AnaptysBio Announces Third Quarter 2022 Financial Results and Provides Pipeline Update

November 8, 2022

- Anticipate Rosnilimab, our anti-PD-1 agonist antibody, top-line data in the ongoing AZURE Phase 2 trial in moderate-to-severe alopecia areata in Q1 2023
- Anticipate ANB032, our anti-BTLA agonist antibody, U.S. IND submission for a Phase 2 trial in Q4 2022
- Announced our third wholly owned immune cell modulator program, ANB033, our anti-CD122 antagonist antibody, with a U.S. IND submission for a Phase 1 trial in 1H 2024
- Sold our interest in future Zejula royalties to a wholly-owned subsidiary of DRI Healthcare Trust for up to $45 million during Q3 2022

SAN DIEGO, Nov. 08, 2022 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today reported operating results for the third quarter ended September 30, 2022 and provided pipeline updates.

“We are excited about the potential of our novel immune cell modulator pipeline, including our two checkpoint agonists in clinical-stage development, rosnilimab and ANB032. We believe their mechanisms of action, acting directly on cell types mediating disease pathology, have the potential to treat a broad range of autoimmune and inflammatory disorders” said Daniel Faga, interim president and chief executive officer of AnaptysBio. “We’re well capitalized to execute with over $590 million in cash at the end of Q3 as we move forward in our strategic portfolio review.”

Rosnilimab (Anti-PD-1 agonist) Program

- Rosnilimab, our investigational wholly owned anti-PD-1 agonist antibody, is in the ongoing AZURE Phase 2 clinical trial in moderate-to-severe alopecia areata, and we anticipate top-line data in Q1 2023.

ANB032 (Anti-BTLA agonist) Program

- ANB032, our investigational wholly owned anti-BTLA agonist antibody, will be advancing with a U.S. IND submission for an initial Phase 2 clinical trial in Q4 2022.

ANB033 (Anti-CD122 antagonist) Program

- ANB033, our 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. We anticipate submitting a U.S. IND in first half of 2024.

Imsidolimab (Anti-IL-36 receptor) Program

- Imsidolimab, our investigational wholly owned anti-IL-36R therapeutic antibody, is in Phase 3 trials in generalized pustular psoriasis (GPP), and we anticipate top-line data from the GEMINI-1 Phase 3 clinical trial in Q4 2023 and plan to outlicense imsidolimab prior to potential FDA approval.

GSK Partnered Programs

- PERLA, a head-to head Phase 2 trial of JEMPERLI (dostarlimab) vs. Keytruda in patients with metastatic non-squamous non-small cell lung cancer met its primary endpoint of objective response rate (ORR) of dostarlimab plus chemotherapy versus pembrolizumab plus chemotherapy as assessed by blinded independent central review per RECIST v1.1.
    - GSK will present full results, including the primary endpoint of ORR and the key secondary endpoint of progression-free survival, at the ESMO Immuno-Oncology Annual Congress on Friday, December 9th.
- COSTAR, a Phase 2 trial of dostarlimab plus cobolimab, an anti-TIM-3 antagonist antibody, achieved pre-specified efficacy and safety criteria, and GSK is advancing both arms of the COSTAR Lung clinical trial from Phase 2 to Phase 3, testing both doublet and triplet combinations of dostarlimab plus chemotherapy, and cobolimab plus dostarlimab plus chemotherapy in advanced non-small cell lung cancer who have progressed on prior anti-PD-(L)1 therapy and chemotherapy.
    - Cobolimab was discovered at AnaptysBio and licensed to TESARO, Inc., (GSK) as part of the same collaboration

agreement as dostarlimab.
    - AnaptysBio earned a $5 million milestone from GSK in October 2022 on initiation of the first Phase 3 trial with cobolimab.
- Sold our royalty interest on future global net sales of Zejula to a wholly-owned subsidiary of DRI Healthcare Trust for up to $45 million during Q3.
    - Received an upfront payment of $35 million and are eligible for a further $10 million from DRI upon FDA approval of Zejula for the treatment of endometrial cancer, for which the drug is currently in a fully-enrolled ongoing Phase 3 study, to the extent that such approval occurs on or before December 31, 2025.

Third Quarter Financial Results

- Cash, cash equivalents and investments totaled $590.5 million as of September 30, 2022, compared to $615.2 million as of December 31, 2021, for a decrease of $24.7 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 $1.3 million and $3.5 million for the three and nine months ended September 30, 2022, compared to $20.9 million and $62.2 million for the three months and nine months ended September 30, 2021. The decrease relates primarily to one development milestone achieved for JEMPERLI for the three months ended September 30, 2021, and four development milestones achieved for JEMPERLI for the nine months ended September 30, 2021, and no development milestones achieved during the nine months ended September 30, 2022.
- Research and development expenses were $22.1 million and $65.4 million for the three and nine months ended September 30, 2022, compared to $22.2 million and $71.7 million for the three and nine months ended September 30, 2021. The year-to-date decrease was due primarily to reduced clinical costs and manufacturing costs for the Company's programs. The R&D non-cash, stock-based compensation expense was $1.5 million and $5.0 million for the three and nine months ended September 30, 2022, as compared to $1.8 million and $4.4 million in the same period in 2021.
- General and administrative expenses were $8.9 million and $27.2 million for the three and nine months ended September 30, 2022, compared to $5.4 million and $16.1 million for the three and nine months ended September 30, 2021. The increase was due primarily to $3.8 million of costs incurred from personnel changes in the first quarter of 2022 and non-cash stock compensation expense. The G&A non-cash, stock-based compensation expense was $4.7 million and $15.7 million for the three and nine months ended September 30, 2022, which includes $3.2 million of the $3.8 million one-time costs described earlier as compared to $2.6 million and $7.0 million in the same period in 2021.
- Net loss was $33.5 million and $102.3 million for the three and nine months ended September 30, 2022, or a net loss per share of $1.18 and $3.64, compared to a net loss of $6.7 million and $25.3 million for the three and nine months ended September 30, 2021, or a net loss per share of $0.24 and $0.92.

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. We are developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, our anti-PD-1 agonist program in Phase 2 for the treatment of moderate-to-severe alopecia areata; and ANB032, our anti-BTLA agonist program. AnaptysBio is also developing imsidolimab, our anti-IL-36R antibody in Phase 3 for the treatment of generalized pustular psoriasis, or GPP. We also have additional preclinical programs and discovery research of potentially innovative immunology therapeutics, including ANB033, an anti-CD122 antagonist antibody for the treatment of inflammatory diseases. AnaptysBio has also developed multiple therapeutic antibodies in an immuno-oncology collaboration with GSK, 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 the release of data from our clinical trials, including imsidolimab's Phase 3 clinical trial in GPP and rosnilimab' s Phase 2 clinical trial in alopecia areata; and the timing of ANB032's IND filing for a Phase 2 clinical trial and the timing of ANB033's IND filing; our ability to find a licensing partner for imsidolimab and the timing of any such transaction; and our projected use of our cash resources. 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 our 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:
Dennis Mulroy
AnaptysBio, Inc.
858.732.0201
dmulroy@anaptysbio.com

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,547	$ 495,729
Receivables from collaborative partners	1,180	876
Short-term investments	384,419	52,368
Prepaid expenses and other current assets	6,298	4,903
Total current assets	450,444	553,876
Property and equipment, net	1,972	2,283
Operating lease right-of-use assets	18,320	19,558
Long-term investments	147,511	67,097
Other long-term assets	256	256
Total assets	$ 618,503	$ 643,070
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,006	$ 1,741
Accrued expenses	16,453	12,853
Current portion of operating lease liability	1,604	1,505
Total current liabilities	21,063	16,099
Liability related to sale of future royalties	301,586	251,093
Operating lease liability, net of current portion	18,235	19,450
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 28,354 shares and 27,647 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	28	28
Additional paid in capital	707,662	678,575
Accumulated other comprehensive loss	(6,007)	(422)
Accumulated deficit	(424,064)	(321,753)
Total stockholders' equity	277,619	356,428
Total liabilities and stockholders' equity	$ 618,503	$ 643,070

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,	
	2022	2021	2022	2021
Collaboration revenue	$ 1,293	$ 20,890	$ 3,479	$ 62,164
Operating expenses:				
Research and development	22,064	22,221	65,424	71,720

General and administrative	8,862	5,432	27,236	16,101
Total operating expenses	30,926	27,653	92,660	87,821
Loss from operations	(29,633)	(6,763)	(89,181)	(25,657)
Other income (expense), net:				
Interest income	2,262	64	3,711	363
Non-cash interest expense for the sale of future royalties	(6,135)	—	(16,857)	—
Other income, net	4	33	16	36
Total other income (expense), net	(3,869)	97	(13,130)	399
Net loss	(33,502)	(6,666)	(102,311)	(25,258)
Unrealized loss on available for sale securities	(2,146)	(24)	(5,585)	(196)
Comprehensive loss	$ (35,648)	$ (6,690)	$ (107,896)	$ (25,454)
Net loss per common share:				
Basic and diluted	$ (1.18)	$ (0.24)	$ (3.64)	$ (0.92)
Weighted-average number of shares outstanding:				
Basic and diluted	28,289	27,436	28,071	27,397

Source: AnaptysBio, Inc.