AnaptysBio Announces Fourth Quarter and Full Year 2018 Financial Results and Provides Pipeline Updates

February 28, 2019

- Reported positive top-line data from an interim analysis of a Phase 2a proof-of-concept trial of etokimab in severe eosinophilic asthma
- Four top-line Phase 2 clinical efficacy readouts from our wholly-owned pipeline anticipated in 2019
- IND filing for new wholly-owned program anticipated in second half of 2019

SAN DIEGO, Feb. 28, 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 fourth quarter and year ended December 31, 2018 and provided pipeline updates.

“We continued to advance the clinical development of our wholly-owned etokimab and ANB019 programs for severe inflammatory disease indications during 2018,” said Hamza Suria, president and chief executive officer of AnaptysBio. “Top-line data from our etokimab Phase 2a trial in severe adult eosinophilic asthma patients demonstrated rapid and sustained improvement in Forced Exhaled Volume In One Second versus placebo, with corresponding reduction in blood eosinophil levels. We look forward to announcing four Phase 2 top-line data readouts from ongoing clinical trials of etokimab and ANB019 during 2019 and expanding our pipeline with an IND filing for a new wholly-owned anti-inflammatory antibody program.”

Etokimab (ANB020 Anti-IL-33 Program)

- In September 2018, the Company announced positive top-line proof-of-concept data for etokimab, its investigational anti-IL-33 therapeutic antibody, in a single dose Phase 2a clinical trial in adult patients with severe eosinophilic asthma. Patients administered with etokimab rapidly improved their Forced Exhaled Volume In One Second, or FEV1, which is a measure of lung function, with an eight percent FEV1 improvement over placebo at Day 2. FEV1 improvement was sustained through Day 64, with an 11 percent increase over placebo. Blood eosinophil reduction was sustained through the interim analysis period, with a 31 percent reduction at Day 2 and a 46 percent reduction at Day 64 over placebo, which was consistent with FEV1 improvement observed in this trial. Etokimab was generally well tolerated in all patients and no serious adverse events were reported as of this interim analysis. The Company plans to report full data from this trial at a medical conference in 2019. The Company also plans to continue development of etokimab in eosinophilic asthma with a multi-dose Phase 2b randomized, double-blinded, placebo-controlled trial, which is expected to be initiated 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.

- The Company 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 10-patient, single arm, open-label Phase 2 trial of ANB019 in generalized pustular psoriasis, or GPP, also known as the GALLOP trial, with top-line data anticipated in mid-2019.

- The Company is conducting a randomized, placebo-controlled 50-patient multi-dose Phase 2 trial in palmoplantar pustulosis, or PPP, also known as the POPLAR trial, with top line data anticipated in the second half of 2019.

Corporate Highlights

- On September 28, 2018, the Company completed an underwritten public offering of 2,530,000 shares of common stock at a price to the public of $94.46, which included the exercise by the underwriters of their option to purchase an additional 330,000 shares of common stock. AnaptysBio, received net proceeds from the offering of $227.5 million, after deducting underwriting discounts and commissions.

Fourth Quarter and Full Year Financial Results

- Cash, cash equivalents and investments totaled $500.2 million as of December 31, 2018 compared to $324.3 million as of December 31, 2017, for an increase of $175.9 million. The increase primarily relates to net proceeds received by the Company of $227.5 million from the public offering, partially offset by cash used for operating activities.

- Collaboration revenue was $5.0 million for the year ended December 31, 2018, related to a milestone for the first Phase 3 trial of TSR-042 by TESARO. Collaboration revenue was $3.0 million and $10.0 million for the three months and year ended December 31, 2017, respectively, for two TESARO related milestones.

- Research and development expenses were $15.9 million and $56.2 million for the three months and year ended December 31, 2018, as compared to $7.6 million and $29.4 million for the three months and year ended December 31, 2017. 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 and year ended December 31, 2018.

- General and administrative expenses were $3.7 million and $15.5 million for the three months and year ended December 31, 2018, as compared to $2.5 million and $9.3 million for the three months and year ended December 31, 2017. The increase was primarily attributable to additional personnel-related expenses, including share-based compensation.

- Net loss was $17.0 million and $61.7 million for the three months and year ended December 31, 2018, or a net loss per share of $0.64 and $2.50, respectively, as compared to a net loss of $6.9 million and $30.1 million for the three months and year ended December 31, 2017, or a net loss per share of $0.30 and $1.52, respectively.

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 second half of 2019.

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, previously referred to as palmo-plantar pustular psoriasis; 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 (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, the timing of an IND filing for a new wholly-owned anti-inflammatory antibody program, and the success of our partnership with TESARO (recently acquired by GlaxoSmithKline) and Celgene. 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)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 113,596	$ 81,189
Australian tax incentive receivable	174	1,601
Short-term investments	313,486	167,218
Prepaid expenses and other current assets	6,960	2,688
Total current assets	434,216	252,696
Property and equipment, net	1,445	665
Long-term investments	73,128	75,897
Other long-term assets	148	46
Restricted cash	60	60
Total assets	$ 508,997	$ 329,364
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,443	$ 2,323
Accrued expenses	8,761	4,875
Notes payable, current portion	7,574	6,875
Other current liabilities	58	17
Total current liabilities	21,836	14,090
Notes payable, net of current portion	625	7,553
Deferred rent	171	140
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 26,922 shares and 23,791 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	27	24
Additional paid in capital	633,251	393,017
Accumulated other comprehensive loss	(223)	(426)
Accumulated deficit	(146,690)	(85,034)
Total stockholders' equity	486,365	307,581

Total liabilities, preferred stock and stockholders' equity	$ 508,997	$ 329,364

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
Collaboration revenue	$ —	$ 3,000	$ 5,000	$ 10,000
Operating expenses:				
Research and development	15,920	7,606	56,196	29,443
General and administrative	3,743	2,545	15,526	9,338
Total operating expenses	19,663	10,151	71,722	38,781
Loss from operations	(19,663)	(7,151)	(66,722)	(28,781)
Other income (expense), net:				
Interest expense	(365)	(456)	(1,652)	(1,775)
Change in fair value of liability for preferred stock warrants	—	—	—	(1,366)
Interest income	2,834	862	6,685	1,623
Other income (expense), net	8	(116)	(159)	229
Total other income (expense), net	2,477	290	4,874	(1,289)
Loss before income taxes	(17,186)	(6,861)	(61,848)	(30,070)
Provision for income taxes	192	—	192	—
Net loss	(16,994)	(6,861)	(61,656)	(30,070)
Other comprehensive income (loss):				
Unrealized income (loss) on available for sale securities	373	(383)	258	(426)
Income tax expense related to other comprehensive income	(55)	—	(55)	—
Other comprehensive income (loss), net of tax	318	(383)	203	(426)
Comprehensive loss	$ (16,676)	$ (7,244)	$ (61,453)	$ (30,496)
Net loss per common share:				
Basic and diluted	$ (0.64)	$ (0.30)	$ (2.50)	$ (1.52)
Weighted-average number of shares outstanding:				
Basic and diluted	26,788	23,089	24,673	19,782

AnaptysBio

Source: AnaptysBio, Inc.