Anaptys Announces Third Quarter 2024 Financial Results and Provides Business Update

November 5, 2024

- Top-line Phase 2b data anticipated for ANB032, our BTLA agonist, in atopic dermatitis (AD) in December 2024
- Top-line Phase 2b data anticipated for rosnilimab, our PD-1 agonist, in rheumatoid arthritis (RA) in February 2025
- Phase 1 trial initiated in healthy volunteers for ANB033, our anti-CD122 antagonist
- Reiterating cash runway through year-end 2026

SAN DIEGO, Nov. 05, 2024 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today reported financial results for the third quarter ended Sept. 30, 2024 and provided a business update.

"We remain confident in the potential best-in-class profiles of our programs targeting BTLA and PD-1 co-inhibitory receptors to drive differentiated results as we approach multiple clinical catalysts and value drivers for Anaptys, including top-line Phase 2b data in AD for ANB032, our BTLA agonist, in December. We've also completed enrollment for the Phase 2b trial of rosnilimab, our PD-1 agonist, in RA and are narrowing our guidance for top-line data to February 2025," said Daniel Faga, president and chief executive officer of Anaptys. "Additionally, enrollment in healthy volunteers has commenced for the Phase 1 trial for ANB033, our anti-CD122 antagonist, and we look forward to disclosing the Phase 1b indication in 2025. Looking to the end of the year, we are on track to have four programs in clinical development."

Updates on Wholly Owned ICM Pipeline

ANB032 (BTLA agonist antibody)

- Top-line Week 14 data for global Phase 2b trial in moderate-to-severe AD anticipated in December 2024
  - Enrolled approximately 200 patients in a 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 EASI-75 and IGA 0/1
  - Enrollment included approximately 15% of patients with Dupixent/anti-IL-13 treatment experience
- Presented analyses that characterize a BTLA transcriptomic signature in AD at the European Academy of Dermatology and Venerology (EADV) Congress in September 2024
  - Poster presentation is available here

Rosnilimab (PD-1 agonist antibody)

- Top-line Week 12 data for global Phase 2b trial in moderate-to-severe RA anticipated in February 2025
  - Completed enrollment of approximately 420 patients in a 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
- Enrollment ongoing for global Phase 2 trial in moderate-to-severe ulcerative colitis (UC)
  - 132-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
    - In October 2024, an optional 26-week, blinded treatment extension period (TEP) was implemented for patients who remain in clinical response at Week 24 in the U.S.; EU implementation anticipated in early 2025
  - Top-line Week 12 data anticipated in Q1 2026
- Presented data evaluating the PD-1 depletion and agonism mechanisms of rosnilimab *in vitro* with UC patient-derived PBMCs and a mouse model of colitis at the 2024 United European Gastroenterology Week (UEGW) in October 2024

- Poster presentation is available here

ANB033 (anti-CD122 antagonist antibody)

- Phase 1 trial initiated in healthy volunteers in October 2024
  - Phase 1b indication to be disclosed in 2025

ANB101 (BDCA2 modulator antibody)

- Submitted investigational new drug (IND) application and plan to initiate enrollment for Phase 1 trial in healthy volunteers in Q1 2025

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

- Presented full data from the Phase 3 GEMINI-1 and GEMINI-2 trials of imsidolimab (IL-36R) in generalized pustular psoriasis (GPP) at the EADV Congress in September 2024
  - Poster presentation is available here
- Intend to out-license imsidolimab in 2024

GSK Immuno-Oncology Financial Collaboration

- GSK anticipates top-line data in H1 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
- GSK anticipates top-line data in Q4 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 Runway

- Cash and investments of $458.0 million as of September 30, 2024 and reiterating cash runway through year-end 2026

Third Quarter Financial Results

- Cash, cash equivalents and investments totaled $458.0 million as of September 30, 2024, compared to $417.9 million as of December 31, 2023, for an increase of $40.1 million due primarily to the $100.0 million underwritten registered direct offering completed in Q3 and $50.0 million received from the Sagard royalty monetization in Q2 offset by operating activities.
- Collaboration revenue was $30.0 million and $48.2 million for the three and nine months ended September 30, 2024, compared to $3.3 million and $8.2 million for the three and nine months ended September 30, 2023. The increase in non-cash revenue is due to a $15.0 million commercial milestone earned for annual *Jemperli* sales exceeding $250.0 million and increased royalties recognized for sales of *Jemperli*.
- Research and development expenses were $42.2 million and $121.3 million for the three and nine months ended September 30, 2024, compared to $30.9 million and $98.8 million for the three and nine months ended September 30, 2023. The increase was due primarily to development costs for rosnilimab, ANB032, ANB033 and ANB101 offset by a decrease in development costs for imsidolimab. The R&D non-cash, stock-based compensation expense was $4.0 million and $10.9 million for the three and nine months ended September 30, 2024 as compared to $2.2 million and $7.7 million in the same period in 2023.
- General and administrative expenses were $10.6 million and $32.2 million for the three and nine months ended September 30, 2024, compared to $10.2 million and $31.7 million for the three and nine months ended September 30, 2023. The G&A non-cash, stock-based compensation expense was $4.2 million and $14.9 million for the three and nine months ended September 30, 2024 as compared to $5.6 million and $17.4 million in the same period in 2023.
- Net loss was $32.9 million and $123.4 million for the three and nine months ended September 30, 2024, or a net loss per share of $1.14 and $4.46, compared to a net loss of $37.3 million and $121.4 million for the three and nine months ended September 30, 2023, or a net loss per share of $1.41 and $4.49.

About Anaptys

Anaptys is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics for autoimmune and inflammatory diseases. Its pipeline includes two programs targeting co-inhibitory receptors: 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. It also has other antibodies in its portfolio, including ANB033, an anti-CD122 antagonist, in a Phase 1 trial and ANB101, a BDCA2 modulator, soon to enter clinical development. 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 (*Jemperli* (dostarlimab-gxly)) and an anti-TIM-3 antagonist (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 initiation of ANB101's Phase 1 clinical trial; the timing of disclosure of the Phase 1b indication for ANB033; 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.

Contact:
Nick Montemarano
Senior Director, Investor Relations and Strategic Communications
858.732.0178
investors@anaptysbio.com

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

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 191,581	$ 35,965
Receivables from collaborative partners	12,195	6,851
Short-term investments	238,536	354,939
Prepaid expenses and other current assets	6,369	9,080
Total current assets	448,681	406,835
Property and equipment, net	1,728	2,098
Operating lease right-of-use assets	14,839	16,174
Long-term investments	27,914	27,026
Other long-term assets	256	256
Total assets	$ 493,418	$ 452,389
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,592	$ 4,698
Accrued expenses	38,401	30,967
Current portion of operating lease liability	1,887	1,777
Total current liabilities	43,880	37,442
Liability related to sale of future royalties	350,564	310,807
Operating lease liability, net of current portion	14,607	16,037
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at September 30, 2024 and December 31, 2023, respectively	—	—

Common stock, $0.001 par value, 500,000 shares authorized, 30,429 shares and 26,597 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	30	27
Additional paid in capital	821,121	702,969
Accumulated other comprehensive gain (loss)	759	(797)
Accumulated deficit	(737,543)	(614,096)
Total stockholders' equity	84,367	88,103
Total liabilities and stockholders' equity	$ 493,418	$ 452,389

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,	
	2024	**2023**	**2024**	**2023**
Collaboration revenue	$ 30,017	$ 3,318	$ 48,167	$ 8,152
Operating expenses:				
Research and development	42,212	30,878	121,251	98,758
General and administrative	10,562	10,172	32,195	31,670
Total operating expenses	52,774	41,050	153,446	130,428
Loss from operations	(22,757)	(37,732)	(105,279)	(122,276)
Other (expense) income, net:				
Interest income	5,324	4,854	14,531	13,993
Non-cash interest expense for the sale of future royalties	(15,413)	(4,431)	(32,683)	(13,125)
Other (expense) income, net	(5)	1	(7)	—
Total other (expense) income, net	(10,094)	424	(18,159)	868
Loss before income taxes	(32,851)	(37,308)	(123,438)	(121,408)
Provision for income taxes	—	—	(9)	—
Net loss	(32,851)	(37,308)	(123,447)	(121,408)
Unrealized gain on available for sale securities	1,174	1,261	1,556	2,896
Comprehensive loss	$ (31,677)	$ (36,047)	$ (121,891)	$ (118,512)
Net loss per common share:				
Basic and diluted	$ (1.14)	$ (1.41)	$ (4.46)	$ (4.49)
Weighted-average number of shares outstanding:				
Basic and diluted	28,893	26,546	27,688	27,038

Source: AnaptysBio, Inc.