



Anaptys Announces First Quarter 2024 Financial Results and Provides Business Update

May 9, 2024

- Enrollment ongoing for global Phase 2b trial to treat atopic dermatitis (AD) with ANB032, our BTLA agonist; reiterating top-line data anticipated by year-end 2024
- Enrollment ongoing for global Phase 2b trial to treat rheumatoid arthritis (RA) and global Phase 2 trial to treat ulcerative colitis (UC) with rosnilimab, our PD-1 agonist; reiterating top-line data anticipated by mid 2025 and H1 2026, respectively
- IND submissions for ANB033 (anti-CD122 antagonist) and ANB101 (BDCA2 modulator) anticipated Q2 2024 and H2 2024, respectively
- Announced positive top-line GEMINI-2 Phase 3 trial results of imsidolimab, our IL-36R mAb, in generalized pustular psoriasis
- Announced a \$50 million capped non-recourse royalty monetization from amended agreement with Sagard in exchange for additional *Jemperli* royalties

SAN DIEGO, May 09, 2024 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today reported financial results for the first quarter ended March 31, 2024 and provided a business update.

"This quarter, we continued to enroll patients globally across three Phase 2 trials for our two best-in-class checkpoint agonists: ANB032, our BTLA agonist, and rosnilimab, our PD-1 agonist. By year end, we anticipate sharing top-line data from ANB032's Phase 2b trial in atopic dermatitis, as well as moving our two preclinical immune cell modulators, ANB033 and ANB101, into clinical development," said Daniel Faga, president and chief executive officer of Anaptys. "Additionally, we are excited to further strengthen our balance sheet by adding \$50 million through a capped non-recourse monetization of *Jemperli* royalties as well as share incremental data from the imsidolimab Phase 3 program."

Updates on Wholly Owned Immune Cell Modulator Pipeline

ANB032 (BTLA agonist antibody)

- Enrollment ongoing for 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 then followed for a six-month off-drug follow-up period
 - Reiterating top-line Week 14 data anticipated by year-end 2024
- Primary endpoint in Phase 2b trial to be updated from absolute change in EASI score to EASI-75 at Week 14, which is a well-accepted registrational endpoint that enables more relevant comparisons to benchmark therapies
- Presented posters on previously reported ANB032 preclinical data supporting the modulation of dendritic cell (DC) maturation and function and preclinical graft vs. host disease (GvHD) data at the 2024 American Academy of Dermatology (AAD) Annual Meeting in March 2024 and American Association of Immunologists (AAI) Annual Meeting in May 2024
 - Poster presentations are available [here](#)

Rosnilimab (PD-1 agonist antibody)

- Enrollment ongoing for global Phase 2b trial in moderate-to-severe RA
 - 420-patient placebo-controlled trial assessing three dose levels of subcutaneously administered rosnilimab (randomized 1:1:1:1) for a 12-week treatment duration on well-established endpoints, including DAS28-CRP, CDAI and ACR20/50/70
 - At Week 14, rosnilimab-treated patients who achieve low disease activity, defined as CDAI≤10, are eligible to be dosed for an additional 16-week all-active treatment period and then followed for a three-month off-drug follow-up period
 - Reiterating top-line Week 12 data anticipated by mid 2025
- Enrollment ongoing for global Phase 2 trial in moderate-to-severe UC
 - 130-patient placebo-controlled trial assessing two dose levels of subcutaneously administered rosnilimab (randomized 1:1:1) for a 12-week treatment duration on well-established endpoints, including clinical response on modified Mayo score (mMS), clinical remission on mMS and endoscopic remission

- Rosnilimab and placebo-treated patients who achieved clinical response on mMS are eligible to continue on their assigned treatment for an additional 12 weeks, while patients on placebo who are non-responders will be crossed over to the high-dose rosnilimab treatment arm, in an all-active treatment period and then followed for a three-month off-drug follow-up period
 - Reiterating top-line Week 12 data anticipated by H1 2026
 - Presented poster on previously reported rosnilimab Phase 1 data and membrane proximal binding epitope to optimize PD-1 agonist signaling at the 19th Congress of the European Crohn's and Colitis Organisation (ECCO) in February 2024
 - Poster presentation is available [here](#)

ANB033 (anti-CD122 antagonist antibody)

- Plan to submit an Investigational New Drug (IND) application in Q2 2024

ANB101 (BDCA2 modulator antibody)

- Plan to submit an IND application in H2 2024

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

- Announced positive top-line results from its global GEMINI-1 and GEMINI-2 Phase 3 trials evaluating the safety and efficacy of investigational imsidolimab (IL-36R mAb) in patients with generalized pustular psoriasis (GPP)
 - See full press release [here](#)
- Plan to submit a comprehensive data abstract for GEMINI-1 and GEMINI-2 to a H2 2024 medical meeting
- Intend to out-license imsidolimab in 2024

Updates on GSK Immuno-Oncology Financial Collaboration

- Announced a \$50 million capped non-recourse monetization from amended agreement with Sagard in exchange for additional *Jemperli* (dostarlimab) royalties
 - See full press release [here](#)
- GSK anticipates top-line data in H2 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 2025 from COSTAR Lung Phase 3 trial comparing cobolimab, a TIM-3 antagonist, plus dostarlimab, a PD-1 antagonist, 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

First Quarter Financial Results and Cash Runway

- Excluding the \$50 million in proceeds from the capped non-recourse monetization of *Jemperli* royalties by Sagard, cash, cash equivalents and investments totaled \$370.1 million as of March 31, 2024, compared to \$417.9 million as of December 31, 2023, for a decrease of \$36.9 million relating primarily to cash used for operating activities as well as a one-time non-operating cash payment of \$10.9 million during the quarter.
 - Reiterating cash runway through year-end 2026
- Collaboration revenue was \$7.2 million for the three months ended March 31, 2024, compared to \$1.4 million for the three months ended March 31, 2023. The change is due primarily to increased royalties recognized for sales of *Jemperli*.
- Research and development expenses were \$37.0 million for the three months ended March 31, 2024, compared to \$35.0 million for the three months ended March 31, 2023. The increase was due primarily to development costs for rosnilimab, ANB032 and ANB033 offset by a decrease in development costs for imsidolimab. The R&D non-cash, stock-based compensation expense was \$3.5 million for the three months ended March 31, 2024 as compared to \$2.8 million in the same period in 2023.
- General and administrative expenses were \$12.3 million for the three months ended March 31, 2024, compared to \$10.8 million for the three months ended March 31, 2023. The G&A non-cash, stock-based compensation expense was \$6.7 million for the three months ended March 31, 2024 as compared to \$6.1 million in the same period in 2023.
- Net loss was \$43.9 million for the three months ended March 31, 2024, or a net loss per share of \$1.64, compared to a net loss of \$44.3 million for the three months ended March 31, 2023, or a net loss per share of \$1.58.

About Anaptys

Anaptys is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. It is developing immune cell modulators, including two checkpoint agonists for autoimmune and inflammatory disease: ANB032, its BTLA agonist, in a Phase 2b trial for the treatment of atopic dermatitis and rosnilimab, its PD-1 agonist, in a Phase 2b trial for the treatment of rheumatoid arthritis and in a Phase 2 trial for the treatment of ulcerative colitis. Its preclinical immune cell modulator portfolio includes ANB033, an anti-CD122 antagonist antibody, and ANB101, a BDCA2 modulator antibody, for the treatment of

autoimmune and inflammatory diseases. In addition, Anaptys has developed two cytokine antagonists available for out-licensing: imsidolimab, an anti-IL-36R antagonist, that has completed Phase 3 trials for the treatment of generalized pustular psoriasis, and etokimab, an anti-IL-33 antagonist that is Phase 2/3 ready. Anaptys has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immuno-oncology, including an anti-PD-1 antagonist antibody (*Jemperli* (dostarlimab-gxly)) and an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889). To learn more, visit www.AnaptysBio.com or follow us on [LinkedIn](#) and [X](#).

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 the Company’s clinical trials, including ANB032’s Phase 2b clinical trial in atopic dermatitis and rosnilimab’s Phase 2b clinical trial in rheumatoid arthritis and Phase 2 clinical trial in ulcerative colitis; the timing of IND filings for ANB033 and ANB101; the timing of a presentation of Phase 3 clinical data at a medical conference; the potential to receive any additional royalties from the GSK collaboration; 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,” “intend,” “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.

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

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 53,695	\$ 35,965
Receivables from collaborative partners	7,089	6,851
Short-term investments	300,970	354,939
Prepaid expenses and other current assets	10,666	9,080
Total current assets	372,420	406,835
Property and equipment, net	1,954	2,098
Operating lease right-of-use assets	15,732	16,174
Long-term investments	15,473	27,026
Other long-term assets	256	256
Total assets	\$ 405,835	\$ 452,389
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	\$ 4,582	\$ 4,698
Accrued expenses	25,903	30,967
Current portion of operating lease liability	1,813	1,777
Total current liabilities	32,298	37,442
Liability related to sale of future royalties	310,184	310,807
Operating lease liability, net of current portion	15,575	16,037

Stockholders' equity:

Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Common stock, \$0.001 par value, 500,000 shares authorized, 27,317 shares and 26,597 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	27	27
Additional paid in capital	706,407	702,969
Accumulated other comprehensive loss	(624)	(797)
Accumulated deficit	(658,032)	(614,096)
Total stockholders' equity	<u>47,778</u>	<u>88,103</u>
Total liabilities and stockholders' equity	\$ 405,835	\$ 452,389

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

	Three Months Ended March 31,	
	2024	2023
Collaboration revenue	\$ 7,179	\$ 1,374
Operating expenses:		
Research and development	37,042	34,957
General and administrative	12,338	10,818
Total operating expenses	<u>49,380</u>	<u>45,775</u>
Loss from operations	<u>(42,201)</u>	<u>(44,401)</u>
Other (expense) income, net:		
Interest income	4,584	4,486
Non-cash interest expense for the sale of future royalties	(6,317)	(4,336)
Other expense, net	(2)	(4)
Total other (expense) income, net	<u>(1,735)</u>	<u>146</u>
Net loss	<u>(43,936)</u>	<u>(44,255)</u>
Unrealized gain on available for sale securities	173	1,979
Comprehensive loss	<u>\$ (43,763)</u>	<u>\$ (42,276)</u>
Net loss per common share:		
Basic and diluted	<u>\$ (1.64)</u>	<u>\$ (1.58)</u>
Weighted-average number of shares outstanding:		
Basic and diluted	26,801	27,953



Source: AnaptysBio, Inc.