AnaptysBio Announces Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

March 1, 2023

- Initiating a global Phase 2b trial for rosnilimab (PD-1 agonist) to treat rheumatoid arthritis anticipated Q3 2023
- Initiating a global Phase 2b trial for ANB032 (BTLA agonist) to treat atopic dermatitis anticipated Q2 2023
- Initiating second Phase 2 trial for rosnilimab in an indication to be announced anticipated year-end 2023
- Filing IND for ANB033 (anti-CD122 antagonist) anticipated H1 2024
- Top-line data from the GEMINI-1 Phase 3 trial for imsidolimab (anti-IL-36R antagonist) to treat GPP anticipated Q4 2023
- Reiterating cash runway through year end 2026

SAN DIEGO, March 01, 2023 (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, 2022 and provided business updates.

“2022 was a significant year of transition for AnaptysBio as we refocused the company on broadly advancing our portfolio of best-in-class immune cell modulators. We are excited by the near-term initiation of our two global Phase 2b trials across rosnilimab, our PD-1 agonist, in rheumatoid arthritis and ANB032, our BTLA agonist, in atopic dermatitis. We believe their mechanisms of action have the potential to meaningfully impact large and significantly underserved patient populations, to restore immune balance by acting directly on cell types mediating disease pathology,” said Daniel Faga, interim president and chief executive officer of AnaptysBio. “As we continue to progress our strategic portfolio review, we are well capitalized to deliver on multiple Phase 2 readouts across our wholly owned checkpoint agonists, as well as to advance ANB033, our anti-CD122 antagonist, through clinical proof-of-concept.”

Rosnilimab (PD-1 agonist antibody)

- Rosnilimab, its investigational wholly owned PD-1 agonist, demonstrates best-in-class activity *in vitro* with superior inhibition of T cell proliferation, reduction in inflammatory cytokine secretion (Th1, Th2, Th17) and depletion of PD-1+ T cells via effector function compared to Lilly PD-1 agonist
- PD-1+ T cells are clinically validated drivers of disease in rheumatoid arthritis (RA)
    - RA patient synovial biopsies have dense T cell infiltrates, with >80% of T cells expressing PD-1 and insufficient PD-L1 expression to down-regulate T cell activity
    - Rosnilimab targets multiple distinct inflammatory mechanisms addressed by approved therapies to treat RA
- Initiation in Q3 2023 of a global Phase 2b trial in moderate-to-severe RA
    - Multi-hundred patient placebo-controlled trial assessing three dose levels of subcutaneously administered rosnilimab for approximately 6 months on well-established endpoints including ACR20/50/70 and DAS28
    - Top-line interim data anticipated by mid-year 2025
- Second global Phase 2 trial, in an indication to be announced, with study initiation anticipated by year-end 2023

ANB032 (BTLA agonist antibody)

- ANB032, its investigational wholly owned BTLA agonist, demonstrates best-in-class activity *in vitro* with superior inhibition of T cell proliferation and reduction in inflammatory cytokine secretion (Th1, Th2, Th17) compared to Lilly BTLA agonist
- While Th2 targeted therapies provide benefit to patients with chronic moderate-to-severe atopic dermatitis (AD), there is compelling evidence that AD is broader than a Th2 driven disease, as Th1, Th17 and other cell types, including dendritic cells, may contribute significantly to its pathogenesis
    - ANB032 inhibits inflammatory activity of Th1, Th2 and Th17 and modulates additional cell types such as B cells and dendritic cells, with the potential for broader, deeper and more durable responses than more narrowly targeted interventions
- Initiation in Q2 2023 of a 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 12 weeks on well-established endpoints, including EASI75 and IGA 0/1
    - Top-line interim data anticipated by year-end 2024

ANB033 (anti-CD122 antagonist antibody)

- ANB033, its investigational wholly owned anti-CD122 antagonist antibody, targets the common beta subunit shared by the IL-15 and IL-2 receptors
    - IL-15 signaling mediates the survival and maintenance of tissue resident memory T cells (T_{RM})
    - The presence of long-lived and persistent T_{RM} have been shown to drive tissue-specific immune-mediated inflammation
- IND anticipated H1 2024

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

- Imsidolimab, its investigational wholly owned anti-IL-36R antagonist antibody, is in Phase 3 trials for generalized pustular psoriasis (GPP)
    - Top-line data from the GEMINI-1 Phase 3 trial anticipated Q4 2023
    - Plan to out-license imsidolimab prior to potential FDA approval
- Etokimab, its investigational wholly owned anti-IL-33 antagonist antibody, is Phase 2/3-ready for the treatment of respiratory disorders
    - No further internal investment in etokimab is being pursued

GSK Immuno-Oncology Financial Collaboration

- Dostarlimab, an anti-PD-1 antagonist antibody, cobolimab, an anti-TIM-3 antagonist antibody, and GSK4074386, an anti-LAG-3 antagonist antibody, were discovered at AnaptysBio and licensed by GSK
- JEMPERLI (dostarlimab-gxly) has the potential for a first-in-class approval in primary advanced or recurrent endometrial cancer after meeting the primary endpoint in the pivotal RUBY Phase 3 trial demonstrating JEMPERLI plus chemotherapy significantly improved PFS versus chemotherapy plus placebo
    - Regulatory submissions anticipated H1 2023
    - GSK expects to publish full results in a medical journal and present at an upcoming scientific meeting
- Dostarlimab plus ZEJULA in the pivotal FIRST Phase 3 trial in 1st line ovarian cancer is ongoing with an interim analysis expected in H2 2023
- Dostarlimab plus cobolimab plus chemotherapy vs. dostarlimab plus chemotherapy is in the pivotal COSTAR Lung Phase 3 trial in advanced non-small cell lung cancer in patients who have progressed on prior anti-PD-(L)1 therapy

Stock Repurchase Plan

- In January 2023, the Board of Directors authorized a Stock Repurchase Plan under which the Company may repurchase up to $50.0 million of the Company's outstanding common stock. The Stock Repurchase Plan will expire on December 31, 2023, may be suspended or discontinued at any time, and does not obligate the company to acquire any amount of common stock.

Fourth Quarter Financial Results

- Cash, cash equivalents and investments totaled $584.2 million as of December 31, 2022, compared to $615.2 million as of December 31, 2021, for a decrease of $31.0 million. The decrease relates primarily to cash used for operating activities offset by cash received from the Zejula royalty sale and stock option exercises.
- Collaboration revenue was $6.8 million and $10.3 million for the three and twelve months ended December 31, 2022, compared to $1.0 million and $63.2 million for the three and twelve months ended December 31, 2021. The increase for the three months ended December 31, 2022 relates primarily to one development milestone achieved for cobolimab and no development milestones achieved during the three months ended December 31, 2021. The decrease for the twelve months ended December 31, 2022 relates primarily to four development milestones achieved for JEMPERLI for the twelve months ended December 31, 2021, and one development milestone achieved during the twelve months ended December 31, 2022.
- Research and development expenses were $23.4 million and $88.8 million for the three and twelve months ended December 31, 2022, compared to $26.8 million and $98.5 million for the three and twelve months ended December 31, 2021. The decrease for the three and twelve months ended December 31, 2022 was due primarily to reduced clinical and manufacturing costs for the Company's programs. The R&D non-cash, stock-based compensation expense was $1.8 million and $6.8 million for the three and twelve months ended December 31, 2022, as compared to $1.5 million and $5.9

million in the same period in 2021.

- General and administrative expenses were $9.4 million and $36.6 million for the three and twelve months ended December 31, 2022, compared to $5.4 million and $21.5 million for the three and twelve months ended December 31, 2021. The increase was primarily due to stock compensation expense and $3.8 million of costs incurred from personnel changes in the first quarter of 2022. The G&A non-cash, stock-based compensation expense was $4.9 million and $20.6 million for the three and twelve months ended December 31, 2022, which includes $3.2 million of the $3.8 million one-time costs described earlier as compared to $2.5 million and $9.5 million in the same period in 2021.

- Non-cash interest expense was $4.3 million and $21.1 million for the three and twelve months ended December 31, 2022, compared to $1.5 million for the three and twelve months ended December 31, 2021. The increase in non-cash interest expense during the period is directly related to the interest expense accrued on the liability related to the sale of future royalties, of which we had a full year of expense during 2022 as compared to one month of expense during 2021. We also had an additional sale of future royalties in 2022 compared to period in 2021.

- Net loss was $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, compared to a net loss of $32.5 million and $57.8 million for the three and twelve months ended December 31, 2021, or a net loss per share of $1.18 and $2.11.

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. It is developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, its PD-1 agonist, in a planned Phase 2b trial for the treatment of moderate-to-severe rheumatoid arthritis; and ANB032, its BTLA agonist, in a planned Phase 2b trial for the treatment of moderate-to-severe atopic dermatitis. Its preclinical immune cell modulator portfolio includes ANB033, an anti-CD122 antagonist antibody for the treatment of autoimmune and inflammatory diseases. In addition, AnaptysBio 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. AnaptysBio has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immune-oncology, including an anti-PD-1 antagonist antibody (JEMPERLI (dostarlimab-gxly)), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889) and an anti-LAG-3 antagonist antibody (GSK4074386).

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 initiation of the company's clinical trials, including rosnilimab's clinical trials in rheumatoid arthritis and in a second indication and ANB032's clinical trial in atopic dermatitis; the timing of the release of data from the company's clinical trials, including imsidolimab's Phase 3 clinical trial in GPP, rosnilimab's Phase 2b clinical trial in rheumatoid arthritis and ANB032's Phase 2b clinical trial in atopic dermatitis; the timing of ANB033's IND filing; 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," "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
AnaptysBio, Inc.
858.732.0178
investors@anaptysbio.com

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

	December 31, 2022	December 31, 2021

ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,308	$ 495,729
Receivables from collaborative partners	1,419	876
Short-term investments	369,933	52,368
Prepaid expenses and other current assets	4,545	4,903
Total current assets	447,205	553,876
Property and equipment, net	2,089	2,283
Operating lease right-of-use assets	17,898	19,558
Long-term investments	142,935	67,097
Other long-term assets	256	256
Total assets	$ 610,383	$ 643,070
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,784	$ 1,741
Accrued expenses	21,633	12,853
Current portion of operating lease liability	1,637	1,505
Total current liabilities	26,054	16,099
Liability related to sale of future royalties	304,413	251,093
Operating lease liability, net of current portion	17,813	19,450
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 28,513 shares and 27,647 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	29	28
Additional paid in capital	717,797	678,575
Accumulated other comprehensive loss	(5,246)	(422)
Accumulated deficit	(450,477)	(321,753)
Total stockholders' equity	262,103	356,428
Total liabilities and stockholders' equity	$ 610,383	$ 643,070

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Collaboration revenue	$ 6,808	$ 1,011	$ 10,287	$ 63,175
Operating expenses:				
Research and development	23,374	26,776	88,798	98,496
General and administrative	9,407	5,392	36,643	21,493
Total operating expenses	32,781	32,168	125,441	119,989
Loss from operations	(25,973)	(31,157)	(115,154)	(56,814)
Other income (expense), net:				
Interest income	3,839	68	7,550	431
Non-cash interest expense for the sale of future royalties	(4,251)	(1,450)	(21,108)	(1,450)
Other (expense) income, net	(4)	1	12	37
Total other expense, net	(416)	(1,381)	(13,546)	(982)
Loss before income taxes	(26,389)	(32,538)	(128,700)	(57,796)
Provision for income taxes	(24)	—	(24)	—
Net loss	(26,413)	(32,538)	(128,724)	(57,796)
Other comprehensive income (loss):				
Unrealized income (loss) on available for sale securities	761	(222)	(4,824)	(418)
Comprehensive loss	$ (25,652)	$ (32,760)	$ (133,548)	$ (58,214)
Net loss per common share:				
Basic and diluted	$ (0.93)	$ (1.18)	$ (4.57)	$ (2.11)

Weighted-average number of shares outstanding:				
Basic and diluted	28,446	27,534	28,165	27,431

Source: AnaptysBio, Inc.