



AnaptysBio Announces Third Quarter 2018 Financial Results and Provides Pipeline Updates

November 8, 2018

- Reported positive top-line data from an interim analysis of its ongoing Phase 2a proof-of-concept clinical trial of etokimab in severe eosinophilic asthma
- Initiated Phase 2 ECLIPSE trial of etokimab in chronic rhinosinusitis with nasal polyps and Phase 2 POPLAR trial of ANB019 in palmo-plantar pustulosis
- Four top-line clinical efficacy readouts from wholly-owned pipeline anticipated in 2019

SAN DIEGO, Nov. 08, 2018 (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 third quarter ended September 30, 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 the third quarter of 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 further advancement of our wholly-owned pipeline with four additional readouts from ongoing clinical trials of etokimab and ANB019 during 2019."

Etokimab (ANB020 Anti-IL-33 Program)

- In September, the Company announced positive topline proof-of-concept data for etokimab, its investigational anti-IL-33 therapeutic antibody, in an ongoing 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. This Phase 2a trial is currently ongoing and the company plans to report full data from this trial at a medical conference in 2019 following trial completion. AnaptysBio 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 enrolling 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 clinical trial, to assess different dose levels and dosing frequencies of subcutaneously-administered etokimab for a 16-week treatment period followed by an eight-week monitoring period, with data expected in the second half of 2019.
- The Company has cleared an IND and initiated a randomized, placebo-controlled Phase 2 trial, also referred to as the ECLIPSE trial, in approximately 100 adult patients with chronic rhinosinusitis with nasal polyps. Patients will be treated with two multi-dosing frequencies of subcutaneous-administered etokimab or placebo, each in combination with mometasone furoate nasal spray as background therapy, for a treatment period of 16 weeks followed by an eight-week monitoring period. 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)

- AnaptysBio has initiated a 10-patient, single arm, open-label Phase 2 trial of ANB019 in generalized pustular psoriasis, or GPP, also known as the GALLOP trial, and top-line data are anticipated in mid-2019. All patients will be treated with an intravenous loading dose of ANB019 upon enrollment, followed by subcutaneously-administered monthly doses of ANB019 for a treatment period of up to 16 weeks post enrollment and followed by an eight-week monitoring period.
- AnaptysBio has cleared an IND with the FDA and has initiated a randomized, placebo-controlled 50-patient multi-dose Phase 2 trial in palmoplantar pustulosis, or PPP, also known as the POPLAR trial, where top line data are anticipated in the second half of 2019. Patients will be treated with a (i) a subcutaneously-administered loading dose of ANB019 upon enrollment, followed by subcutaneously-administered monthly doses of ANB019, or (ii) placebo, each for a treatment period of 16 weeks post enrollment and followed an eight-week monitoring period.

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.

Third Quarter Financial Results

- Cash, cash equivalents and investments totaled \$512.4 million as of September 30, 2018 compared to \$324.3 million as of December 31, 2017, for an increase of \$188.1 million. The increase primarily relates to net proceeds received by the Company of \$227.5 million from the public offering, offset by operating cash outflow for clinical and manufacturing related expenses, as well as personnel costs.
- Collaboration revenue was \$5.0 million for the three and nine months ended September 30, 2018 related to a milestone for the first Phase 3 trial of TSR-042 by TESARO compared to no revenue and \$7.0 million for two TESARO milestones for the three and nine months ended September 30, 2017, respectively.
- Research and development expenses were \$17.9 million for the three months ended September 30, 2018, as compared to \$6.7 million for the three months ended September 30, 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 ended September 30, 2018.
- General and administrative expenses were \$4.0 million for the three months ended September 30, 2018, as compared to \$2.4 million for the three months ended September 30, 2017. The increase was primarily attributable to additional personnel-related expenses, including share based compensation, to support the Company's growth.

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 enrolling 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 data is anticipated in the second half of 2019. The company has also initiated its ECLIPSE trial, a randomized, double-blinded, placebo-controlled Phase 2 trial of etokimab in approximately 100 adult patients with CRSwNP with 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 conducted a Phase 1 clinical trial in healthy volunteers, where 54 subjects are dosed with ANB019 and 18 are dosed with placebo in single and multi-dose cohorts at various subcutaneous and intravenously administered dose levels. In May 2018, AnaptysBio presented data from this Phase 1 clinical trial, which demonstrated favorable safety, pharmacokinetics and pharmacodynamic properties that support advancement of ANB019 into Phase 2 studies. AnaptysBio is enrolling its GALLOP trial, a Phase 2 study of ANB019 in GPP where data is anticipated in the second quarter of 2019, and have initiated its POPLAR trial, a Phase 2 study in PPP where 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, 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 and an inflammation partnership with Celgene, 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), which are currently under clinical development with TESARO, and an anti-PD-1 checkpoint agonist antibody (CC-90006) currently in the clinic with Celgene.

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 polyps and ANB019's Phase 2 clinical trials in GPP and PPP, and the timing of and our ability to launch a Phase 2b clinical trial of etokimab in eosinophilic asthma patients, and the success of our partnership with TESARO 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.

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

	September 30, 2018	December 31, 2017
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 293,408	\$ 81,189
Receivable from collaborative partners	5,000	—
Australian tax incentive receivable	173	1,601
Short-term investments	200,406	167,218
Prepaid expenses and other current assets	4,035	2,688
Total current assets	503,022	252,696
Property and equipment, net	1,344	665
Long-term investments	18,616	75,897
Other long-term assets	79	46
Restricted cash	60	60
Total assets	\$ 523,121	\$ 329,364
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,180	\$ 2,323
Accrued expenses	7,145	4,875
Notes payable, current portion	7,500	6,875
Other current liabilities	48	17
Total current liabilities	20,873	14,090
Notes payable, net of current portion	2,409	7,553
Deferred rent	162	140
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at September 30, 2018 and December 31, 2017, respectively	—	—
Common stock, \$0.001 par value, 500,000 shares authorized, 26,749 shares and 23,791 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	27	24
Additional paid in capital	629,887	393,017
Accumulated other comprehensive loss	(541)	(426)
Accumulated deficit	(129,696)	(85,034)

Total stockholders' equity	499,677	307,581
Total liabilities, preferred stock and stockholders' equity	<u>\$ 523,121</u>	<u>\$ 329,364</u>

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Collaboration revenue	\$ 5,000	\$ —	\$ 5,000	\$ 7,000
Operating expenses:				
Research and development	17,883	6,697	40,276	21,837
General and administrative	4,004	2,390	11,783	6,793
Total operating expenses	<u>21,887</u>	<u>9,087</u>	<u>52,059</u>	<u>28,630</u>
Loss from operations	<u>(16,887)</u>	<u>(9,087)</u>	<u>(47,059)</u>	<u>(21,630)</u>
Other income (expense), net:				
Interest expense	(400)	(452)	(1,287)	(1,319)
Change in fair value of liability for preferred stock warrants	—	—	—	(1,366)
Interest income	1,369	358	3,851	762
Other income (expense), net	(40)	91	(167)	344
Total other income (expense), net	<u>929</u>	<u>(3)</u>	<u>2,397</u>	<u>(1,579)</u>
Net loss	<u>(15,958)</u>	<u>(9,090)</u>	<u>(44,662)</u>	<u>(23,209)</u>
Unrealized income (loss) on available for sale securities	136	16	(115)	(43)
Other comprehensive income (loss)	136	16	(115)	(43)
Comprehensive loss	<u>\$ (15,822)</u>	<u>\$ (9,074)</u>	<u>\$ (44,777)</u>	<u>\$ (23,252)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.66)</u>	<u>\$ (0.45)</u>	<u>\$ (1.86)</u>	<u>\$ (1.24)</u>
Weighted-average number of shares outstanding:				
Basic and diluted	<u>24,146</u>	<u>20,382</u>	<u>23,961</u>	<u>18,668</u>



Source: AnaptysBio, Inc.