

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 7, 2023
(Date of earliest event reported)

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

Delaware
(State or Other Jurisdiction of Incorporation)

001-37985
(Commission File Number)

20-3828755
(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 2.02 Results of Operations and Financial Condition.

On August 7, 2023, AnaptysBio, Inc. (“AnaptysBio”) issued a press release announcing its financial results for the three and six months ended June 30, 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

(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 and six months ended June 30, 2023, dated August 7, 2023.
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.

Date: August 7, 2023

AnaptysBio, Inc.

By: /s/Dennis Mulroy

Name: Dennis Mulroy

Title: Chief Financial Officer

AnaptysBio Announces Second Quarter 2023 Financial Results and Provides Business Update

- Completed enrollment of the GEMINI-1 Phase 3 trial for imsidolimab (IL-36R) in generalized pustular psoriasis (GPP) and anticipate top-line data in Q4 2023
- Initiating a global Phase 2b trial for rosnilimab, a PD-1 agonist antibody, in rheumatoid arthritis (RA) later in Q3 2023 and a second Phase 2 trial, in an indication yet to be announced, by year-end 2023
- Daniel Faga appointed to the permanent position of president and chief executive officer
- Reiterating cash runway through year-end 2026 and updated expected year-end 2023 cash and investments of \$380 – \$395 million

SAN DIEGO, August 7, 2023 — AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today reported operating results for the second quarter ended June 30, 2023 and provided a business update.

“We have made substantial operating progress including initiating a Phase 2b trial in atopic dermatitis (AD) for ANB032, our BTLA agonist, and approaching initiation of a Phase 2b trial in RA for rosnilimab, our PD-1 agonist” said Daniel Faga, president and chief executive officer of AnaptysBio. “Additionally, we are excited to share that we recently completed enrollment of the GEMINI-1 Phase 3 clinical trial for imsidolimab in GPP and expect to share top-line data in Q4 2023.”

“We are excited to appoint Dan Faga to the permanent position of president and CEO,” said Jamie Topper, M.D., Ph. D., chairman of the Board of Directors. “Over the last year, Anaptys has completed its strategic portfolio review and Dan led the transition refocusing on the broad development of our differentiated immune cell modulators, including our checkpoint agonist pipeline, in autoimmune and inflammatory diseases. With Dan and his talented team in place, and our strong capital position, the company is well positioned as it enters its next phase of development and growth.”

Updates on Wholly Owned Immune Cell Modulator Pipeline

ANB032 (BTLA agonist antibody)

- Initiated a global Phase 2b trial in moderate-to-severe AD
 - 160 patient placebo-controlled trial assessing three dose levels of subcutaneously administered ANB032 (randomized 1:1:1:1) for a 14-week treatment duration and six-month follow-up period on well-established endpoints, including EASI75 and IGA 0/1
 - Top-line week 14 data anticipated by year-end 2024
- Hosted a virtual BTLA Agonist (ANB032) R&D Event in May 2023
 - Replay of the audio webcast is available at <https://ir.anaptysbio.com/events>

Rosnilimab (PD-1 agonist antibody)

- Anticipate initiation later in Q3 2023 of a global Phase 2b trial in moderate-to-severe RA
 - Multi-hundred patient placebo-controlled trial assessing three dose levels of subcutaneously administered rosnilimab for up to six months on well-established endpoints including ACR20/50/70 and DAS28
 - Top-line week 12 data anticipated by mid-year 2025
- Plan to initiate a second global Phase 2 trial, in a yet to-be-announced indication, by year-end 2023
- Plan to host a virtual PD-1 Agonist (rosnilimab) R&D event in Q4 2023

ANB033 (anti-CD122 antagonist antibody)

- Presented poster on preclinical data for ANB033, an anti-CD122 antagonist for the treatment of inflammatory diseases, at the Federation of Clinical Immunology Societies (FOCIS) Annual Meeting, in June 2023
 - Poster presentation is available at <https://www.anaptysbio.com/technology/#anb033>
- Plan to submit an Investigational New Drug (IND) application in H1 2024

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

- Completed enrollment of the GEMINI-1 Phase 3 trial for imsidolimab (IL-36R) in GPP per the initial target enrollment (n=45)
 - Top-line data anticipated in Q4 2023
- Plan to out-license imsidolimab prior to potential FDA approval

Updates on GSK Immuno-Oncology Financial Collaboration

- GSK received U.S. FDA approval for *Jemperli* (dostarlimab) in combination with chemotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer on July 31, 2023
 - *Jemperli* is the first immuno-oncology treatment approved in the frontline setting for this patient population in combination with chemotherapy
- GSK anticipates top-line data in H1 2024 from the FIRST Phase 3 trial for platinum-based therapy with dostarlimab and niraparib versus platinum-based therapy as first-line treatment of Stage III or IV nonmucinous epithelial ovarian cancer
- GSK anticipates top-line data in H2 2024 from COSTAR Lung Phase 3 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

Organizational Updates

- Announced appointment of Daniel Faga to the permanent position of president and chief executive officer of the Company
 - Mr. Faga will retain his position on the Company's Board of Directors
- Announced appointments of Luisa Salter-Cid, Ph.D., and Dolca Thomas, M.D., to the Company's Scientific Advisory Board (SAB)
 - Dr. Salter-Cid is the current chief scientific officer at Pioneering Medicines, a strategic initiative within Flagship Pioneering. She had extensive experience at Bristol-Meyers Squibb where she led teams that advanced more than 20 compounds into clinical development.
 - Dr. Thomas is currently a venture partner at Samsara and serves on the Board of Directors of Allakos Therapeutics, Chinook Therapeutics and Ventus Therapeutics. Dr. Thomas has extensive experience in both large pharma and biotech. Among her prior roles includes serving as Principia's chief medical officer from 2018 until the Sanofi acquisition in September 2020. Dr. Thomas was also vice president and global head of Translational Medicine for Immunology, Inflammation, and Infectious Disease at Roche, where she was responsible for advancing multiple product candidates through clinical development.
 - Read their full bios <https://www.anaptysbio.com/about/#tab>

Year-End Cash Guidance

- Reiterating cash runway through year-end 2026 with updated expected year-end 2023 cash and investments of \$380 – \$395 million

Second Quarter Financial Results

- Cash, cash equivalents and investments totaled \$488.7 million as of June 30, 2023, compared to \$584.2 million as of December 31, 2022, for a decrease of \$95.5 million. The decrease relates primarily to cash used for the \$50 million stock repurchase program and operating activities.
- Collaboration revenue was \$3.5 million and \$4.8 million for the three and six months ended June 30, 2023, compared to \$1.2 million and \$2.2 million for the three and six months ended June 30, 2022. The change is due primarily to increased royalties recognized for sales of *Jemperli*.
- Research and development expenses were \$32.9 million and \$67.9 million for the three and six months ended June 30, 2023, compared to \$20.8 million and \$43.4 million for the three and six months ended June 30, 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 \$2.7 million and \$5.5 million for the three and six months ended June 30, 2023 as compared to \$1.8 million and \$3.4 million in the same period in 2022.
- General and administrative expenses were \$10.7 million and \$21.5 million for the three and six months ended June 30, 2023, compared to \$8.2 million and \$18.4 million for the three and six months ended June 30, 2022. The G&A non-cash, stock-based compensation expense was \$5.7 million and \$11.8 million for the three and six months ended June 30, 2023 as compared to \$4.9 million and \$11.0 million in the same period in 2022.
- Net loss was \$39.8 million and \$84.1 million for the three and six months ended June 30, 2023, or a net loss per share of \$1.50 and \$3.08, compared to a net loss of \$32.6 million and \$68.8 million for the three and six months ended June 30, 2022, or a net loss per share of \$1.15 and \$2.46.

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 trial 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; timing of the release of data from GSK's clinical trials; 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:

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

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 35,206	\$ 71,308
Receivables from collaborative partners	3,182	1,419
Short-term investments	394,280	369,933
Prepaid expenses and other current assets	5,867	4,545
Total current assets	<u>438,535</u>	<u>447,205</u>
Property and equipment, net	2,023	2,089
Operating lease right-of-use assets	17,047	17,898
Long-term investments	59,239	142,935
Other long-term assets	256	256
Total assets	<u>\$ 517,100</u>	<u>\$ 610,383</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,761	\$ 2,784
Accrued expenses	35,164	21,633
Current portion of operating lease liability	1,706	1,637
Total current liabilities	<u>41,631</u>	<u>26,054</u>
Liability related to sale of future royalties	310,073	304,413
Operating lease liability, net of current portion	16,946	17,813
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Common stock, \$0.001 par value, 500,000 shares authorized, 26,531 shares and 28,513 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	27	29
Additional paid in capital	686,611	717,797
Accumulated other comprehensive loss	(3,611)	(5,246)
Accumulated deficit	(534,577)	(450,477)
Total stockholders' equity	<u>148,450</u>	<u>262,103</u>
Total liabilities and stockholders' equity	<u>\$ 517,100</u>	<u>\$ 610,383</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,	
	2023	2022	2023	2022
Collaboration revenue	\$ 3,460	\$ 1,216	\$ 4,834	\$ 2,186
Operating expenses:				
Research and development	32,923	20,844	67,880	43,360
General and administrative	10,680	8,171	21,498	18,374
Total operating expenses	43,603	29,015	89,378	61,734
Loss from operations	(40,143)	(27,799)	(84,544)	(59,548)
Other income (expense), net:				
Interest income	4,653	1,107	9,139	1,449
Non-cash interest expense for the sale of future royalties	(4,358)	(5,868)	(8,694)	(10,722)
Other income (expense), net	3	6	(1)	12
Total other income (expense), net	298	(4,755)	444	(9,261)
Net loss	(39,845)	(32,554)	(84,100)	(68,809)
Unrealized (loss) gain on available for sale securities	(344)	(1,427)	1,635	(3,439)
Comprehensive loss	\$ (40,189)	\$ (33,981)	\$ (82,465)	\$ (72,248)
Net loss per common share:				
Basic and diluted	\$ (1.50)	\$ (1.15)	\$ (3.08)	\$ (2.46)
Weighted-average number of shares outstanding:				
Basic and diluted	26,629	28,204	27,288	27,960