# AnaptysBio Announces Second Quarter 2021 Financial Results and Provides Pipeline Updates

August 9, 2021

- Imsidolimab GPP GEMINI-1 Phase 3 trial anticipated to initiate in Q3 2021 following recent FDA end-of-Phase 2 Meeting
- Imsidolimab GALLOP GPP Phase 2 trial 16-week data to be orally presented at the EADV Congress on October 2nd, 2021
- Imsidolimab Phase 2 trials ongoing in acne, hidradenitis suppurativa, EGFR-mediated skin toxicity and ichthyosis, with multiple top-line data readouts anticipated in 2022
- Rosnilimab, previously referred to as ANB030, Phase 1 healthy volunteer top-line data and initiation of a Phase 2 trial in alopecia areata anticipated in Q4 2021
- JEMPERLI (dostarlimab), our PD-1 antagonist antibody, which our partner GlaxoSmithKline (GSK) anticipates to reach peak annual sales of £1-£2 billion, was approved for endometrial cancer in the US and EU, earning $30 million in cash milestones in Q2 2021 and 8-25% royalties on global net sales of JEMPERLI going forward

SAN DIEGO, Aug. 09, 2021 (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, 2021 and provided pipeline updates.

“We continue to make progress in advancing our wholly-owned pipeline and look forward to multiple clinical data readouts over the upcoming 18 months,” said Hamza Suria, president and chief executive officer of AnaptysBio. “The recent approval of JEMPERLI, which is the first AnaptysBio-generated antibody to be approved in the US and EU, validates AnaptysBio’s antibody discovery platform and provides additional revenues to support our capital-efficient business model.”

*Imsidolimab (Anti-IL-36 Receptor) Program*

- Following an end-of-Phase 2 meeting with the FDA in Q2, we publicly disclosed trial designs for our imsidolimab generalized pustular psoriasis (GPP) Phase 3 trials, called GEMINI-1 and GEMINI-2. We anticipate initiating GEMINI-1 in Q3 2021. The primary endpoint of our Phase 3 program is the proportion of patients achieving clear or almost clear skin as determined by a Generalized Pustular Psoriasis Physician’s Global Assessment (GPPPGA) score of zero or 1 at week 4 of GEMINI-1, while GEMINI-2 is designed for 6 months of safety follow-up assessment.

- We continue to enroll GPP patients in our worldwide registry of GPP patients, called RADIANCE, which is designed to improve our understanding of GPP patient journeys and support enrollment of our GEMINI Phase 3 trials. Medical claims analyses recently conducted by IQVIA indicate approximately 37,000 unique patients were diagnosed with GPP at least once, and approximately 15,000 unique patients were diagnosed with GPP at least twice, in the United States by a physician between 2017 and 2019 using the International Classification of Diseases 10th Revision (ICD-10) billing code pertaining to GPP (L40.1).

- Full data from our completed Phase 2 GALLOP trial of imsidolimab in GPP, including efficacy and safety of imsidolimab treatment through week 16, will be disclosed in an oral presentation at the European Academy of Dermatology and Venereology (EADV) Congress on October 2nd, 2021.

- We are continuing to advance imsidolimab through Phase 2 clinical trials in multiple additional indications associated with IL-36 signaling dysfunction. Our 120-patient placebo-controlled ACORN Phase 2 trial of imsidolimab in moderate-to-severe acne is anticipated to read out top-line data in the first half of 2022. Imsidolimab is also being tested versus placebo in hidradenitis suppurativa, where our 120-patient HARP trial is anticipated to generate top-line data in the second half of 2022. We continue to enroll our 45-patient placebo-controlled EMERGE Phase 2 trial of imsidolimab in EGFR/MEK-mediated skin toxicities, where we anticipate an interim analysis by the end of 2021. We also continue to enroll patients in our INSPIRE Phase 2 trial in ichthyosis where top-line data is anticipated during 2022.

*Rosnilimab (Anti-PD-1 Agonist) Program*

- We anticipate top-line data in Q4 2021 from our ongoing Phase 1 healthy volunteer clinical trial of rosnilimab, our wholly-owned PD-1 agonist antibody, designed to assess the safety, pharmacokinetics and pharmacodynamics of rosnilimab in single and multiple ascending dose cohorts.

- We plan to initiate a placebo-controlled Phase 2 clinical trial of rosnilimab in alopecia areata in Q4 2021.

*ANB032 (Anti-BTLA Modulator) Program*

- We are advancing ANB032, our wholly-owned BTLA modulator antibody, in a healthy volunteer Phase 1 single and multiple ascending dose clinical trial where top-line data is anticipated during the first half of 2022.

*GSK Partnered Programs*

- JEMPERLI (dostarlimab), our proprietary anti-PD-1 antagonist antibody, was approved by the FDA and the European Medicines Agency (EMA) during April 2021 for treatment of advanced or recurrent mismatch repair deficient endometrial cancer. This is the first AnaptysBio-generated antibody, of eight currently under clinical development, to obtain regulatory approval. GSK has recently disclosed peak annual sales estimates of £1-£2 billion for JEMPERLI, and AnaptysBio will earn 8-25% royalties on global net sales of JEMPERLI. We received $20 million and $10 million milestone payments upon FDA and EMA approval of JEMPERLI, respectively. We anticipate earning an additional $20 million milestone payment upon a second FDA BLA approval for JEMPERLI in pan-deficient mismatch repair tumors during the second half of 2021. AnaptysBio is due an additional $15 million and $165 million upon certain JEMPERLI regulatory and commercial milestones, respectively.

*Second Quarter Financial Results*

- Cash, cash equivalents and investments totaled $396.3 million as of June 30, 2021, compared to $411.2 million as of December 31, 2020, for a decrease of $14.9 million. The decrease relates primarily to cash used for operating activities.

- Collaboration revenue was $30 million and $41.3 million for the three and six months ended June 30, 2021. The $30 million earned during the second quarter relates to milestone revenue for the US and EU approval of JEMPERLI (dostarlimab), compared to zero and $15 million of milestone revenue for the three and six months ended June 30, 2020.

- Research and development expenses were $25.3 million and $49.5 million for the three and six months ended June 30, 2021, compared to $17.9 million and $38.9 million for the three and six months ended June 30, 2020. The increase was due primarily to continued advancement of the Company’s clinical programs.

- General and administrative expenses were $5.2 million and $10.7 million for the three and six months ended June 30, 2021, compared to $4.7 million and $9 million for the three and six months ended June 30, 2020. The increase was due primarily to personnel-related expenses, including share-based compensation.

- Net loss was $0.4 million and $18.6 million for the three and six months ended June 30, 2021, or a net loss per share of $0.02, and $0.68, compared to a net loss of $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.

*Financial Guidance*

AnaptysBio expects its net cash burn in 2021 will be less than $100 million. We anticipate that our cash, cash equivalents and anticipated revenues will fund our current operating plan at least into 2024.

**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 imsidolimab, its anti-IL-36R antibody, previously referred to as ANB019, for the treatment of dermatological inflammatory diseases, including generalized pustular psoriasis, or GPP, acne, hidradenitis suppurativa, EGFRi skin toxicity and ichthyosis; its anti-PD-1 agonist program, rosnilimab, 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 (JEMPERLI (dostarlimab-gxly)), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889) 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 imsidolimab’s Phase 2 clinical trials in acne, hidradenitis suppurativa, EGFRi and ichthyosis, rosnilimab’s Phase 1 healthy volunteer clinical trial and Phase 2 clinical trial in alopecia areata, and ANB032’s healthy volunteer Phase 1 trial; the timing of the

initiation of imsidolimab's GPP Phase 3 clinical trials; the milestones and royalty payments to be received under the GSK collaboration; and our projected 2021 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)**
**(unaudited)**

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 332,254 | $ 250,456 |
| Receivable from collaborative partners | 642 | — |
| Short-term investments | 58,597 | 143,197 |
| Prepaid expenses and other current assets | 6,508 | 2,908 |
| Restricted cash | 60 | — |
| Total current assets | 398,061 | 396,561 |
| Property and equipment, net | 2,488 | 1,783 |
| Operating lease right-of-use assets | 20,278 | 344 |
| Long-term investments | 5,484 | 17,546 |
| Other long-term assets | 258 | 258 |
| Restricted cash | — | 60 |
| Total assets | $ 426,569 | $ 416,552 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,103 | $ 4,217 |
| Accrued expenses | 15,958 | 15,262 |
| Current portion of operating lease liability | 555 | 342 |
| Total current liabilities | 20,616 | 19,821 |
| Operating lease liability, net of current portion | 20,222 | — |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at June 30, 2021 and December 31, 2020, respectively | — | — |
| Common stock, $0.001 par value, 500,000 shares authorized, 27,433 shares and 27,356 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively | 27 | 27 |
| Additional paid in capital | 668,429 | 660,665 |
| Accumulated other comprehensive loss | (176) | (4) |
| Accumulated deficit | (282,549) | (263,957) |
| Total stockholders' equity | 385,731 | 396,731 |
| Total liabilities and stockholders' equity | $ 426,569 | $ 416,552 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Collaboration revenue | $ 30,027 | $ — | $ 41,274 | $ 15,000 |
| Operating expenses: | | | | |
| Research and development | 25,314 | 17,948 | 49,499 | 38,916 |
| General and administrative | 5,246 | 4,687 | 10,669 | 8,972 |
| Total operating expenses | 30,560 | 22,635 | 60,168 | 47,888 |
| Loss from operations | (533) | (22,635) | (18,894) | (32,888) |
| Other income, net: | | | | |
| Interest income | 104 | 1,061 | 299 | 2,958 |
| Other income, net | — | 26 | 3 | 120 |
| Total other income, net | 104 | 1,087 | 302 | 3,078 |
| Net loss | (429) | (21,548) | (18,592) | (29,810) |
| Unrealized (loss) income on available for sale securities | (65) | (392) | (172) | 415 |
| Comprehensive loss | $ (494) | $ (21,940) | $ (18,764) | $ (29,395) |
| Net loss per common share: | | | | |
| Basic and diluted | $ (0.02) | $ (0.79) | $ (0.68) | $ (1.09) |
| Weighted-average number of shares outstanding: | | | | |
| Basic and diluted | 27,391 | 27,279 | 27,377 | 27,271 |

Source: AnaptysBio, Inc.