AnaptysBio Announces First Quarter 2019 Financial Results and Provides Pipeline Updates

May 7, 2019

- Multiple Top-line Phase 2 Clinical Efficacy Readouts from Wholly-owned Pipeline Anticipated in 2019
- Etokimab Phase 2a Severe Eosinophilic Asthma Data to be Presented at the 2019 EAACI Congress
- IND Filing for New Wholly-owned Anti-inflammatory Program Anticipated in Second Half of 2019

SAN DIEGO, May 07, 2019 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation, today reported operating results for the first quarter ended March 31, 2019 and provided pipeline updates.

“2019 is set to be an important year for AnaptysBio, with multiple top-line data readouts from our wholly-owned pipeline, initiation of a new Phase 2b trial of etokimab in eosinophilic asthma and submission of an IND for our next development candidate in our wholly-owned pipeline,” said Hamza Suria, president and chief executive officer of AnapytsBio. “We look forward to advancing each of these programs as we work to bring novel treatments to patients with severe inflammatory diseases.”

Etokimab (ANB020 Anti-IL-33 Program)

- In September 2018, the Company reported positive interim top-line data from its Phase 2a proof-of-concept clinical trial of etokimab in adult patients with severe eosinophilic asthma. The Company will present the full data from this trial at the 2019 European Academy of Allergy and Clinical Immunology (EAACI) Congress. AnaptysBio also plans to initiate a multi-dose Phase 2b randomized, double-blinded, placebo-controlled trial of etokimab in eosinophilic asthma in 2019.
- The Company is conducting a Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in 300 adult patients with moderate-to-severe atopic dermatitis, also referred to as the ATLAS trial, to assess different dose levels and dosing frequencies of subcutaneously-administered etokimab, with top-line data expected in the second half of 2019.
- AnaptysBio is conducting a randomized, placebo-controlled Phase 2 trial in approximately 100 adult patients with chronic rhinosinusitis with nasal polyps, also referred to as the ECLIPSE trial. Patients are being treated with two multi-dosing frequencies of subcutaneously-administered etokimab or placebo, each in combination with mometasone furoate nasal spray as background therapy. The Company anticipates top-line data from the ECLIPSE trial will be available in the second half of 2019.

ANB019 (Anti-IL-36 Receptor Program)

- The Company is conducting a single arm, open-label Phase 2 trial of ANB019 in approximately 10 patients with generalized pustular psoriasis, or GPP, also known as the GALLOP trial, with top-line data expected in mid-2019.
- The Company is conducting a randomized, placebo-controlled, multi-dose Phase 2 trial in 50 patients with palmoplantar pustulosis, or PPP, also known as the POPLAR trial, with top-line data anticipated in the first half of 2020.

First Quarter Financial Results

- Cash, cash equivalents and investments totaled $484.2 million as of March 31, 2019 compared to $500.2 million as of December 31, 2018, for a decrease of $16.0 million. The decrease primarily relates to cash used for operating activities.
- Research and development expenses were $20.6 million for the three months ended March 31, 2019, as compared to $11.8 million for the three months ended March 31, 2018. The increase was primarily due to continued advancement of the Company’s etokimab and ANB019 clinical programs and additional personnel-related expenses including share-based compensation during the three months ended March 31, 2019.
- General and administrative expenses were $4.1 million for the three months ended March 31, 2019, as compared to $3.9 million for the three months ended March 31, 2018. The increase was primarily attributable to additional personnel-related expenses, including share-based compensation.
- Net loss was $22.1 million for the three months ended March 31, 2019, or a net loss per share of $0.82, as compared to a net loss of $15.1 million for the three months ended March 31, 2018, or a net loss per share of $0.63.

Financial Guidance

AnaptysBio expects that its cash, cash equivalents and investments will fund its current operating plan at least through the end of 2020.

About Etokimab

Etokimab, previously referred to as ANB020, is an antibody that potently binds and inhibits the activity of interleukin-33, or IL-33, a pro-inflammatory cytokine that multiple studies have indicated is a central mediator of atopic diseases, which AnaptysBio believes is broadly applicable to the treatment of atopic inflammatory disorders, such as atopic dermatitis, eosinophilic asthma, chronic rhinosinusitis with nasal polyps, or CRSwNP, and potentially other allergic conditions. Following completion of a healthy volunteer Phase 1 trial of etokimab, AnaptysBio continued clinical development of etokimab into a Phase 2a trial for moderate-to-severe adult atopic dermatitis and a placebo-controlled Phase 2a trial in severe adult eosinophilic asthma patients. AnaptysBio is conducting its ATLAS trial, a randomized, double-blinded, placebo-controlled multi-dose Phase 2b clinical trial of etokimab in 300 moderate-to-severe adult atopic dermatitis patients where top-line data is anticipated in the second half of 2019. The Company is conducting its ECLIPSE trial, a randomized, double-blinded, placebo-controlled Phase 2 trial of etokimab in approximately 100 adult patients with CRSwNP with top-line data anticipated in the second half of 2019. AnaptysBio also plans to initiate a randomized, double-blinded, placebo-controlled, multi-dose Phase 2b trial of etokimab in patients with eosinophilic asthma in 2019.

About ANB019

ANB019 is an antibody that inhibits the function of the interleukin-36-receptor, or IL-36R, which AnaptysBio plans to initially develop as a potential first-in-class therapy for patients suffering from generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP. AnaptysBio has previously presented data from this Phase 1 clinical trial, which demonstrated favorable safety, pharmacokinetics and pharmacodynamic properties that supported advancement of ANB019 into Phase 2 studies. AnaptysBio is conducting its GALLOP trial, a Phase 2 study of ANB019 in GPP where top-line data is anticipated in mid-2019, and its POPLAR trial, a Phase 2 study in PPP where top-line data is anticipated in the first half of 2020.

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation. The Company's proprietary anti-inflammatory pipeline includes its anti-IL-33 antibody etokimab, previously referred to as ANB020, for the treatment of moderate-to-severe atopic dermatitis, eosinophilic asthma, and adult chronic rhinosinusitis with nasal polyps, or CRSwNP; its anti-IL-36R antibody ANB019 for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP; and novel anti-inflammatory checkpoint receptor modulator antibodies for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated. AnaptysBio's antibody pipeline has been developed using its proprietary somatic hypermutation, or SHM platform, which uses in vitro SHM for antibody discovery and is designed to replicate key features of the human immune system to overcome the limitations of competing antibody discovery technologies. AnaptysBio has also developed multiple therapeutic antibodies in an immuno-oncology partnership with TESARO (recently acquired by GlaxoSmithKline), including an anti-PD-1 antagonist antibody (dostarlimab (TSR-042)), an anti-TIM-3 antagonist antibody (TSR-022) and an anti-LAG-3 antagonist antibody (TSR-033), and an inflammation partnership with Celgene, including an anti-PD-1 checkpoint agonist antibody (CC-90006) currently in clinical development.

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 etokimab's Phase 2a clinical trial in severe adult eosinophilic asthma patients, etokimab's Phase 2b clinical trial in moderate-to-severe adult atopic dermatitis patients, etokimab's Phase 2 clinical trial in adult patients with chronic rhinosinusitis with nasal polys and ANB019's Phase 2 clinical trials in GPP and PPP, the timing of and our ability to launch a Phase 2b clinical trial of etokimab in eosinophilic asthma patients, and the timing of an IND filing for a new wholly-owned anti-inflammatory antibody program. 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:
Dominic Piscitelli
AnaptysBio, Inc.

858.362.6348
dpiscitelli@anaptysbio.com

ANAPTYSBIO, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value data)

	March 31, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 105,853	$ 113,596
Australian tax incentive receivable	175	174
Short-term investments	309,812	313,486
Prepaid expenses and other current assets	6,102	6,960
Total current assets	421,942	434,216
Property and equipment, net	1,584	1,445
Long-term investments	68,551	73,128
Other long-term assets	2,089	148
Restricted cash	60	60
Total assets	$ 494,226	$ 508,997
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,072	$ 5,443
Accrued expenses	8,400	8,761
Notes payable, current portion	6,488	7,574
Other current liabilities	794	58
Total current liabilities	24,754	21,836
Other long-term liabilities	1,317	796
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at March 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 27,006 shares and 26,922 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	27	27
Additional paid in capital	636,692	633,251
Accumulated other comprehensive income (loss)	204	(223)
Accumulated deficit	(168,768)	(146,690)
Total stockholders' equity	468,155	486,365
Total liabilities and stockholders' equity	$ 494,226	$ 508,997

ANAPTYSBIO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31,	
	2019	2018
Collaboration revenue	$ —	$ —
Operating expenses:		
Research and development	20,631	11,810
General and administrative	4,141	3,947
Total operating expenses	24,772	15,757
Loss from operations	(24,772)	(15,757)
Other income (expense), net:		

Interest expense	(320)	(451)
Interest income	2,988	1,185
Other income (expense), net	7	(63)
Total other income (expense), net	2,675	671
Loss before income taxes	(22,097)	(15,086)
Provision for income taxes	19	—
Net loss	(22,078)	(15,086)
Other comprehensive income (loss):		
Unrealized income (loss) on available for sale securities, net of tax of $115 and $0, respectively	427	(801)
Other comprehensive income (loss), net of tax	427	(801)
Comprehensive loss	$ (21,651)	$ (15,887)
Net loss per common share:		
Basic and diluted	$ (0.82)	$ (0.63)
Weighted-average number of shares outstanding:		
Basic and diluted	26,981	23,801

Source: AnaptysBio, Inc.