



AnaptysBio Announces First Quarter 2020 Financial Results and Provides Pipeline Updates

May 6, 2020

- Interim Top-Line Data From Etokimab ECLIPSE Phase 2 Trial in Chronic Rhinosinusitis with Nasal Polyps Anticipated in Third Quarter of 2020, Decided to Over-Enroll Trial Due to COVID-19
- Additional Topline Data from GALLOP Phase 2 Clinical Trial of ANB019 Monotherapy in Moderate-to-Severe Generalized Pustular Psoriasis on Track for Second Half of 2020
- Topline Data from POPLAR Phase 2 Clinical Trial of ANB019 Monotherapy in Palmoplantar Pustulosis on Track for Second Half of 2020
- IND Cleared For Company's Third Wholly-Owned Program, ANB030, an anti-PD-1 Agonist Antibody, and Phase 1 Trial Initiation Anticipated in First Half of 2020
- US BLA and EU MAA for Dostarlimab, Our PD-1 Antagonist Antibody Partnered With GlaxoSmithKline (GSK), in Endometrial Cancer Accepted by the FDA and the EMA, Respectively

SAN DIEGO, May 06, 2020 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on emerging immune control mechanisms applicable to inflammation and immuno-oncology indications, today reported operating results for the first quarter ended March 31, 2020 and provided pipeline updates.

"Our wholly-owned pipeline continues to advance with three Phase 2 clinical trial readouts anticipated in the remainder of 2020," said Hamza Suria, president and chief executive officer of AnaptysBio. "AnaptysBio's capital-efficient business model has resulted in the advancement of 7 internally-generated antibodies to the clinic to date, and we anticipate continued discovery and development of novel antibodies in the upcoming future. We also look forward to significant revenues associated with regulatory filing related milestone payment and future royalties upon FDA approval of dostarlimab under our GSK partnership later this year."

Etokimab (ANB020 Anti-IL-33) Program

- AnaptysBio is conducting a randomized, placebo-controlled Phase 2 trial in 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. We have over-enrolled this trial beyond the first 100 patients to compensate for lost patient visits due to the COVID-19 pandemic, and hence anticipate interim top-line data from this trial to be available in the third quarter of 2020.
- As previously announced, the Company has decided to postpone the initiation of its planned Phase 2b etokimab clinical trial in eosinophilic asthma, a multi-dose, randomized, double-blinded, placebo-controlled trial in 300-400 patients, until results are available from the ECLIPSE trial.

ANB019 (Anti-IL-36 Receptor) Program

- In September, AnaptysBio announced positive topline data from an interim analysis of its Phase 2 clinical trial of ANB019 monotherapy in moderate-to-severe generalized pustular psoriasis, or GPP, also known as the GALLOP trial. In this interim analysis, both patients achieved the primary endpoint of disease score improvement at Day 29 and Day 113 without requiring rescue therapy, demonstrated rapid and sustained mJDA score improvement, with reduction of 58% at Day 8 and 63% at Day 113, and showed complete clearance of skin pustules by Day 8 and through Day 113, with CRP levels decreasing to nearly normal. The Company anticipates additional clinical data and a regulatory strategy update for the development of ANB019 in GPP during the second half of 2020.
- The Company is also 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 topline data anticipated in the second half of 2020.
- Enrollment of the GALLOP and POPLAR trials has been enhanced by expanding clinical sites and geographies involved. While the Company does not believe that the aforementioned timelines are materially impacted by the COVID-19 pandemic at this point, some of the sites involved in the GALLOP and POPLAR trials have been affected by the COVID-19 pandemic, and the Company will continue to monitor the situation over the upcoming months.

ANB030 (Anti-PD-1 Agonist) Program

- ANB030 is a wholly-owned antibody that binds PD-1 in an agonistic manner, leading to reduced T cell activity and anti-inflammatory effects *in vivo*. Genetic mutations in the PD-1 pathway are associated with increased susceptibility to various inflammatory conditions and we believe ANB030 has the potential to suppress inflammatory diseases by restoring insufficient PD-1-mediated negative signaling on activated T cells. The Company plans to focus future clinical development

of ANB030 on certain autoimmune diseases where PD-1 checkpoint receptor function may be under-represented. Our Investigational New Drug Application (IND) for ANB030 has been cleared by the FDA and we plan to initiate a Phase 1 clinical trial in the first half of 2020. Preclinical data from the ANB030 was presented in June at the 2019 FOCIS Annual Meeting.

ANB032 (Anti-BTLA Modulator) Program

- Our fourth wholly-owned program is an anti-BTLA modulator antibody, known as ANB032, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. Mutations in the BTLA signaling pathway are associated with human inflammatory disease and we believe ANB032 silences pro-inflammatory signaling by modulating BTLA binding to HVEM. We anticipate filing an IND for ANB032 in the second half of 2020.

Dostarlimab (Anti-PD-1 Antagonist) Program Partnered with GSK

- In the first quarter of 2020, the FDA accepted the first Biologics License Application (BLA) filing for dostarlimab, an AnaptysBio-generated PD-1 antagonist antibody under partnership with GSK, for the treatment of endometrial cancer. AnaptysBio received a \$10.0 million cash milestone payment upon this acceptance, and anticipates an additional \$20.0 million cash milestone upon first FDA approval of dostarlimab during 2020. Also in the first quarter of 2020, the EMA accepted GSK's Marketing Authorization Application (MAA) for approval of dostarlimab in the EU for endometrial cancer, for which AnaptysBio has earned a \$5.0 million milestone payment. Including additional cash milestones due upon future development and commercialization of dostarlimab, TSR-022, an AnaptysBio-generated TIM-3 antibody, and TSR-033, an AnaptysBio-generated LAG-3 antibody, AnaptysBio can potentially receive a total of \$1.1 billion in aggregate milestone payments under this GSK partnership. In addition, AnaptysBio is due a 4% to 8% royalty from GSK, tiered upon global sales, for each of the aforementioned programs.

First Quarter Financial Results

- Cash, cash equivalents and investments totaled \$412.7 million as of March 31, 2020 compared to \$428.5 million as of December 31, 2019, for a decrease of \$15.8 million. The decrease relates primarily to cash used for operating activities.
- Collaboration revenue was \$15.0 million for the three months ended March 31, 2020, which related to milestone payments for successful BLA and MAA filings for dostarlimab, compared to zero for the three months ended March 31, 2019.
- Research and development expenses were \$21.0 million for the three months ended March 31, 2020, compared to \$20.6 million for the three months ended March 31, 2019. The increase was due primarily to continued advancement of the Company's preclinical programs.
- General and administrative expenses were \$4.3 million for the three months ended March 31, 2020, compared to \$4.1 million for the three months ended March 31, 2019. The increase was due primarily to personnel-related expenses, including share-based compensation.
- Net loss was \$8.3 million for the three months ended March 31, 2020, or a net loss per share of \$0.30, compared to a net loss of \$22.1 million for the three months ended March 31, 2019, or a net loss per share of \$0.82.

Financial Guidance

AnaptysBio expects its net cash burn in 2020 will be approximately \$60.0 million, and that its cash, cash equivalents and investments will fund its current operating plan at least into 2023.

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 chronic rhinosinusitis with nasal polyps, or CRSwNP, and eosinophilic asthma; its anti-IL-36R antibody ANB019 for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP; its anti-PD-1 agonist program, ANB030, for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated, and its BTLA modulator program, ANB032, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. 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 GSK, 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 2 clinical trial in adult patients with CRSwNP 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 a regulatory strategy update for GPP, the timing of initiation of a Phase 1 clinical trial for ANB030, the timing of an IND filing for ANB032, the

milestones and royalty payments to be received under the GSK partnership, and our projected 2020 cash burn and cash runway. 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:

Eric Loumeau
 AnaptysBio, Inc.
 858.732.0179
eloumeau@anaptysbio.com

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

	March 31, 2020	December 31, 2019
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 165,317	\$ 171,017
Receivable from collaborative partners	5,000	—
Short-term investments	197,166	203,210
Prepaid expenses and other current assets	3,572	3,506
Total current assets	371,055	377,733
Property and equipment, net	1,610	1,618
Long-term investments	50,215	54,305
Other long-term assets	1,293	1,481
Restricted cash	60	60
Total assets	\$ 424,233	\$ 435,197
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	\$ 8,571	\$ 16,237
Accrued expenses	13,781	11,052
Notes payable, current portion	—	1,375
Other current liabilities	898	871
Total current liabilities	23,250	29,535
Other long-term liabilities	419	654
Stockholders’ equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at March 31, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.001 par value, 500,000 shares authorized, 27,277 shares and 27,255 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	27	27
Additional paid in capital	651,680	648,669
Accumulated other comprehensive income	1,145	338
Accumulated deficit	(252,288)	(244,026)
Total stockholders’ equity	400,564	405,008
Total liabilities and stockholders’ equity	\$ 424,233	\$ 435,197

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

	Three Months Ended March 31,	
	2020	2019
Collaboration revenue	\$ 15,000	\$ —
Operating expenses:		—
Research and development	20,968	20,631
General and administrative	4,285	4,141
Total operating expenses	<u>25,253</u>	<u>24,772</u>
Loss from operations	<u>(10,253)</u>	<u>(24,772)</u>
Other income (expense), net:		
Interest expense	—	(320)
Interest income	1,897	2,988
Other income, net	94	7
Total other income (expense), net	<u>1,991</u>	<u>2,675</u>
Loss before income taxes	<u>(8,262)</u>	<u>(22,097)</u>
Provision for income taxes	—	19
Net loss	<u>(8,262)</u>	<u>(22,078)</u>
Other comprehensive income:		
Unrealized income on available for sale securities, net of tax of \$0 and \$115, respectively	807	427
Comprehensive loss	<u>\$ (7,455)</u>	<u>\$ (21,651)</u>
Net loss per common share:		
Basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.82)</u>
Weighted-average number of shares outstanding:		
Basic and diluted	<u>27,264</u>	<u>26,981</u>



Source: AnaptysBio, Inc.