AnaptysBio Announces Second Quarter 2020 Financial Results and Provides Pipeline Updates

August 10, 2020

- Interim 8-Week Top-Line Data From Etokimab ECLIPSE Phase 2 Trial in Chronic Rhinosinusitis with Nasal Polyps Did Not Demonstrate Statistical Significance For Either Q4W or Q8W Versus Placebo; Company Plans To Assess Path Forward for Etokimab After Complete 16-Week Trial Data by year-end 2020
- Following Orphan Drug Designation by the FDA, Additional Topline Data from GALLOP Phase 2 Clinical Trial of Imsidolimab Monotherapy in Moderate-to-Severe Generalized Pustular Psoriasis on Track for Fourth Quarter 2020
- Topline Data from POPLAR Phase 2 Clinical Trial of Imsidolimab Monotherapy in Palmoplantar Pustulosis Anticipated in First Quarter 2021
- Expansion of Imsidolimab Program Into Two New Clinical Indications, EGFRi-Mediated Skin Toxicities and Ichthyosis, With Phase 2 Trials To Be Initiated in Fourth Quarter 2020
- Healthy Volunteer Phase 1 Clinical Trial Initiated for ANB030, the Company's Wholly-Owned PD-1 Agonist Antibody
- $20MM Milestone Payment Due Upon US BLA Approval for Dostarlimab, Our PD-1 Antagonist Antibody Partnered With GlaxoSmithKline (GSK), in Endometrial Cancer, Anticipated in Second Half of 2020

SAN DIEGO, Aug. 10, 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 second quarter ended June 30, 2020 and provided pipeline updates.

"While we are disappointed with the recent interim analysis results from our ongoing ECLIPSE trial, we look forward to additional Phase 2 clinical trial readouts anticipated over the upcoming quarters," said Hamza Suria, president and chief executive officer of AnaptysBio. "We remain focused on the continued discovery and development of novel antibodies using our capital-efficient business model which has already advanced 7 internally-generated antibodies to the clinic to date. We also anticipate significant milestone and royalty revenues from the FDA approval of dostarlimab under our GSK partnership."

Etokimab (ANB020 Anti-IL-33) Program

- In an interim analysis at week 8 of the ongoing ECLIPSE Phase 2 trial of etokimab in chronic rhinosinusitis with nasal polyps, patients dosed with etokimab every four (q4w) or eight weeks (q8w) failed to achieve statistically significant improvement in their bilateral nasal polyps score (NPS), an endoscopic measure of nasal occlusion, and their sino-nasal outcome test (SNOT-22), a patient reported quality-of-life assessment, versus placebo at the week 8 timepoint. Both endpoints demonstrated statistically significant improvement over baseline levels of NPS and SNOT-22. Blood eosinophil levels, which are a biomarker of etokimab's mechanism, demonstrated statistically significant reduction relative to baseline in both etokimab treatment arms. The Company intends to decide on a path forward for the etokimab program after reviewing week 16 primary endpoint data by year-end 2020.

Imsidolimab (Anti-IL-36 Receptor) Program

- In July we announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for imsidolimab, the company's proprietary anti-interleukin-36 receptor (IL-36R) antibody, for the treatment of patients with GPP. Treatment of GPP by imsidolimab is being evaluated in the GALLOP Phase 2 trial, where additional clinical data and a regulatory update is anticipated in the fourth quarter 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 first quarter of 2021, following COVID-19-related site closures that impacted enrollment in POPLAR during the second quarter.
- We anticipate expanding the imsidolimab program in two new indications based upon human translational data that suggests each of these conditions are mediated by dysregulated signaling through the IL-36 pathway:
    - Treatment of solid tumors with inhibitors of epidermal growth factor (EGFRi) and MAPK/ERK kinase (MEKi) is frequently limited by the occurrence of skin toxicities. These toxicities, which can lead to dose reduction and discontinuation of treatment, have been reported to occur as a result of excess IL-36 signaling, leading to IL-8-mediated cutaneous neutrophilia and acneiform rash. Based on existing claims data, approximately 60,000 patients are prescribed EGFRi and/or MEKi treatments annually, and the vast majority of these patients experience dermatological toxicity. Current standard-of-care treatments are generally ineffective in patients with the most severe grades of EGFRi and/or MEKi mediated acneiform rash. During the fourth quarter of 2020, we anticipate initiating a Phase 2 trial of imsidolimab, in combination with EGFRi/MEKi inhibitors, to assess its efficacy in the treatment of this indication.

- Ichthyosis is a family of rare, inherited, dermatological disorders characterized by dry, scaling and thickened skin. Approximately 6,000 patients in the United States are affected with moderate-to-severe levels of ichthyosis and no approved therapies are available for this disease. Recent translational data supports the role of IL-36 signaling in ichthyosis, and we anticipate initiating a Phase 2 trial of imsidolimab in this indication during the fourth quarter of 2020.

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. Preclinical translational data using ANB030 was presented in March 2020 at the Festival of Biologics Meeting. We initiated a Phase 1 healthy volunteer clinical trial, designed to assess the safety, pharmacokinetics and pharmacodynamics of ANB030 in single and multiple ascending dose cohorts, during the first half of 2020, and top-line data from this trial is anticipated in mid-2021.

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 fourth quarter 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 advanced or recurrent deficient mismatch repair (dMMR) endometrial cancer. AnaptysBio received a $10.0 million cash milestone payment upon this acceptance, and anticipates an additional $20.0 million cash milestone payment upon first FDA approval of dostarlimab during the second half of 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 received a $5.0 million milestone payment and anticipates an additional $10.0 million cash milestone payment upon EMA approval.
- AnaptysBio also expects to receive milestone payments from GSK during 2021 for acceptance and approval by the FDA of dostarlimab in dMMR pan-tumor cancer. All milestone payment amounts for this second indication for dostarlimab will be the same as the corresponding milestone payment amounts for the first indication.
- Including additional cash milestones due upon future development and commercialization of dostarlimab, GSK4069889A, an AnaptysBio-generated TIM-3 antibody, and GSK4074386, 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.

Second Quarter Financial Results

- Cash, cash equivalents and investments totaled $392.2 million as of June 30, 2020 compared to $428.5 million as of December 31, 2019, for a decrease of $36.3 million. The decrease relates primarily to cash used for operating activities.
- Collaboration revenue was zero and $15.0 million for the three and six months ended June,30 2020, which related to milestone payments for successful BLA and MAA filings for dostarlimab by GSK, compared to $5 million for both the three and six months ended June 30, 2019.
- Research and development expenses were $17.9 million and $38.9 million for the three and six months ended June 30, 2020, compared to $27.4 million and $48.0 million for the three and six months ended June 30, 2019. The decrease was due primarily to reduced outside services for manufacturing expenses based on the timing of projects.
- General and administrative expenses were $4.7 million and $9.0 million for the three and six months ended June 30, 2020, compared to $4.3 million and $8.4 million for the three and six months ended June 30, 2019. The increase was due primarily to increased legal and insurance expenses.
- Net loss was $21.5 million and $29.8 million for the three and six months ended June 30, 2020, or a net loss per share of $0.79 and $1.09, compared to a net loss of $24.0 million and $46.0 million for the three and six months ended June 30, 2019, or a net loss per share of $0.89 and $1.70.

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 emerging immune control mechanisms applicable to inflammation and immuno-oncology indications. 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 imsidolimab, previously referred to as ANB019, for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, palmoplantar pustulosis, or PPP, EGFRi and ichthyosis; 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 collaboration with GSK, including an anti-PD-1 antagonist antibody (dostarlimab (GSK4057190A)), an anti-TIM-3 antagonist antibody (GSK4069889A) and an anti-LAG-3 antagonist antibody (GSK4074386), and an inflammation collaboration with Bristol-Myers Squibb, 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 week 16 data for the ECLIPSE Phase 2 clinical trial in chronic rhinosinusitis with nasal polyps and imsidolimab's Phase 2 clinical trials in GPP and PPP; the timing of initiation of imsidolimab's Phase 2 clinical trials in EGFRi /MEKi and ichthyosis; the timing of a regulatory strategy update for GPP; the timing of an IND filing for ANB032; the milestones and royalty payments to be received under the GSK collaboration; 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.

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AnaptysBio, Inc.
Consolidated Balance Sheets
(in thousands, except par value data)

	June 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 221,172	$ 171,017
Short-term investments	156,706	203,210
Prepaid expenses and other current assets	6,638	3,506
Total current assets	384,516	377,733
Property and equipment, net	1,495	1,618
Long-term investments	14,321	54,305
Other long-term assets	1,354	1,481
Restricted cash	60	60
Total assets	$ 401,746	$ 435,197
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,289	$ 16,237

Accrued expenses	12,916	11,052
Notes payable, current portion	—	1,375
Other current liabilities	925	871
Total current liabilities	20,130	29,535
Other long-term liabilities	180	654
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 27,287 shares and 27,255 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	27	27
Additional paid in capital	654,492	648,669
Accumulated other comprehensive income	753	338
Accumulated deficit	(273,836)	(244,026)
Total stockholders' equity	381,436	405,008
Total liabilities and stockholders' equity	$ 401,746	$ 435,197

AnaptysBio, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Collaboration revenue	$ —	$ 5,000	$ 15,000	$ 5,000
Operating expenses:				
Research and development	17,948	27,350	38,916	47,981
General and administrative	4,687	4,307	8,972	8,448
Total operating expenses	22,635	31,657	47,888	56,429
Loss from operations	(22,635)	(26,657)	(32,888)	(51,429)
Other income (expense), net:				
Interest expense	—	(281)	—	(601)
Interest income	1,061	2,957	2,958	5,945
Other income (expense), net	26	(41)	120	(34)
Total other income (expense), net	1,087	2,635	3,078	5,310
Loss before income taxes	(21,548)	(24,022)	(29,810)	(46,119)
Provision for income taxes	—	60	—	79
Net loss	(21,548)	(23,962)	(29,810)	(46,040)
Other comprehensive (loss) income:				
Unrealized (loss) income on available for sale securities, net of tax of $0, $99, $0 and $214, respectively	(392)	370	415	797
Comprehensive loss	$ (21,940)	$ (23,592)	$ (29,395)	$ (45,243)
Net loss per common share:				
Basic and diluted	$ (0.79)	$ (0.89)	$ (1.09)	$ (1.70)
Weighted-average number of shares outstanding:				
Basic and diluted	27,279	27,026	27,271	27,004

AnaptysBio

Source: AnaptysBio, Inc.