Invivyd Reports First Quarter 2023 Financial Results and Business Highlights

May 11, 2023

Completed dosing of the Phase 1 clinical trial of VYD222, a broadly neutralizing monoclonal antibody (mAb) candidate being developed to protect immunocompromised people from COVID-19

Initial data readouts from Phase 1 VYD222 clinical trial planned for Q2 with additional clinical readouts from the VYD222 program anticipated in 2023

Published landmark clinical research in Science Translational Medicine that provides strong scientific rationale for using surrogate endpoints to expedite clinical development of mAbs for the prevention of symptomatic COVID-19

Well capitalized with $333.4 million in cash, cash equivalents and marketable securities expected to support operating runway into second half of 2024 excluding potential contribution of commercial product revenue

Conference call scheduled for Thursday, May 11th at 4:30 p.m. ET

WALTHAM, Mass., May 11, 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 March 31, 2023, and recent business highlights.

"We've made great strides in the first part of 2023, including the swift progress in our Phase 1 VYD222 clinical trial underway in Australia, the FDA clearance of our VYD222 IND application, and the continued advancement of our work engineering and characterizing potential next-generation mAb candidates targeting SARS-CoV-2," said Dave Hering, chief executive officer of Invivyd. "These are all important steps in our strategy to serially innovate at a speed that matches the pace of SARS-CoV-2 viral evolution. With the previously authorized anti-SARS-CoV-2 mAbs losing activity against variants of concern, our mission is critical for the millions of immunocompromised people who may not generate adequate protection from COVID-19 vaccines and are at increased risk for severe outcomes."

Mr. Hering continued, "We look forward to continuing to engage with global regulators with the aim to establish new clinical and regulatory paradigms that reflect the rate of SARS-CoV-2 viral evolution. Leveraging clinical data from our previous adintrevimab trial, we are proud to have recently published landmark research which showed that serum virus neutralizing titers predicted protection against symptomatic SARS-CoV-2 infection, a finding that we believe has the potential to substantially accelerate our clinical development of VYD222. We believe that the use of surrogate endpoints will be an important component of new paradigms."

Recent VYD222 Program Updates

- **Completed dosing in ongoing VYD222 Phase 1 clinical trial, with initial readouts from the clinical trial on track for Q2:** In March 2023, Invivyd announced dosing of the first participants in a Phase 1 clinical trial of VYD222 being conducted outside the U.S. In May 2023, the company finished dosing all 30 participants. The company is on track to provide initial readouts from the Phase 1 clinical trial in the second quarter of 2023, including early insights into serum virus neutralizing activity (sVNA), an important biomarker that has been shown to predict protection against symptomatic COVID-19. The ongoing Phase 1 clinical trial is a randomized, blinded, placebo-controlled, dose-ranging trial that will evaluate the safety, pharmacokinetics, tolerability, and sVNA of VYD222 (NCT05791318).
- **IND application for VYD222 cleared by the FDA:** In April 2023, Invivyd announced that the U.S. Food and Drug Administration (FDA) cleared its Investigational New Drug (IND) application for VYD222, an important step in the company's plans to advance a stream of mAbs designed to keep pace with SARS-CoV-2 viral evolution.
- **Plans to evaluate VYD222 for the prevention of COVID-19 in vulnerable populations, such as immunocompromised people:** Invivyd is in dialogue with global regulators regarding the VYD222 clinical development program and, pending feedback from regulators, plans to provide an update once the VYD222 pivotal trial design is finalized.

Recent Corporate Updates

- **Published research demonstrating that serum neutralizing antibody titers predict prevention of symptomatic COVID-19**: In March 2023, the company and collaborators authored an article in the peer-reviewed journal *Science Translational Medicine* titled "Antibody-mediated protection against symptomatic COVID-19 can be achieved at low serum neutralizing titers." The results of the research provide strong scientific rationale for using serum virus neutralizing antibody titers as surrogate markers of protection against symptomatic COVID-19 disease. The company believes that the use of

surrogate endpoints has the potential to substantially accelerate the clinical development of mAbs designed to prevent COVID-19.

- **Continued progress developing 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, provided through its internal expertise and collaborations, to identify and optimize potential next generation mAb candidates. The company has multiple anti-SARS-CoV-2 mAb candidates in the discovery/preclinical stage and recently nominated an additional candidate for further preclinical characterization.
- **Recent leadership appointments and updates:** In April 2023, Invivyd announced key leadership appointments that broaden the company's industry expertise in support of its product discovery and manufacturing activities, including the appointment of Robert Allen, Ph.D., as chief scientific officer and the appointment of Stacy Price, M.S., as chief technology and manufacturing officer. Dr. Allen oversees the scientific direction of the company and has responsibility for supporting the discovery of therapies across Invivyd's pipeline. Ms. Price leads the chemistry, manufacturing and controls (CMC) programs and technical operations functions. In May 2023, the company announced the conclusion of Fred Driscoll's service as interim chief financial officer and his planned retirement, effective May 31, 2023.

First Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $333.4 million as of March 31, 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 second half 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 $28.0 million for the quarter ended March 31, 2023, compared to $92.0 million for the comparable period of 2022. This decrease is attributable to a decrease in contract manufacturing costs driven by adintrevimab commercial manufacturing in 2022 with no comparable commercial manufacturing costs in 2023 and lower clinical trial costs due to wind-down of adintrevimab clinical trials.
- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were $11.0 million for the quarter ended March 31, 2023, compared to $8.7 million for the comparable period of 2022. This increase is attributable to lower stock-based compensation expense in 2022, partially offset by reduced consulting costs, professional fees and public company costs in 2023.
- **Net Loss and Net Loss per Share:** Net loss was $35.3 million for the quarter ended March 31, 2023, compared to $100.7 million for the comparable period in 2022. Basic and diluted net loss per share was $0.32 for the quarter ended March 31, 2023, compared to $0.93 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/. Interested parties may also 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 timing of anticipated dosing completion and data readouts with respect to the company's VYD222 program; the company's continued work engineering and characterizing potential next-generation mAb candidates targeting SARS-CoV-2; the company's plans to continue to engage with global regulators with the aim to establish new clinical and regulatory paradigms, which may involve use of surrogate endpoints, which may accelerate clinical development of mAbs designed to prevent COVID-19; the potential for the adintrevimab clinical data to support accelerated development of VYD222; the company's strategy to serially innovate, plans to advance a stream of mAb candidates designed to keep pace with SARS-CoV-2 viral evolution, and progress developing the company's platform and pipeline of anti-SARS-CoV-2 mAbs; the potential for VYD222 or other product candidates to demonstrate activity against predominant SARS-CoV-2 variant(s); the company's expectations regarding the anticipated timeline of its cash runway; anticipated benefits to the company of recent executive officer appointments; the company's ability to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats; 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 could be used in prevention or treatment of serious viral threats, starting with COVID-19 and expanding into influenza and other high-need indications; and other statements that are not historical fact. We 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 alignment with the applicable regulatory authorities on the clinical trial design and development pathway for VYD222 and the timing thereof; the timing and progress of the company's discovery, preclinical and clinical development activities; 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 pipeline product candidates based on neutralizing activity in preclinical studies; 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, including the outcome of the company's discussions with regulatory authorities concerning its clinical trials and platform-based approach to development; whether VYD222 or any other product candidate or combination of candidates is able to demonstrate and sustain neutralizing activity against predominant SARS-CoV-2 variant(s); whether VYD222 or other product candidates will be high-quality, long-lasting antibodies with the potential to resist viral escape; whether the company is able to successfully submit an emergency use authorization in the future, and the outcome of any such emergency use authorization 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 (the "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.

Contacts

Media Contact:
Kate Burdick, Evoke Canale
860-462-1569
kate.burdick@evokegroup.com

Investor Contact:
Chris Brinzey, ICR Westwicke
339-970-2843
chris.brinzey@westwicke.com

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 126,473	$ 92,076
Marketable securities	206,955	279,915
Prepaid expenses and other current assets	11,195	4,926
Total current assets	344,623	376,917
Property and equipment, net	2,252	2,282
Operating lease right-of-use assets	3,398	3,777
Other non-current assets	291	191
Total assets	$ 350,564	$ 383,167
Liabilities, Preferred Stock and Stockholders' Equity		

Current liabilities:		
Accounts payable	$ 5,913	$ 1,517
Accrued expenses	14,501	21,911
Operating lease liabilities, current	1,585	1,559
Other current liabilities	58	44
Total current liabilities	22,057	25,031
Operating lease liabilities, non-current	1,758	2,165
Early-exercise liability	—	1
Total liabilities	23,815	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 March 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 109,316,226 shares issued and outstanding at March 31, 2023; 109,044,046 shares issued and outstanding at December 31, 2022	11	11
Additional paid-in capital	895,600	889,657
Accumulated other comprehensive loss	(115)	(272)
Accumulated deficit	(568,747)	(533,426)
Total stockholders' equity	326,749	355,970
Total liabilities, preferred stock and stockholders' equity	$ 350,564	$ 383,167

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

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Operating expenses:		
Research and development[1]	$ 27,201	$ 92,035
Acquired in-process research and development[2]	825	—
Selling, general and administrative	11,045	8,704
Total operating expenses	39,071	100,739
Loss from operations	(39,071)	(100,739)
Other income:		
Other income	3,750	73
Total other income	3,750	73
Net loss	(35,321)	(100,666)
Other comprehensive income (loss)		
Unrealized gain on available-for-sale securities, net of tax	157	8
Comprehensive loss	$ (35,164)	$ (100,658)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.32)	$ (0.93)
Weighted-average common shares outstanding, basic and diluted	108,785,519	107,869,570

(1) Includes related-party amounts of $2,960 and $2,000 for the three months ended March 31, 2023 and 2022, respectively.
(2) Includes related-party amounts of $375 and $0 for the three months ended March 31, 2023 and 2022, respectively.