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 4, 2021
(Date of earliest event reported)

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

Delaware	**001-37985**	**20-3828755**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 November 4, 2021, AnaptysBio, Inc. ("AnaptysBio") issued a press release announcing its financial results for the three and nine months ended September 30, 2021. 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 and nine months ended September 30, 2021, dated November 4, 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 thereunto duly authorized.

AnaptysBio, Inc.

Date: November 4, 2021

By: /s/Dennis Mulroy

Name: Dennis Mulroy

Title: Chief Financial Officer

AnaptysBio Announces Third Quarter 2021 Financial Results and Provides Pipeline Updates

- Imsidolimab GPP GALLOP Phase 2 16-week data presented at 2021 EADV Congress and GEMINI-1 Phase 3 trial initiated subsequent to FDA end-of-Phase 2 meeting
- Top-line data from ongoing imsidolimab ACORN Phase 2 trial in moderate-to-severe acne anticipated in H1 2022 and HARP Phase 2 trial in moderate-to-severe hidradenitis suppurativa in H2 2022
- Rosnilimab Phase 1 healthy volunteer top-line data and initiation of AZURE Phase 2 trial in alopecia areata anticipated in Q4 2021
- JEMPERLI (dostarlimab) was approved for mismatch repair deficient (dMMR) recurrent or advanced solid tumors in the US, earning $20 million cash milestone during Q3 2021
- JEMPERLI royalty monetization transaction signed with Sagard Healthcare Royalty Partners for $250 million upfront payment in exchange for capped return on royalties and certain milestones below $1 billion in annual sales
- Expect to end 2021 with approximately $600 million in cash and will continue to operate in a capital-efficient manner

SAN DIEGO, November 4, 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 third quarter ended September 30, 2021 and provided pipeline updates.

“Our wholly-owned pipeline continues to make progress with the recent initiation of our imsidolimab GEMINI-1 Phase 3 trial in GPP and anticipated initiation of our rosnilimab AZURE alopecia areata Phase 2 trial during the remainder of 2021,” said Hamza Suria, president and chief executive officer of AnaptysBio. “We believe the recent royalty monetization transaction with Sagard validates the future revenue stream anticipated from JEMPERLI sales and further supports AnaptysBio’s capital-efficient business model.”

Imsidolimab (Anti-IL-36 Receptor) Program

- Following an end-of-Phase 2 meeting with the FDA in Q2 2021, we publicly disclosed Phase 3 trial designs for imsidolimab in generalized pustular psoriasis (GPP), GEMINI-1 and GEMINI-2. The primary endpoint of our GEMINI-1 Phase 3 trial is the proportion of patients achieving a score of clear (0) or almost clear (1) skin on the Generalized Pustular Psoriasis Physician’s Global Assessment (GPPPGA) at week 4 in 45 patients randomized against placebo. GEMINI-2 will assess 6 months of monthly subcutaneous dosing and safety follow-up of those same patients. GEMINI-1 was initiated in Q3 2021.

- Full data from the Phase 2 GALLOP trial in GPP, including efficacy and safety of imsidolimab treatment through week 16, was disclosed in an oral presentation by Dr. Johann Gudjonsson, professor of Dermatology at the University of Michigan, at the European Academy of Dermatology and Venereology (EADV) Congress on October 2nd, 2021. Imsidolimab demonstrated rapid and sustained efficacy with 6 of 8 (75%) GPP patients achieving the primary endpoint at week 4 and 16. We also observed early reduction of erythema with pustules by 60% at week 1, 94% reduction at week 4, 98% reduction at week 16, each versus baseline.

- We anticipate top-line data from the ACORN Phase 2 trial of imsidolimab in moderate-to-severe acne in H1 2022 and from the HARP Phase 2 trial in moderate-to-severe hidradenitis suppurativa in H2 2022.

Rosnilimab (Anti-PD-1 Agonist) Program

- We anticipate top-line data in Q4 2021 from our ongoing Phase 1 healthy volunteer trial of rosnilimab, our wholly-owned PD-1 agonist antibody, designed to assess the safety, pharmacokinetics and pharmacodynamics of rosnilimab in single and multiple ascending dose cohorts.

- We plan to initiate a randomized, placebo-controlled Phase 2 clinical trial of rosnilimab in alopecia areata in Q4 2021.

ANB032 (Anti-BTLA Modulator) Program

- We are advancing ANB032, our wholly-owned BTLA modulator antibody, in a healthy volunteer Phase 1 single and multiple ascending dose clinical trial where top-line data is anticipated during the first half of 2022.

GSK Partnered Programs

- JEMPERLI (dostarlimab), our proprietary anti-PD-1 antagonist antibody under an immune-oncology partnership with GSK, was approved in a second clinical indication by the FDA in August 2021 for the treatment of pan-deficient mismatch repair tumors. We received $20 million from GSK upon this approval.

- We announced the signing of a royalty monetization agreement with Sagard Healthcare Royalty Partners where AnaptysBio will receive a $250 million payment upon closing in exchange for JEMPERLI royalties due to AnaptysBio on annual commercial sales below $1 billion and certain future milestones starting October 2021. The aggregate JEMPERLI royalties and milestones to be received by Sagard under this Agreement is capped at certain fixed multiples of the upfront payment. The closing of the transaction is subject to the satisfaction of customary closing conditions and is anticipated by year-end 2021.

Third Quarter Financial Results

- Cash, cash equivalents and investments totaled $389.3 million as of September 30, 2021, compared to $411.2 million as of December 31, 2020, for a decrease of $21.9 million. The decrease relates primarily to cash used for operating activities.

- Collaboration revenue was $20.9 million and $62.2 million for the three and nine months ended September 30, 2021. The $20.9 million earned during the third quarter primarily relates to milestone and royalty revenue for the US approval of JEMPERLI (dostarlimab), compared to zero and $15.0 million of milestone revenue for the three and nine months ended September 30, 2020.

- Research and development expenses were $22.2 million and $71.7 million for the three and nine months ended September 30, 2021, compared to $19.5 million and $58.5 million for the three and nine months ended September 30, 2020. The increase was due primarily to continued advancement of the Company’s clinical programs.

- General and administrative expenses were $5.4 million and $16.1 million for the three and nine months ended September 30, 2021, compared to $4.8 million and $13.8 million for the three and nine months ended September 30, 2020. The increase was due primarily to personnel-related expenses, including share-based compensation.

- Net loss was $6.7 million and $25.3 million for the three and nine months ended September 30, 2021, or a net loss per share of $0.24, and $0.92, compared to a net loss of $23.8 million and $53.6 million for the three and nine months ended September 30, 2020, or a net loss per share of $0.87 and $1.96.

Financial Guidance

Following the anticipated closing of the Sagard royalty monetization transaction by the end of 2021, we anticipate ending 2021 with approximately $600 million in cash and will continue to operate in a capital-efficient manner.

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 imsidolimab, its anti-IL-36R antibody, previously referred to as ANB019, for the treatment of dermatological inflammatory diseases, including generalized pustular psoriasis, or GPP, acne, and hidradenitis suppurativa; rosnilimab, its anti-PD-1 agonist program, previously referred to as ANB030, for the 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 GSK, including an anti-PD-1 antagonist antibody (JEMPERLI (dostarlimab-gxly) GSK4057190), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889) 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 trials in acne, and hidradenitis suppurativa, rosnilimab's Phase 1 healthy volunteer clinical trial and Phase 2 clinical trial in alopecia areata, and ANB032's healthy volunteer Phase 1 trial; the timing of the initiation of imsidolimab's GPP Phase 3 clinical trials; including the risk that the transaction with Sagard may not close when expected, or at all, the risk that commercial sales of JEMPERLI may not reach expected levels, 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.

Contact:
Dennis Mulroy
AnaptysBio, Inc.
858.732.0201
dmulroy@anaptysbio.com

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 336,328	$ 250,456
Receivables from collaborative partners	761	—
Short-term investments	37,736	143,197
Prepaid expenses and other current assets	11,759	2,908
Short-term restricted cash	60	—
Total current assets	386,644	396,561
Property and equipment, net	2,413	1,783
Operating lease right-of-use assets	19,778	344
Long-term investments	15,242	17,546
Other long-term assets	258	258
Long-term restricted cash	—	60
Total assets	$ 424,335	$ 416,552
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,717	$ 4,217
Accrued expenses	14,075	15,262
Current portion of operating lease liability	1,097	342
Total current liabilities	20,889	19,821
Operating lease liability, net of current portion	19,838	—
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 27,454 shares and 27,356 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	27	27
Additional paid in capital	672,996	660,665
Accumulated other comprehensive loss	(200)	(4)
Accumulated deficit	(289,215)	(263,957)
Total stockholders' equity	383,608	396,731
Total liabilities and stockholders' equity	$ 424,335	$ 416,552

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,	
	2021	2020	2021	2020
Collaboration revenue	$ 20,890	$ —	$ 62,164	$ 15,000
Operating expenses:				
Research and development	22,221	19,542	71,720	58,458
General and administrative	5,432	4,794	16,101	13,766
Total operating expenses	27,653	24,336	87,821	72,224
Loss from operations	(6,763)	(24,336)	(25,657)	(57,224)
Other income, net:				
Interest income	64	625	363	3,583
Other income (expense), net	33	(56)	36	64
Total other income, net	97	569	399	3,647
Net loss	(6,666)	(23,767)	(25,258)	(53,577)
Unrealized loss on available for sale securities	(24)	(494)	(196)	(79)
Comprehensive loss	$ (6,690)	$ (24,261)	$ (25,454)	$ (53,656)
Net loss per common share:				
Basic and diluted	$ (0.24)	$ (0.87)	$ (0.92)	$ (1.96)
Weighted-average number of shares outstanding:				
Basic and diluted	27,436	27,316	27,397	27,286