Invivyd Reports Second Quarter 2023 Financial Results and Business Highlights

August 10, 2023

- *Reported positive initial Phase 1 VYD222 clinical trial data, including favorable safety data and robust serum neutralizing titers from all three dose levels tested*
- *Plans to pursue rapid initiation of a 750-participant pivotal clinical trial of VYD222 (CANOPY) that will utilize Day 28 serum neutralizing titers from a subset of the population as part of a potential EUA submission for the prevention of symptomatic COVID-19*
- *The company expects to have initial primary endpoint data from CANOPY by approximately the end of 2023*
- *Cash, cash equivalents and marketable securities of $298.4 million expected to support operating runway into the fourth quarter of 2024, excluding potential contribution of commercial product revenue*
- *Conference call scheduled for Thursday, August 10th at 4:30 p.m. ET*

WALTHAM, Mass, Aug. 10, 2023 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD), a clinical-stage biopharmaceutical company on a mission to protect the vulnerable from serious viral infectious diseases, today announced financial results for the quarter ended June 30, 2023, and recent business highlights.

“I am very excited with the progress we made in the second quarter. On the heels of positive initial data from our Phase 1 VYD222 clinical trial and productive conversations with the FDA on a rapid pathway to a potential EUA, we are working with urgency to initiate a pivotal clinical trial of VYD222 for the prevention of symptomatic COVID-19, referred to as the CANOPY trial,” said Dave Hering, Chief Executive Officer of Invivyd. “With the size and efficient design of the CANOPY trial, including a primary efficacy endpoint based on the analysis of serum neutralizing titers at Day 28, we believe that we can swiftly enroll the trial and generate the data necessary to enable a potential EUA submission. We’ve continued to see strong interest from our clinical sites and immunocompromised people, with more than 1,000 immunocompromised individuals now in our database of potentially eligible individuals, which speaks to the strong unmet medical need.”

Recent VYD222 Program Updates:

- **Plans to initiate VYD222 pivotal clinical trial using a surrogate endpoint to generate the clinical data needed to enable a potential emergency use authorization (EUA) submission:** In a pivotal clinical trial of VYD222, referred to as the CANOPY trial, Invivyd plans to enroll approximately 750 participants across two cohorts in parallel. Cohort A is expected to enroll approximately 300 participants who are significantly immunocompromised. For Cohort A, the company plans to use serum neutralizing titers against relevant SARS-CoV-2 variants at Day 28 as the primary efficacy endpoint. The primary efficacy analysis will use an immunobridging approach comparing data obtained in the CANOPY trial for VYD222 to certain historical data from the company’s previous Phase 2/3 clinical trial of adintrevimab for the prevention of symptomatic COVID-19, in which serum neutralizing titers correlated with observed clinical efficacy. All Cohort A participants will receive VYD222 administered via IV infusion.

  In Cohort B, the company expects to enroll approximately 450 participants at risk of exposure to SARS-CoV-2. The primary endpoint will be safety and tolerability. Secondary and exploratory endpoints will include serum neutralizing titers and clinical efficacy. Cohort B participants will be randomized 2:1 to receive VYD222 or placebo administered via IV infusion.

  Invivyd plans to initiate the CANOPY trial with the 4500 mg dose of VYD222. While the company believes that all three VYD222 doses tested in the Phase 1 clinical trial (1500 mg, 2500 mg, and 4500 mg) have the potential to provide clinically meaningful protection against symptomatic COVID-19, the company has decided to initiate the CANOPY trial with the VYD222 dose that provided the highest serum neutralizing titers against Omicron XBB.1.5. This decision was informed by the FDA’s preference for a conservative serum neutralizing titer benchmark and the 4500 mg VYD222 dose. The company believes that the 4500 mg dose has the potential to provide a significant duration of protection, while also providing protection against potential loss of neutralization activity as SARS-CoV-2 evolves over time.

  The company expects to have initial primary endpoint data from the CANOPY trial by approximately the end of 2023.

- **Reported positive initial Phase 1 VYD222 clinical trial data:** In June and July 2023, Invivyd announced positive initial data from the ongoing Phase 1 healthy volunteer clinical trial of VYD222. The initial Phase 1 data showed a favorable safety and tolerability profile, as well as robust serum neutralizing titers against Omicron XBB.1.5 at Day 7 from all three dose levels tested (1500 mg, 2500 mg, and 4500 mg). Previous COVID-19 vaccine and monoclonal antibody (mAb) clinical trials, including the company’s past Phase 2/3 adintrevimab clinical trial, have demonstrated that serum neutralizing titers are correlated with the prevention of symptomatic COVID-19.

- **Reached general alignment with FDA on pathway to potential EUA for VYD222 and anticipated follow-on mAb**

candidates designed to prevent COVID-19: Based on FDA feedback, the use of a correlate of protection, or a surrogate of clinical efficacy, in an immunobridging approach to a pivotal clinical trial may be a reasonable approach to support an EUA for new mAb candidates when clinical trial data from a "prototype" mAb are available, provided that certain criteria are met. Invivyd plans to leverage its previous candidate, adintrevimab, as the prototype mAb for VYD222.

Recent Corporate Updates:

- **Continued progress advancing the company's platform and pipeline of anti-SARS-CoV-2 mAbs:** As part of its commitment to serial innovation, Invivyd is continuously monitoring SARS-CoV-2 viral evolution and leveraging its predictive modeling, B-cell mining and antibody engineering capabilities to identify and optimize potential next generation mAb candidates. The company continues to advance its preclinical work characterizing potential future anti-SARS-CoV-2 mAb candidates.

- **Appointed Sara Cotter to board of directors:** In July 2023, Invivyd appointed Sara Cotter to its board of directors. Ms. Cotter brings extensive leadership experience spanning healthcare investment management and drug development, including experience as the founder and chief executive officer of Levo Therapeutics, Inc.

Second Quarter 2023 Financial Results:

- **Cash position:** Cash, cash equivalents and marketable securities were $298.4 million as of June 30, 2023.

- **Cash runway:** Based on current operating plans, Invivyd expects its existing total cash, cash equivalents and marketable securities will enable the company to fund its operating expenses into the fourth quarter of 2024, excluding potential contribution of commercial product revenue if a mAb candidate is authorized or approved.

- **Research & development (R&D) expenses (including in-process research & development):** R&D expenses were $43.8 million for the quarter ended June 30, 2023, compared to $37.1 million for the comparable period of 2022. This increase is attributable to higher contract manufacturing costs driven by VYD222 commercial manufacturing, partially offset by a decrease in adintrevimab-related contract manufacturing and contract research activities.

- **Selling, general & administrative (SG&A) expenses:** SG&A expenses were $10.1 million for the quarter ended June 30, 2023, compared to $14.6 million for the comparable period of 2022. This decrease is attributable primarily to reduced consulting costs, professional fees and public company costs.

- **Net loss and net loss per share:** Net loss was $50.2 million for the quarter ended June 30, 2023, compared to $51.0 million for the comparable period in 2022. Basic and diluted net loss per share was $0.46 for the quarter ended June 30, 2023, compared to $0.47 for the comparable period in 2022.

Conference Call
In connection with this announcement, Invivyd will host a conference call and webcast today at 4:30 p.m. ET. A live audio webcast will be available at https://investors.invivyd.com/. Listeners can register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available in the investor section of the company's website approximately two hours after the end of the call. Those who plan on participating are advised to join 15 minutes prior to the start time.

About Invivyd
Invivyd, Inc. (Nasdaq: IVVD) is a biopharmaceutical company on a mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with ySARS-CoV-2. Invivyd's technology works at the intersection of evolutionary virology, predictive modeling, and antibod engineering, and is designed to identify high-quality, long-lasting antibodies with the potential to resist viral escape. The company is generating a robust pipeline of product candidates which could be used in prevention or treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications. Visit https://invivyd.com/ to learn more.

Cautionary Note Regarding Forward Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "could," "expects," "intends," "potential," "projects," and "future" or similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, the future of the COVID-19 landscape; the company's ongoing research and clinical development plans and the timing thereof, including with respect to the clinical development of VYD222; the company's plans to initiate a pivotal clinical trial of VYD222 (CANOPY) using a surrogate endpoint to generate the clinical data needed to enable a potential EUA submission, and the timing of anticipated initial primary endpoint data from the CANOPY trial; the company's anticipated CANOPY trial design; the possibility for VYD222 and anticipated follow-on mAb candidates designed to prevent COVID-19 to follow a development pathway for mAbs in the U.S. using a correlate of protection in an immunobridging approach to a pivotal clinical trial, and the company's plans to utilize adintrevimab as the prototype mAb for VYD222; the company's progress advancing its platform and pipeline of anti-SARS-CoV-2 mAbs; the company's expectations regarding the anticipated timeline of its cash runway; the company's ability to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning

with SARS-CoV-2; the potential for VYD222 and other product candidates to be high-quality, long-lasting antibodies with the potential to resist viral escape; the company's plans to generate a robust pipeline of product candidates which, if authorized or approved, could be used in prevention or treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications; and other statements that are not historical fact. The company may not actually achieve the plans, intentions or expectations disclosed in the company's forward-looking statements and you should not place undue reliance on the company's forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause the company's actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: the ability to gain complete alignment with the applicable regulatory authorities on the clinical trial design and development pathway for VYD222, including the use of an immunobridging pathway in the U.S., and the timing thereof; the timing and progress of the company's discovery, preclinical and clinical development activities, including the company's ability to rapidly initiate a VYD222 pivotal clinical; the ability of the company to generate and utilize tools to discover and develop a pipeline of antibodies to treat current and potential future SARS-CoV-2 variants; the impacts of the COVID-19 pandemic on the company's business and those of its collaborators, the company's clinical trials and its financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of VYD222 or other product candidates based on neutralizing activity in preclinical studies; the risk that results of preclinical studies or clinical trials may not be predictive of future results in connection with current or future clinical trials; variability of results in models used to predict activity against SARS-CoV-2 variants of concern; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; whether VYD222 or any other product candidate or combination of candidates is able to demonstrate and sustain neutralizing activity against predominant SARS-CoV-2 variants, particularly in the face of viral evolution; whether VYD222 or other product candidates will be high-quality, long-lasting antibodies that resist viral escape; whether the company is able to successfully submit an EUA in the future, and the outcome of any such EUA submission; whether the company's research and development efforts will identify and result in safe and effective therapeutic options for infectious diseases other than COVID-19; and whether the company has adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause the company's actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission (SEC), and in the company's other filings with the SEC, and in its future reports to be filed with the SEC and available at www.sec.gov. Such risks may be amplified by the impacts of the COVID-19 pandemic. Forward-looking statements contained in this press release are made as of this date, and Invivyd undertakes no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

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INVIVYD, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 121,947	$ 92,076
Marketable securities	176,483	279,915
Prepaid expenses and other current assets	11,556	4,926
Total current assets	309,986	376,917
Property and equipment, net	2,123	2,282
Operating lease right-of-use assets	3,014	3,777
Other non-current assets	291	191

Total assets	$ 315,414	$ 383,167
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,112	$ 1,517
Accrued expenses	26,744	21,911
Operating lease liabilities, current	1,611	1,559
Other current liabilities	38	44
Total current liabilities	32,505	25,031
Operating lease liabilities, non-current	1,346	2,165
Early-exercise liability	—	1
Total liabilities	33,851	27,197
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 109,570,333 shares issued and outstanding at June 30, 2023; 109,044,046 shares issued and outstanding at December 31, 2022	11	11
Additional paid-in capital	900,549	889,657
Accumulated other comprehensive loss	(22)	(272)
Accumulated deficit	(618,975)	(533,426)
Total stockholders' equity	281,563	355,970
Total liabilities, preferred stock and stockholders' equity	$ 315,414	$ 383,167

INVIVYD, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Operating expenses:				
Research and development(1)	$ 43,618	$ 37,129	$ 70,819	$ 129,164
Acquired in-process research and development(2)	150	—	975	—
Selling, general and administrative	10,107	14,620	21,152	23,324
Total operating expenses	53,875	51,749	92,946	152,488
Loss from operations	(53,875)	(51,749)	(92,946)	(152,488)
Other income:				
Other income	3,647	759	7,397	832
Total other income	3,647	759	7,397	832
Net loss	(50,228)	(50,990)	(85,549)	(151,656)
Other comprehensive income (loss)				

Unrealized gain on available-for-sale securities, net of tax	93	—	250	8
Comprehensive loss	$ (50,135)	$ (50,990)	$ (85,299)	$ (151,648)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.46)	$ (0.47)	$ (0.78)	$ (1.40)
Weighted-average common shares outstanding, basic and diluted	109,450,071	108,166,890	109,119,630	108,019,051

(1) Includes related-party amounts of $2,258 and $5,218 for the three and six months ended June 30, 2023, respectively, and $2,285 and $4,285 for the three and six months ended June 30, 2022, respectively.

(2) Includes related-party amounts of $0 and $375 for the three and six months ended June 30, 2023, respectively, and includes no related-party amounts for both the three and six months ended June 30, 2022.