



Anaptys Announces Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

March 11, 2024

- Enrollment ongoing for global Phase 2b trial to treat atopic dermatitis (AD) with ANB032, our BTLA agonist, with 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, with top-line data anticipated by mid 2025 and H1 2026, respectively
- IND filings for ANB033 (anti-CD122 antagonist) and ANB101 (BDCA2 modulator) anticipated Q2 2024 and H2 2024, respectively
- Year end 2023 cash and investments of \$417 million and reiterating cash runway through year-end 2026

SAN DIEGO, March 11, 2024 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today reported operating results for the fourth quarter and year ended December 31, 2023 and provided a business update.

"2023 was a remarkable year for Anaptys as we implemented a multi-year development plan investing across our best-in-class immune cell modulators (ICMs) to bring transformational medicines to patients living with heterogeneous, systemic autoimmune and inflammatory diseases, with the goal of restoring immune balance," said Daniel Faga, president and chief executive officer of Anaptys. "Enrollment is ongoing in three global Phase 2 trials for ANB032, our BTLA agonist, in atopic dermatitis and rosnilimab, our PD-1 agonist, in rheumatoid arthritis and ulcerative colitis. Additionally, we expanded our portfolio by acquiring the rights to ANB101, a BDCA2 modulator, which targets plasmacytoid dendritic cells, known to be key drivers of interferon secretion and antigen presentation."

"We will have a number of important events in 2024 including the top-line data readout of ANB032's Phase 2b trial in atopic dermatitis by year end," adds Faga. "We also plan to move our third and fourth ICMs -- ANB033, our anti-CD122 antagonist, and ANB101 -- into the clinic this year, with IND filings planned for Q2 and H2, respectively."

Updates on Wholly Owned Immune Cell Modulator Pipeline

ANB032 (BTLA agonist antibody)

- Enrollment ongoing for global Phase 2b trial in moderate-to-severe atopic dermatitis (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 on well-established endpoints, including EASI75 and IGA 0/1
 - Reiterating top-line Week 14 data anticipated by year-end 2024
- Presented poster on ANB032 preclinical data supporting the modulation of dendritic cell (DC) maturation and function, representing one of the mechanisms to address atopic dermatitis pathophysiology, at the 2024 AAD Annual Meeting in March 2024
 - Poster presentation is 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

- o Reiterating top-line Week 12 data anticipated by H1 2026

- Presented posters on previously reported rosnilimab Phase 1 data and membrane proximal binding epitope to optimize PD-1 agonist signaling at the American College of Rheumatology (ACR) Convergence 2023 in November 2023 and at the 19th Congress of the European Crohn's and Colitis Organisation (ECCO) in February 2024
 - o Poster presentations are available [here](#)
- Hosted a virtual Rosnilimab (PD-1 Agonist) R&D Event in October 2023
 - o Replay of the audio webcast is available [here](#)

ANB033 (anti-CD122 antagonist antibody)

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

ANB101 (BDCA2 modulator antibody)

- Announced exclusive global license of ANB101 in November 2023
 - o Anaptys also received the same rights to ANB102, an extended half-life BDCA2 modulator with the potential to enable quarterly or less frequent dosing
- License from Centessa Pharmaceuticals in exchange for a one-time upfront cash payment of \$7 million, inclusive of \$3 million for manufactured and released GMP supply of ANB101
- 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 GEMINI-1 Phase 3 clinical trial results of imsidolimab (IL-36R) in generalized pustular psoriasis (GPP) in October 2023
 - o Plan to submit comprehensive data abstract for GEMINI-1 and top-line GEMINI-2 results to a medical meeting in H2 2024
- Intend to out-license imsidolimab in 2024

Updates on GSK Immuno-Oncology Financial Collaboration

- GSK anticipates top-line data in H2 2024 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
- 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

Cash Position

- Year end 2023 cash and investments of \$417 million and reiterating cash runway through year-end 2026

Fourth Quarter and Full Year 2023 Financial Results

- Cash, cash equivalents and investments totaled \$417.9 million as of December 31, 2023, compared to \$584.2 million as of December 31, 2022, for a decrease of \$166.3 million. The decrease relates primarily to cash used for operating activities and the \$50 million stock repurchase program.
- Collaboration revenue was \$9.0 million and \$17.2 million for the three and twelve months ended December 31, 2023, compared to \$6.8 million and \$10.3 million for the three and twelve months ended December 31, 2022. The change is due primarily to increased royalties recognized for sales of *Jemperli* offset by one development milestone achieved for cobolimab in 2022.
- Research and development expenses were \$33.5 million and \$132.3 million for the three and twelve months ended December 31, 2023, compared to \$23.4 million and \$88.8 million for the three and twelve months ended December 31, 2022. The increase was due primarily to manufacturing and development costs for rosnilimab, ANB032 and ANB033. The R&D non-cash, stock-based compensation expense was \$2.5 million and \$10.2 million for the three and twelve months ended December 31, 2023 as compared to \$1.8 million and \$6.8 million in the same period in 2022.
- General and administrative expenses were \$10.3 million and \$41.9 million for the three and twelve months ended December 31, 2023, compared to \$9.4 million and \$36.6 million for the three and twelve months ended December 31, 2022. The G&A non-cash, stock-based compensation expense was \$5.6 million and \$23.0 million for the three and twelve months ended December 31, 2023 as compared to \$4.9 million and \$20.6 million in the same period in 2022.

- Acquired in-process research and development of \$7.3 million for the three and twelve months ended December 31, 2023 related to the exclusive licensing agreement with Centessa Pharmaceuticals.
- Net loss was \$42.2 million and \$163.6 million for the three and twelve months ended December 31, 2023, or a net loss per share of \$1.59 and \$6.08, compared to a net loss of \$26.4 million and \$128.7 million for the three and twelve months ended December 31, 2022, or a net loss per share of \$0.93 and \$4.57.

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: 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; and ANB032, its BTLA agonist, in a Phase 2b trial for the treatment of atopic dermatitis. 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, 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. 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 rosnilimab’s Phase 2b clinical trial in rheumatoid arthritis and Phase 2 clinical trial in ulcerative colitis and ANB032’s Phase 2b clinical trial in atopic dermatitis; 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)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 35,965	\$ 71,308
Receivables from collaborative partners	6,851	1,419
Short-term investments	354,939	369,933
Prepaid expenses and other current assets	9,080	4,545
Total current assets	406,835	447,205
Property and equipment, net	2,098	2,089
Operating lease right-of-use assets	16,174	17,898

Long-term investments	27,026	142,935
Other long-term assets	256	256
Total assets	<u>\$ 452,389</u>	<u>\$ 610,383</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,698	\$ 2,784
Accrued expenses	30,967	21,633
Current portion of operating lease liability	1,777	1,637
Total current liabilities	<u>37,442</u>	<u>26,054</u>
Liability related to sale of future royalties	310,807	304,413
Operating lease liability, net of current portion	16,037	17,813
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at December 31, 2023 and December 31, 2022, respectively	—	—
Common stock, \$0.001 par value, 500,000 shares authorized, 26,597 shares and 28,513 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	27	29
Additional paid in capital	702,969	717,797
Accumulated other comprehensive loss	(797)	(5,246)
Accumulated deficit	<u>(614,096)</u>	<u>(450,477)</u>
Total stockholders' equity	<u>88,103</u>	<u>262,103</u>
Total liabilities and stockholders' equity	<u>\$ 452,389</u>	<u>\$ 610,383</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Collaboration revenue	\$ 9,005	\$ 6,808	\$ 17,157	\$ 10,287
Operating expenses:				
Research and development	33,525	23,374	132,283	88,798
General and administrative	10,276	9,407	41,946	36,643
Acquired in-process research and development	7,339	—	7,339	—
Total operating expenses	<u>51,140</u>	<u>32,781</u>	<u>181,568</u>	<u>125,441</u>
Loss from operations	<u>(42,135)</u>	<u>(25,973)</u>	<u>(164,411)</u>	<u>(115,154)</u>
Other income (expense), net:				
Interest income	4,880	3,839	18,873	7,550
Non-cash interest expense for the sale of future royalties	(4,958)	(4,251)	(18,083)	(21,108)
Other (expense) income, net	(2)	(4)	(2)	12
Total other income (expense), net	<u>(80)</u>	<u>(416)</u>	<u>788</u>	<u>(13,546)</u>
Loss before income taxes	(42,215)	(26,389)	(163,623)	(128,700)
Benefit (Provision) for income taxes	4	(24)	4	(24)
Net loss	<u>(42,211)</u>	<u>(26,413)</u>	<u>(163,619)</u>	<u>(128,724)</u>
Other comprehensive income (loss):				
Unrealized gain (loss) on available for sale securities	1,553	761	4,449	(4,824)
Comprehensive loss	<u>\$ (40,658)</u>	<u>\$ (25,652)</u>	<u>\$ (159,170)</u>	<u>\$ (133,548)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (1.59)</u>	<u>\$ (0.93)</u>	<u>\$ (6.08)</u>	<u>\$ (4.57)</u>
Weighted-average number of shares outstanding:				
Basic and diluted	26,586	28,446	26,924	28,165



Source: AnaptysBio, Inc.