Anaptys Announces Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

February 27, 2025

- Announced rosnilimab, a PD-1 depleter and agonist, achieved positive results from Phase 2b rheumatoid arthritis (RA) trial and highest-ever reported CDAI LDA response over 6 months
- Full clinical and translational data for rosnilimab in RA in Q2 2025
- Top-line Phase 2 data for rosnilimab in ulcerative colitis (UC), moved up to Q4 2025
- Phase 1a trial in healthy volunteers ongoing for ANB033, our CD122 antagonist, and Phase 1a trial to initiate this quarter for ANB101, our BDCA2 modulator
- Announced exclusive global license agreement with Vanda Pharmaceuticals to develop and commercialize imsidolimab, an IL-36R antagonist
- Year-end 2024 cash and investments of ~$420 million and reiterating cash runway through year-end 2027

SAN DIEGO, Feb. 27, 2025 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today reported financial results for the fourth quarter and year ended December 31, 2024, and provided a business update.

“Rosnilimab’s positive Phase 2b data in rheumatoid arthritis has revealed impressive safety, tolerability and three-month efficacy data that was sustained and surpasses six-month data from competitor all-active, head-to-head trials. In Q2 2025, we will report full clinical and translational data, further validating rosnilimab’s transformative potential to restore immune homeostasis, not only in RA but also in other diseases like ulcerative colitis. We also are excited to report top-line Phase 2 data for rosnilimab in UC moved up to Q4 2025,” said Daniel Faga, president and chief executive officer of Anaptys. “Additionally, Phase 1 development of both ANB033 and ANB101 is advancing as planned. With approximately $420 million of cash coming into 2025, we are well capitalized through year-end 2027, which does not include the significant potential residual royalties and milestones from our GSK financial collaboration.”

Updates on Asset Portfolio

Rosnilimab (PD-1 depleter and agonist)

- Announced subcutaneously administered rosnilimab, including two once-monthly doses, achieved positive results in 424-patient Phase 2b RA trial and highest-ever reported clinical disease activity index (CDAI) low disease activity (LDA) response over 6 months
  - Key results for the trial were –
    - Achieved statistical significance on primary endpoint at Week 12 on mean change from baseline DAS28-CRP score across all three rosnilimab doses vs. placebo
    - Achieved statistical significance on key secondary endpoints at Week 12 on ACR20, ACR50 and CDAI LDA
    - Demonstrated highest-ever reported responses on key secondary endpoints at Week 14 on ACR20, ACR50, ACR70 and CDAI LDA
    - 69% (220/318) of rosnilimab-treated patients achieved CDAI LDA at Week 14 and appear to show sustained CDAI LDA and ACR50 responses and potentially deepening ACR70 responses out to Week 28
    - Robust pharmacological activity observed in reduction of PD-1^{high} T cells, increase in total Tregs and reduction of CRP across all doses
    - Rosnilimab was safe and well tolerated with similar adverse event rates vs. placebo
    - Full press release can be found here
  - Full clinical and translational data anticipated in Q2 2025
- Enrollment ongoing for global Phase 2 trial in moderate-to-severe UC
  - 132-patient trial assessing two dose levels of subcutaneously administered rosnilimab vs. placebo (randomized 1:1:1)
    - Primary statistical analysis at Week 12 on well-established endpoints, including the primary endpoint of change from baseline in modified Mayo score (mMS) and supportive secondary endpoints of clinical response on mMS, clinical remission on mMS and endoscopic remission
    - All patients in all three study arms treat-through to Week 24 and remain blinded to treatment arm. Placebo-treated patients who achieved clinical response on partial modified Mayo score (pmMS) at Week 12 remain on placebo, while placebo-treated patients who are non-responders are crossed over to the high-dose

rosnilimab treatment arm
        - Patients who are in clinical response on pmMS at Week 24 are eligible for an additional 26-weeks (50 weeks of total treatment), blinded treatment extension period (TEP)
    - Top-line data anticipated in Q4 2025
- Presented preclinical data in Q4 2024 and Q1 2025 (available here) 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)
    - Inflammatory pathway gene expression in PD-1+ conventional and regulatory T cells in human UC tissue and rosnilimab's effects in a mouse model of colitis at the European Crohn's and Colitis Organisation (ECCO) Congress
    - Synovial levels of PD-1 and the correlation with disease activity in RA at American College of Rheumatology (ACR) Convergence

ANB033 (CD122 antagonist)

- Enrollment ongoing for Phase 1a trial in healthy volunteers
    - Phase 1b indication to be disclosed at a 2025 R&D event

ANB101 (BDCA2 modulator)

- Investigational new drug (IND) application accepted by FDA
- Phase 1a trial to initiate in healthy volunteers in Q1 2025

Imsidolimab (IL-36 antagonist)

- Announced an exclusive global out-license agreement with Vanda Pharmaceuticals to develop and commercialize imsidolimab (IL-36R antagonist)
    - Anaptys received $15 million, comprised of a $10 million upfront payment and $5 million for existing drug supply
    - Anaptys eligible to receive up to $35 million for future regulatory approvals and sales milestones in addition to a 10% royalty on global net sales

GSK Immuno-Oncology Financial Collaboration

- GSK announced strong commercial performance for *Jemperli* ($190 million in Q4 2024 sales) with >100% year-over-year growth
- 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 and to docetaxel alone in patients with advanced NSCLC who have progressed on prior anti-PD-(L)1 therapy and platinum-based chemotherapy
- GSK anticipates top-line data in 2026 from AZUR-1 pivotal Phase 2 trial of dostarlimab monotherapy in patients with untreated stage II/III dMMR/MSI-H locally advanced rectal cancer
    - *Jemperli* received U.S. FDA Breakthrough Therapy Designation for this indication in December 2024

Cash Runway

- Cash and investments of $420.8 million as of Dec. 31, 2024, and reiterating cash runway through year-end 2027

Fourth Quarter and Full Year 2024 Financial Results

- Cash, cash equivalents and investments totaled $420.8 million as of December 31, 2024, compared to $417.9 million as of December 31, 2023, for an increase of $2.9 million due primarily to the $100 million underwritten registered direct offering completed in Q3 and $50.0 million received from the Sagard royalty monetization in Q2 offset by 2024 operating activities.
- Collaboration revenue was $43.1 million and $91.3 million for the three and twelve months ended December 31, 2024, compared to $9.0 million and $17.2 million for the three and twelve months ended December 31, 2023. The increase in non-cash revenue in 2024 is due to $15.0 million and $25.0 million commercial milestones earned for annual *Jemperli* sales exceeding $250.0 million and $500.0 million during the year and increased royalties recognized for sales of *Jemperli*. For the year ended December 31, 2024, GSK reported $598.0 million in sales for *Jemperli,* a greater than 200% sales growth when compared to $175.6 million for the year ended December 31, 2023.
- Research and development expenses were $42.6 million and $163.8 million for the three and twelve months ended December 31, 2024, compared to $33.5 million and $132.3 million for the three and twelve months ended December 31, 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 $3.9 million and $14.8 million for the three and twelve months ended December 31, 2024 as compared to $2.5 million and $10.2 million in the same period in 2023.
- General and administrative expenses were $10.2 million and $42.4 million for the three and twelve months ended December 31, 2024, compared to $10.3 million and $41.9 million for the three and twelve months ended December 31,

2023. The G&A non-cash, stock-based compensation expense was $4.3 million and $19.2 million for the three and twelve months ended December 31, 2024 as compared to $5.6 million and $23.0 million in the same period in 2023.

- Net loss was $21.8 million and $145.2 million for the three and twelve months ended December 31, 2024, or a net loss per share of $0.72 and $5.12, compared to a net loss of $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.

About Anaptys

Anaptys is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics for autoimmune and inflammatory diseases. Its lead program, rosnilimab, a depleter and agonist targeting PD-1+ T cells, is in a Phase 2b trial for the treatment of rheumatoid arthritis and in a Phase 2 trial for the treatment of ulcerative colitis. Other antibodies in its portfolio include ANB033, a CD122 antagonist, in a Phase 1 trial and ANB101, a BDCA2 modulator, entering a Phase 1 trial. Anaptys has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immuno-oncology, including a PD-1 antagonist (*Jemperli* (dostarlimab-gxly)) and a TIM-3 antagonist (cobolimab, GSK4069889). To learn more, visit www.AnaptysBio.com or follow us on LinkedIn.

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 full Phase 2b clinical trial data in rheumatoid arthritis and top-line Phase 2 clinical trial data in ulcerative colitis; whether current trends in full clinical data in rheumatoid arthritis will be maintained once complete data becomes available; whether positive clinical trial results in rosnilimab's Phase 2b clinical trial in rheumatoid arthritis increases the likelihood of getting positive results from rosnilimab's Phase 2 clinical trial in ulcerative colitis; timing of initiation of ANB101's Phase 1 clinical trial; the potential to receive any royalties or milestone payments from the Vanda Pharmaceuticals license agreement; the potential to receive any additional milestones and royalties from the GSK collaboration; 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.

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

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 123,080	$ 35,965
Receivables from collaborative partners	40,765	6,851
Short-term investments	262,293	354,939
Prepaid expenses and other current assets	5,738	9,080
Total current assets	431,876	406,835
Property and equipment, net	1,849	2,098
Operating lease right-of-use assets	14,383	16,174
Long-term investments	35,470	27,026
Other long-term assets	256	256
Total assets	$ 483,834	$ 452,389

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 4,002	$ 4,698
Accrued expenses	39,501	30,967
Current portion of operating lease liability	1,925	1,777
Total current liabilities	45,428	37,442
Liability related to sale of future royalties	353,426	310,807
Operating lease liability, net of current portion	14,112	16,037
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at December 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 30,473 shares and 26,597 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	30	27
Additional paid in capital	829,860	702,969
Accumulated other comprehensive gain (loss)	305	(797)
Accumulated deficit	(759,327)	(614,096)
Total stockholders' equity	70,868	88,103
Total liabilities and stockholders' equity	$ 483,834	$ 452,389

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Collaboration revenue	$ 43,113	$ 9,005	$ 91,280	$ 17,157
Operating expenses:				
Research and development	42,589	33,525	163,840	132,283
General and administrative	10,194	10,276	42,389	41,946
Acquired in-process research and development	—	7,339	—	7,339
Total operating expenses	52,783	51,140	206,229	181,568
Loss from operations	(9,670)	(42,135)	(114,949)	(164,411)
Other (expense) income, net:				
Interest income	5,263	4,880	19,794	18,873
Non-cash interest expense for the sale of future royalties	(17,404)	(4,958)	(50,087)	(18,083)
Other income (expense), net	21	(2)	14	(2)
Total other (expense) income, net	(12,120)	(80)	(30,279)	788
Loss before income taxes	(21,790)	(42,215)	(145,228)	(163,623)
Benefit (Provision) for income taxes	6	4	(3)	4
Net loss	(21,784)	(42,211)	(145,231)	(163,619)
Other comprehensive income (loss):				
Unrealized (loss) gain on available for sale securities	(454)	1,553	1,102	4,449
Comprehensive loss	$ (22,238)	$ (40,658)	$ (144,129)	$ (159,170)
Net loss per common share:				
Basic and diluted	$ (0.72)	$ (1.59)	$ (5.12)	$ (6.08)
Weighted-average number of shares outstanding:				
Basic and diluted	30,448	26,586	28,382	26,924

Source: AnaptysBio, Inc.