Anaptys Announces Third Quarter 2023 Financial Results and Provides Business Update

November 2, 2023

- Initiated a global Phase 2b trial to treat rheumatoid arthritis (RA) with rosnilimab, our PD-1 agonist
- Initiating in Q4 2023 a global Phase 2 trial to treat ulcerative colitis (UC) with rosnilimab
- Announced positive top-line Phase 3 clinical trial results of imsidolimab (IL-36R) in generalized pustular psoriasis (GPP)
- Reiterating cash runway through year-end 2026 and updating expected year-end 2023 cash and investments of $400 to $410 million

SAN DIEGO, Nov. 02, 2023 (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, 2023 and provided a business update.

“We’ve made strong progress this quarter executing against our multi-year plan to develop best-in-class immune cell modulators to drive differentiated clinical outcomes in heterogeneous, systemic autoimmune and inflammatory diseases,” said Daniel Faga, president and chief executive officer of Anaptys. “Enrollment is ongoing in our global Phase 2b trials in atopic dermatitis for ANB032, our BTLA agonist, and rheumatoid arthritis for rosnilimab, our PD-1 agonist, while also initiating a global Phase 2 trial in ulcerative colitis for rosnilimab in Q4 2023.”

Updates on Wholly Owned Immune Cell Modulator Pipeline

Rosnilimab (PD-1 agonist antibody)

- Initiated in August a 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
  - Top-line Week 12 data anticipated by mid 2025
- Anticipate initiation in Q4 2023 of a 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
  - Top-line Week 12 data anticipated by H1 2026
- Hosted a virtual PD-1 Agonist (Rosnilimab) R&D Event in October 2023
  - Replay of the audio webcast is available here
- Announcing two poster presentations at American College of Rheumatology (ACR) Convergence 2023 in San Diego, Nov. 10-15, 2023. Full preliminary program is available online on the ACR website -
  - *Optimizing PD-1 Agonist Signaling with Membrane Proximal Binding of Rosnilimab, a Clinical Stage PD-1 Agonist IgG1 Antibody* (abstract #0086)
  - *Rosnilimab, a Novel PD-1 Agonist Monoclonal Antibody, Inhibits Peripheral T Cell Proliferation and Cytokine Secretion and Reduces Circulating PD-1 High Expressing T Cells: Results from a Phase 1 Healthy Volunteer Clinical Trial* (abstract #0455)

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
    - Top-line Week 14 data anticipated by year-end 2024
- Presented poster on ANB032's previously reported healthy volunteer Phase 1 data and a trial-in-progress poster presentation on ANB032's Phase 2b study in moderate-to-severe AD at the 32 European Academy of Dermatology and Venerology (EADV) Congress in October 2023
    - Poster presentations are available here

ANB033 (anti-CD122 antagonist antibody)

- Plan to submit an Investigational New Drug (IND) application in H1 2024

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

- Announced positive top-line Phase 3 clinical trial results of imsidolimab (IL-36R) in generalized pustular psoriasis (GPP)
    - 53.3% of patients who received a single dose of 750mg IV imsidolimab achieved GPPPGA 0/1 (clear or almost clear) at Week 4 (primary endpoint), compared to 13.3% of patients on placebo (p=0.0131)
    - Demonstrated favorable safety and tolerability with no SAEs, low incidence and no increase of infections vs. placebo and no cases of DRESS or Guillain-Barre in imsidolimab-treated patients
    - Only one of 30 (3.3%) imsidolimab-treated patients had detectable ADA, which were non-neutralizing
- 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
- Anaptys has regained full global rights to GSK4074386, a Phase 2 ready LAG-3 antagonist antibody, from GSK

Year-End Cash Guidance

- Reiterating cash runway through year-end 2026 with updated expected year-end 2023 cash and investments of $400 to $410 million

Third Quarter Financial Results

- Cash, cash equivalents and investments totaled $453.3 million as of September 30, 2023, compared to $584.2 million as of December 31, 2022, for a decrease of $130.9 million. The decrease relates to cash used for the $50 million stock repurchase program and operating activities.
- Collaboration revenue was $3.3 million and $8.2 million for the three and nine months ended September 30, 2023, compared to $1.3 million and $3.5 million for the three and nine months ended September 30, 2022. The change is due primarily to increased royalties recognized for sales of *Jemperli*.
- Research and development expenses were $30.9 million and $98.8 million for the three and nine months ended September 30, 2023, compared to $22.1 million and $65.4 million for the three and nine months ended September 30, 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 $2.2 million and $7.7 million for the three and nine months ended September 30, 2023 as compared to $1.5 million and $5.0 million in the same period in 2022.
- General and administrative expenses were $10.2 million and $31.7 million for the three and nine months ended September 30, 2023, compared to $8.9 million and $27.2 million for the three and nine months ended September 30, 2022. The G&A non-cash, stock-based compensation expense was $5.6 million and $17.4 million for the three and nine months ended September 30, 2023 as compared to $4.7 million and $15.7 million in the same period in 2022.
- Net loss was $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, compared to a net loss of $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.

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 in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, its PD-1 agonist, in a Phase 2b trial for the treatment of rheumatoid arthritis and a planned 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, 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) in second line NSCLC. 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 initiation of the Company's clinical trials, including rosnilimab's clinical trial in ulcerative colitis; 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 ANB033's IND filing; whether any of the Company's product candidates will be best in class; 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 and estimated year-end cash balance. 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)
(unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,295	$ 71,308
Receivables from collaborative partners	3,269	1,419
Short-term investments	386,752	369,933
Prepaid expenses and other current assets	11,684	4,545
Total current assets	428,000	447,205
Property and equipment, net	2,254	2,089
Operating lease right-of-use assets	16,613	17,898
Long-term investments	40,203	142,935
Other long-term assets	256	256
Total assets	$ 487,326	$ 610,383

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 6,521	$ 2,784
Accrued expenses	30,916	21,633
Current portion of operating lease liability	1,741	1,637
Total current liabilities	39,178	26,054
Liability related to sale of future royalties	311,272	304,413
Operating lease liability, net of current portion	16,493	17,813
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 26,575 shares and 28,513 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	27	29
Additional paid in capital	694,591	717,797
Accumulated other comprehensive loss	(2,350)	(5,246)
Accumulated deficit	(571,885)	(450,477)
Total stockholders' equity	120,383	262,103
Total liabilities and stockholders' equity	$ 487,326	$ 610,383

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,	
	2023	2022	2023	2022
Collaboration revenue	$ 3,318	$ 1,293	$ 8,152	$ 3,479
Operating expenses:				
Research and development	30,878	22,064	98,758	65,424
General and administrative	10,172	8,862	31,670	27,236
Total operating expenses	41,050	30,926	130,428	92,660
Loss from operations	(37,732)	(29,633)	(122,276)	(89,181)
Other income (expense), net:				
Interest income	4,854	2,262	13,993	3,711
Non-cash interest expense for the sale of future royalties	(4,431)	(6,135)	(13,125)	(16,857)
Other income, net	1	4	—	16
Total other income (expense), net	424	(3,869)	868	(13,130)
Net loss	(37,308)	(33,502)	(121,408)	(102,311)
Unrealized gain (loss) on available for sale securities	1,261	(2,146)	2,896	(5,585)
Comprehensive loss	$ (36,047)	$ (35,648)	$ (118,512)	$ (107,896)
Net loss per common share:				
Basic and diluted	$ (1.41)	$ (1.18)	$ (4.49)	$ (3.64)
Weighted-average number of shares outstanding:				
Basic and diluted	26,546	28,289	27,038	28,071

Source: AnaptysBio, Inc.