Invivyd Reports Full Year 2022 Financial Results and Business Highlights

March 23, 2023

Advancing VYD222 into clinical development based on in vitro data demonstrating neutralizing activity against multiple important variants of concern, including XBB.1.5

Anticipate near-term designation of an additional monoclonal antibody against SARS-CoV-2 with complementary binding properties to VYD222 for development

Well capitalized with $372 million in cash, cash equivalents and marketable securities expected to support operating runway into second half of 2024

Conference call scheduled for Thursday, March 23rd at 4:30 p.m. ET

WALTHAM, Mass., March 23, 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 year ended December 31, 2022, and recent business highlights.

“2022 was a transformational year for Invivyd as we reformed our strategy and are now squarely focused on leveraging our integrated discovery platform to advance a stream of SARS-CoV-2 monoclonal antibody (mAb) candidates. There continues to be an urgent, unmet medical need for vulnerable populations given no antibodies are currently authorized,” said Dave Hering, CEO of Invivyd. “We are pleased to have recently announced plans to advance VYD222 into clinical development as a novel mAb therapeutic option for COVID-19. We believe VYD222 is a highly attractive candidate that could potentially leverage adintrevimab’s strong clinical data package to support potential accelerated development. Importantly, *in vitro* data on VYD222 has shown neutralizing activity against multiple currently circulating variants of concern, including those that led to the obsolescence of products previously authorized in the U.S. We continue to plan for a Phase 1 clinical trial start in Q1 2023. Assuming positive Phase 1 data, we anticipate rapidly initiating Phase 3 pivotal trials that could support regulatory filings globally."

Recent Business Highlights

- Earlier in March 2023, the company announced plans to advance VYD222 into the clinic as a mAb therapeutic option for COVID-19 with a focus on serving vulnerable populations. VYD222 is one of the two mAb components of NVD200, a combination mAb product candidate that Invivyd had previously selected for advancement prior to evolution in the current global COVID-19 regulatory paradigm. The company is prioritizing the clinical development of VYD222 instead of NVD200 with the aim of providing patients with a therapeutic option for COVID-19 as quickly and efficiently as possible. VYD222 was engineered from adintrevimab, Invivyd’s investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 3 clinical trials for both the prevention and treatment of COVID-19. The adintrevimab clinical data package has the potential to support accelerated development of VYD222.
- In March 2023, the company and collaborators published an article in the journal *Science Translational Medicine* titled, “Antibody-mediated protection against symptomatic COVID-19 can be achieved at low serum neutralizing titers.” The work builds on vaccine studies demonstrating neutralizing antibody titers as correlates of protection against disease and could inform the evolution of regulatory frameworks for therapeutic antibodies.
- The company continues to leverage its integrated discovery platform, mapping common mutational escape routes to predict potential products to treat future variants of the SARS-CoV-2 virus. Beyond VYD222, the company is continuously monitoring evolving variants and engineering to optimize pipeline candidates and has initiated a new mAb campaign that targets re-engineering and affinity maturations of current molecules against the most recent variants of concern, such as XBB.1.5. The company is currently evaluating several of these candidates in preclinical studies to support nomination of additional candidates for IND-enabling and clinical development.
- In December 2022, the company was invited to participate in a U.S. Food and Drug Administration-European Medicines Agency workshop to explore expedited development pathways for mAbs. The meeting featured presentations by scientists, clinicians, regulators, and industry representatives to discuss alternative strategies to support the expedited availability of novel monoclonal antibody therapies. The company aims to leverage evolving COVID-19 regulatory paradigms to deliver this much-needed product for immunocompromised individuals and other vulnerable populations.
- The company has announced key leadership positions that broaden the company’s industry expertise in support of its development and commercial planning.
    - Appointed Jeremy Gowler as chief operating officer and commercial officer. Mr. Gowler brings 20 years of experience across multiple key commercialization functions throughout the product lifecycle.
    - Promoted Pete Schmidt, M.D. to chief medical officer. Dr. Schmidt had served as Invivyd’s vice president of clinical

research for the past two years, and is now responsible for overseeing all medical, clinical development and regulatory activities at Invivyd.

Year End 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $372 million as of December 31, 2022.
- **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.
- **Research & Development (R&D) Expenses (including In-process Research & Development):** R&D expenses were $183.6 million for the year ended December 31, 2022, compared to $190.4 million for the comparable period of 2021. This decrease is attributable to wind-down of adintrevimab clinical trials, partially offset by an increase in contract manufacturing and personnel-related expenses, including an increase of $6.2 million of stock-based compensation expense.
- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were $47.0 million for the year ended December 31, 2022, compared to $36.5 million for the comparable period of 2021. This increase is attributable to higher public company costs and personnel-related expenses.
- **Warrant Expense:** Warrant expense was $17.4 million for the year ended December 31, 2022, compared to $0 for the comparable period of 2021. This increase is attributable to a one-time charge associated with warrants issued to Population Health Partners, L.P. (PHP) as compensation for consulting services to be provided by PHP to the company under the agreement entered into in the fourth quarter of 2022.
- **Net Loss and Net Loss per Share:** Net loss was $241.3 million for the year ended December 31, 2022, compared to $226.8 million for the comparable period in 2021. Basic and diluted net loss per share was $2.23 for the year ended December 31, 2022, compared to $5.32 for the comparable period in 2021.
    - The net loss of $241.3 million for the year ended December 31, 2022 included a one-time charge of $17.4 million related to the fair value of the warrants issued to PHP.

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 invivyd.com/investors. 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 via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

About Invivyd

(Nasdaq: IVVD)

Invivyd, Inc., is a biopharmaceutical company on a mission to rapidly and perpetually deliver antibody-based therapies that protect yvulnerable people from the devastating consequences of circulating viral threats, beginning with SARS-CoV-2. Invivyd's technolog works at the intersection of evolutionary virology, predictive modeling, and antibody engineering, and is designed to identify high-quality, long-lasting antibodies with a high barrier to 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 ability for Invivyd, other companies or combination of companies and industry representatives to influence regulators to change or adopt new development pathways or timelines; the ability of Invivyd to accelerate development timelines for the unmet need for treatment of COVID-19; the interest or acceptance by regulatory authorities of regulatory and clinical strategies to support potentially expedited development of novel monoclonal antibody therapies; the potential for success and or expedited discovery, development, or commercialization of antibody therapies for COVID-19; the continued unmet need for prevention and treatment of COVID-19, particularly for immunocompromised and other vulnerable populations; the viability and acceptability of new regulatory strategy, policy or approach to drug development and the potential of the same to maintain pace with changing COVID-19 variants; the future of the COVID-19 landscape including the expectation of continued evolution and emergence of new variants and subvariants; our ongoing research and clinical development plans and the timing thereof; our plans to advance VYD222 or other early stage candidates as a potential prophylaxis and treatment option for COVID-19, including disease caused by most variants, as either a single or combination agent; the potential for VYD222 or other product candidates to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; the potential for the clinical data package resulting from clinical trials of adintrevimab to support accelerated VYD222 monotherapy development; our plans to advance VYD222 into the clinic; our expectations that we will be able to achieve regulatory alignment and advance pivotal studies with VYD222; our expectations regarding the anticipated timeline of our cash runway; anticipated benefits to the company of recent executive officer appointments and promotions; our plans, technology and resources to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and seasonal influenza, in the U.S. and globally; and other statements that are not historical fact. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our 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 development

pathway for VYD222 and the timing thereof; the ability for Invivyd and/or other companies, scientists, clinicians or industry representatives to impact the strategy, policy or approach to drug development drafted or applied by regulatory authorities, including the FDA and EMA; the impact of any such change on the speed or success of development and commercialization of antibodies for the prevention and/or treatment of COVID-19; the ability of the company to generate and utilize tools to discover and develop antibodies to treat current and potential future variants; the impacts of the COVID-19 pandemic on our business and those of our collaborators, our clinical trials and our financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of VYD222 or other pipeline candidates or combination of candidates based on neutralizing activity in pre-clinical 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 our discussions with regulatory authorities concerning our clinical trials; whether VYD222 or any other pipeline candidate or combination of candidates is able to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; whether we are able to successfully submit an emergency use authorization in the future, and the outcome of any such emergency use authorization submission; whether research and development efforts will improve efficacy of adintrevimab against predominant variants or identify additional monoclonal antibodies or combination of antibodies for the prevention and treatment of COVID-19 and other infectious diseases; whether research and development efforts will identify and result in safe and effective therapeutic or preventative options for other infectious diseases in the U.S. or globally and whether we have adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause our 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 our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 filed with the Securities and Exchange Commission (the “SEC”), and in our other filings with the SEC, and in Invivyd’s 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.
CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 92,076	$ 542,224
Marketable securities	279,915	49,194
Prepaid expenses and other current assets	4,926	25,293
Total current assets	376,917	616,711
Property and equipment, net	2,282	83
Operating lease right-of-use assets	3,777	—
Other non-current assets	191	3,297
Total assets	$ 383,167	$ 620,091
Liabilities, Convertible Preferred Stock and Stockholders’ Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,517	$ 5,783
Accrued expenses	21,911	56,277
Operating lease liabilities, current	1,559	—
Other current liabilities	44	—

Total current liabilities	25,031	62,060
Operating lease liabilities, non-current	2,165	—
Early-exercise liability	1	6
Other non-current liability	—	6
Total liabilities	27,197	62,072
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 December 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 109,044,046 shares issued and outstanding at December 31, 2022; 1,000,000,000 shares authorized, 111,251,660 shares issued and 110,782,909 shares outstanding at December 31, 2021	11	11
Treasury stock, at cost; 0 shares and 468,751 shares at December 31, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	889,657	850,125
Accumulated other comprehensive income (loss)	(272)	(8)
Accumulated deficit	(533,426)	(292,109)
Total stockholders' equity	355,970	558,019
Total liabilities, convertible preferred stock and stockholders' equity	$ 383,167	$ 620,091

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

	Year Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development[1]	$ 179,214	$ 182,891
Acquired in-process research and development[2]	4,400	7,500
Selling, general and administrative	47,044	36,517
Warrant expense[3]	17,373	—
Total operating expenses	248,031	226,908
Loss from operations	(248,031)	(226,908)
Other income (expense):		
Other income (expense), net	6,714	118
Total other income (expense), net	6,714	118
Net loss	(241,317)	(226,790)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities, net of tax	(264)	(8)
Comprehensive loss	$ (241,581)	$ (226,798)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.23)	$ (5.32)
Weighted-average common shares outstanding, basic and diluted	108,268,289	42,621,265

(1) Includes related-party amounts of $8,154 and $4,150 for the years ended December 31, 2022 and 2021, respectively.

(2) Includes related-party amounts of $4,400 and $7,500 for the years ended December 31, 2022 and 2021, respectively.

(3) Includes related-party amounts of $17,373 and $0 for the years ended December 31, 2022 and 2021, respectively.