Circle, Suite San Diego, CA 92121 Address of Principal Executive Offices, and Z	
(I	(858) 362-6295 Registrant's Telephone Number, Including Ar	ea Code)
(For	<b>Not Applicable</b> mer name or former address, if changed since	e last report.)
Check the appropriate box below if the Form 8-K filing it ollowing provisions (see General Instruction A.2. below		the filing obligation of the registrant under any of the
□Written communication pursuant to Rule 425 under the □Soliciting material pursuant to Rule 14a-12 under the E□Pre-commencement communication pursuant to Rule 1□Pre-commencement communication pursuant to Rule 1 securities registered pursuant to Section 12(b) of the Act	Exchange Act (17 CFR 240.14a-12) 4d-2(b) under the Exchange Act (17 3e-4(c) under the Exchange Act (17	
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
his chapter) or Rule 12b-2 of the Securities Exchange Ad	ct of 1934 (17 CFR §240.12b-2 of th	Emerging growth company $\Box$
f an emerging growth company, indicate by check mark or revised financial accounting standards provided pursua		se the extended transition period for complying with any new Act. $\square$

### Item 2.02 Results of Operations and Financial Condition.

On May 11, 2023, AnaptysBio, Inc. ("AnaptysBio") issued a press release announcing its financial results for the three months ended March 31, 2023. 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

document).

(d) Exhibits

Exhibit Number	Exhibit Title or Description
<u>99.1</u>	Press release issued by AnaptysBio, Inc. regarding its financial results for the three months ended March 31,
	2023, dated May 11, 2023.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL

# **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: May 11, 2023 By: /s/Dennis Mulroy

Name: Dennis Mulroy

Title: Chief Financial Officer

# AnaptysBio Announces First Quarter 2023 Financial Results and Provides Pipeline Update

- Initiated a global Phase 2b trial to treat atopic dermatitis with ANB032, a BTLA agonist
- Hosting a virtual BTLA Agonist (ANB032) R&D Event on May 25, 2023
- Announced International Societies for Investigative Dermatology (ISID) Annual Meeting poster presentation for ANB032, a BTLA agonist, Phase 1 data
- Initiating a global Phase 2b trial to treat rheumatoid arthritis in Q3 2023 and a second Phase 2 trial, in an indication to be announced, by year-end 2023 with rosnilimab, a PD-1 agonist
- Reiterating cash runway through year-end 2026 with expected year-end 2023 cash and investments of \$370 \$385 million

**SAN DIEGO, May 11, 2023** — AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today reported operating results for the first quarter ended March 31, 2023 and provided pipeline updates.

"We're excited about our progress as we continue to develop best-in-class antibodies across a number of high-value immune cell modulatory targets. We have initiated our global Phase 2b trial in moderate-to-severe atopic dermatitis (AD) for ANB032, our BTLA agonist, and will host a virtual R&D event on May 25th to highlight the biologic and mechanistic rationale for developing a BTLA agonist in AD," said Daniel Faga, interim president and chief executive officer of AnaptysBio. "We believe our checkpoint agonists, rosnilimab and ANB032, as well as our CD122 antagonist, ANB033, have the potential to treat a broad range of autoimmune and inflammatory disorders by directly acting on immune cells that mediate disease pathology, and we remain well capitalized to execute on our broad development plan."

#### **Updates on Wholly Owned Immune Cell Modulator Pipeline**

#### Rosnilimab (PD-1 agonist antibody)

- Anticipate initiation in Q3 2023 of a global Phase 2b trial in moderate-to-severe rheumatoid arthritis (RA)
  - Multi-hundred patient placebo-controlled trial assessing three dose levels of subcutaneously administered rosnilimab for up to 6 months on well-established endpoints including ACR20/50/70 and DAS28
  - Top-line interim data anticipated by mid-year 2025
- Plan to initiate second global Phase 2 trial, in an indication to be announced, by year-end 2023

#### ANB032 (BTLA agonist antibody)

- Initiated a global Phase 2b trial in moderate-to-severe AD
  - $^{\circ}$  160 patient placebo-controlled trial assessing three dose levels of subcutaneously administered ANB032 (randomized 1:1:1:1) for a 14-week treatment duration on well-established endpoints, including EASI75 and IGA 0/1
  - Top-line interim data anticipated by year-end 2024
- Presented poster on Phase 1 data for ANB032, a BTLA agonist for the treatment of moderate-to-severe AD, at International Societies for Investigative Dermatology (ISID) Annual Meeting, May 11, 2023, in Japan
- Planning to host a virtual BTLA Agonist (ANB032) R&D Event on Thursday, May 25, 2023 at 1:15pm PT / 4:15pm ET
  - Management will host the event via conference call and webcast, with an accompanying slide presentation

• The live audio webcast, as well as a replay of the presentation, will be available on the investor section of the AnaptysBio website at https://ir.anaptysbio.com/events

#### ANB033 (anti-CD122 antagonist antibody)

Plan to submit an Investigational New Drug (IND) application in H1 2024

#### Updates on Legacy Clinical-Stage Cytokine Antagonist Programs Available for Out-Licensing

- Announced publication of Phase 2 GALLOP data for imsidolimab, an investigational, wholly owned, anti-IL-36R antagonist IgG4 antibody in generalized pustular psoriasis (GPP) in *The British Journal of Dermatology* on April 30, 2023
- Anticipate top-line data from the ongoing GEMINI-1 Phase 3 trial in Q4 2023
  - Plan to out-license imsidolimab prior to potential FDA approval

#### **GSK Immuno-Oncology Financial Collaboration**

- GSK announced publication of RUBY Phase 3 clinical data for JEMPERLI (dostarlimab-gxly), an anti-PD-1 antagonist antibody discovered at AnaptysBio and licensed to GSK, in *The New England Journal of Medicine* and presented simultaneously at ESMO Virtual Plenary and SGO Annual Meeting in March 2023
  - JEMPERLI has the potential for a first-in-class approval in primary advanced or recurrent endometrial cancer after meeting the primary endpoint in the pivotal RUBY Phase 3 trial demonstrating JEMPERLI plus chemotherapy significantly improved PFS versus chemotherapy plus placebo
  - GSK plans regulatory submissions in H1 2023
- GSK anticipates top-line data from the ongoing FIRST Phase 3 trial, a randomized, double-blind, comparison of platinum-based therapy with dostarlimab and niraparib versus standard of care platinum-based therapy as first-line treatment of Stage III or IV nonmucinous epithelial ovarian cancer, in H2 2023
- GSK anticipates top-line data from the ongoing COSTAR Lung Phase 3 trial, a randomized, open label 3-arm trial comparing cobolimab plus dostarlimab plus docetaxel to dostarlimab plus docetaxel to docetaxel alone in patients with advanced NSCLC who have progressed on prior anti-PD-(L)1 therapy and chemotherapy, in 2024

#### **Stock Repurchase Program and Year-End Cash Guidance**

- Completed Stock Repurchase Program, authorized in January 2023, of \$50.0 million of the Company's outstanding common stock
- Reiterating cash runway through year-end 2026 with expected year-end 2023 cash and investments of \$370 \$385 million

#### **First Quarter Financial Results**

- Cash, cash equivalents and investments totaled \$526.1 million as of March 31, 2023, compared to \$584.2 million as of December 31, 2022, for a decrease of \$58.1 million. The decrease relates primarily to cash used for the stock repurchase program and operating activities.
- Collaboration revenue was \$1.4 million for the three months ended March 31, 2023, compared to \$1.0 million for the three months ended March 31, 2022. The change is due to increased royalties recognized for sales of JEMPERLI and Zejula in the first quarter of 2023.
- Research and development expenses were \$35.0 million for the three months ended March 31, 2023, compared to \$22.5 million for the three months ended March 31, 2022. The increase was due primarily to manufacturing and development costs for imsidolimab, rosnilimab, ANB032 and ANB033. The R&D non-

cash, stock-based compensation expense was \$2.8 million for the three months ended March 31, 2023 as compared to \$1.7 million in the same period in 2022.

- General and administrative expenses were \$10.8 million for the three months ended March 31, 2023, compared to \$10.2 million for the three months ended March 31, 2022. The G&A non-cash, stock-based compensation expense was \$6.1 million for the three months ended March 31, 2023 and 2022.
- Net loss was \$44.3 million for the three months ended March 31, 2023, or a net loss per share of \$1.58, compared to a net loss of \$36.3 million for the three months ended March 31, 2022, or a net loss per share of \$1.31.

#### **About AnaptysBio**

AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. It is developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, its PD-1 agonist, in a planned Phase 2b trial for the treatment of moderate-to-severe rheumatoid arthritis; and ANB032, its BTLA agonist, currently in a Phase 2b trial for the treatment of moderate-to-severe atopic dermatitis. Its preclinical immune cell modulator portfolio includes ANB033, an anti-CD122 antagonist antibody for the treatment of autoimmune and inflammatory diseases. In addition, AnaptysBio has developed two cytokine antagonists available for out-licensing: imsidolimab, an anti-IL-36R antagonist, in Phase 3 for the treatment of generalized pustular psoriasis, or GPP, and etokimab, an anti-IL-33 antagonist for the treatment of respiratory disorders that is Phase 2/3 ready. AnaptysBio has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immune-oncology, including an anti-PD-1 antagonist antibody (*Jemperli* (dostarlimab-gxly)), 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 initiation of the company's clinical trials, including rosnilimab's clinical trials in rheumatoid arthritis and in a second indication; the timing of the release of data from the company's clinical trials, including imsidolimab's Phase 3 clinical trial in GPP, rosnilimab's Phase 2b clinical trial in rheumatoid arthritis and ANB032's Phase 2b clinical trial in atopic dermatitis; the timing of ANB033's IND filing; the company's ability to find a licensing partner for imsidolimab or etokimab and the timing of any such transaction; and the company's projected 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 its 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:

Nick Montemarano Senior Director, Investor Relations and Strategic Communications AnaptysBio, Inc. 858.732.0178

investors@anaptysbio.com

# AnaptysBio, Inc. Consolidated Balance Sheets (in thousands, except par value data) (unaudited)

	March 31, 2023	D	ecember 31, 2022
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 94,562	\$	71,308
Receivables from collaborative partners	1,523		1,419
Short-term investments	336,589		369,933
Prepaid expenses and other current assets	 4,480		4,545
Total current assets	437,154		447,205
Property and equipment, net	1,982		2,089
Operating lease right-of-use assets	17,471		17,898
Long-term investments	94,929		142,935
Other long-term assets	256		256
Total assets	\$ 551,792	\$	610,383
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$ 3,168	\$	2,784
Accrued expenses	30,956		21,633
Current portion of operating lease liability	 1,671		1,637
Total current liabilities	35,795		26,054
Liability related to sale of future royalties	307,516		304,413
Operating lease liability, net of current portion	17,388		17,813
Stockholders' equity:			
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at March 31, 2023 and December 31, 2022, respectively	_		_
Common stock, \$0.001 par value, 500,000 shares authorized, 27,018 shares and 28,513 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	27		29
Additional paid in capital	689,065		717,797
Accumulated other comprehensive loss	(3,267)		(5,246)
Accumulated deficit	(494,732)		(450,477)
Total stockholders' equity	191,093		262,103
Total liabilities and stockholders' equity	\$ 551,792	\$	610,383

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

		Three Months Ended March 31,		
	2023		2022	
Collaboration revenue	\$ 1,3	74 \$	970	
Operating expenses:				
Research and development	34,9	57	22,516	
General and administrative	10,8	18	10,203	
Total operating expenses	45,7	75	32,719	
Loss from operations	(44,4	01)	(31,749)	
Other income (expense), net:				
Interest income	4,4	86	342	
Non-cash interest expense for the sale of future royalties	(4,3	36)	(4,854)	
Other (expense) income, net		(4)	6	
Total other income (expense), net		46	(4,506)	
Net loss	(44,2	55)	(36,255)	
Unrealized gain (loss) on available for sale securities	1,9	79	(2,012)	
Comprehensive loss	\$ (42,2	76) \$	(38,267)	
Net loss per common share:				
Basic and diluted	<u>\$</u> (1)	58) \$	(1.31)	
Weighted-average number of shares outstanding:				
Basic and diluted	27,9	53	27,713	