UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): January 3, 2024

Invivyd, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-40703**	**85-1403134**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1601 Trapelo Road, Suite 178 **Waltham, MA**	**02451**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 819-0080

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	IVVD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On January 3, 2024, Invivyd, Inc. issued a press release entitled "Invivyd Submits Request for Emergency Use Authorization (EUA) to U.S. FDA for VYD222 for the Pre-exposure Prevention of COVID-19 in Immunocompromised Adults and Adolescents." A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference in this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated January 3, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INVIVYD, INC.

Date: January 3, 2024

By: /s/ Jill Andersen
Jill Andersen
Chief Legal Officer and Corporate Secretary

Invivyd Submits Request for Emergency Use Authorization (EUA) to U.S. FDA for VYD222 for the Pre-exposure Prevention of COVID-19 in Immunocompromised Adults and Adolescents

- *EUA submission is based on positive initial results from the ongoing CANOPY Phase 3 pivotal clinical trial and ongoing in vitro neutralization activity against relevant SARS-CoV-2 variants*
- *VYD222 demonstrates continued in vitro neutralization activity against major SARS-CoV-2 variants, including JN.1, currently the fastest growing variant in the U.S.*
- *Company continues preparations for potential commercial launch if EUA is granted*

WALTHAM, Mass., January 3, 2024 (GLOBE NEWSWIRE) – Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company on a mission to protect the vulnerable from serious viral infectious diseases, today announced that it has requested Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for VYD222, a broadly neutralizing, half-life extended monoclonal antibody candidate, for the pre-exposure prevention of COVID-19 in immunocompromised adults and adolescents. The EUA submission was based on positive initial results from the CANOPY Phase 3 pivotal clinical trial of VYD222, as well as ongoing *in vitro* neutralization activity against relevant variants such as JN.1.

“We are tremendously pleased by the fact that VYD222 continues to demonstrate *in vitro* neutralization activity against the latest dominant variant, JN.1, as well as other prevalent SARS-CoV-2 strains,” said Dave Hering, Chief Executive Officer of Invivyd. “We believe that the demonstrated durability of VYD222 is reflective of our strategy to select antibody candidates that target conserved epitopes to achieve our stated goal of keeping pace with viral evolution.”

Mr. Hering added, “The submission of the EUA request for VYD222 represents an exciting milestone for Invivyd that was only made possible thanks to the unwavering dedication of our employees, the support of our investigators, and the invaluable contributions of all those who participated in the CANOPY trial. Many immunocompromised people do not achieve full benefit from COVID-19 vaccines as their immune systems are unable to provide sufficient defense against SARS-CoV-2. If authorized, we believe VYD222 could provide these vulnerable individuals with an important new preventive option.”

Seth Ginsberg, President and Co-Founder, Global Healthy Living Foundation, commented, “We are eagerly tracking the progress of new monoclonal antibodies because there are still countless immunocompromised people who remain vulnerable to the ravages of COVID-19. Sustained innovation is what is needed to keep pace with this virus, and we commend Invivyd and others working in this space for their commitment and dedication to serving those who are in urgent need of protection.”

On December 18, 2023, Invivyd announced positive initial results from the ongoing CANOPY pivotal clinical trial. VYD222 produced high serum virus neutralizing antibody (sVNA) titer levels against XBB.1.5 in the immunocompromised cohort. The company observed an encouraging, potential early signal of strong clinical protection from symptomatic COVID-19 in CANOPY, which would be expected based on the high sVNA titer levels and dose selected. In addition, the company believes that the initial results from CANOPY support an immunobridging approach which utilizes *in vitro* VYD222 potency data to calculate and efficiently determine the sVNA titer levels against new SARS-CoV-2 variants as they emerge. Initial results showed that the safety and tolerability profile of VYD222 remained favorable with no study drug related serious adverse events reported; adverse events attributed to VYD222 were Grade 1 or 2 (mild or moderate) in severity.

In vitro pseudovirus testing shows that VYD222 has potency against various SARS-CoV-2 variants currently circulating, including JN.1, which is currently the fastest growing variant in the U.S., as well as HV.1, BA.2.86, XBB.1.5.10/EG.5, and HK.3.

If authorized, Invivyd aims to have VYD222 commercially available rapidly thereafter.

About CANOPY

The CANOPY pivotal clinical trial is an ongoing Phase 3 clinical trial designed to evaluate protection against symptomatic COVID-19 after receiving VYD222. The safety, tolerability, pharmacokinetic profile, and immunogenicity of VYD222 will also be evaluated. In November 2023, Invivyd announced the completion of enrollment in the CANOPY clinical trial, with approximately 750 participants enrolled in two cohorts (A and B) across multiple trial sites in the U.S. Cohort A enrolled approximately 300 participants who are significantly immunocompromised. For this cohort, the primary endpoints include safety and tolerability and serum neutralizing titers against relevant SARS-CoV-2 variants at Day 28, which will be calculated based on the pharmacokinetic concentration of VYD222 from the immunocompromised participants and the IC50 value for VYD222 against relevant SARS-CoV-2 variants. The primary efficacy analysis uses an immunobridging approach comparing data obtained in the CANOPY clinical trial to certain historical data from the company's previous Phase 2/3 clinical trial of adintrevimab (ADG20) for the prevention of symptomatic COVID-19 (EVADE), in which serum neutralizing titers correlated with observed clinical efficacy. All Cohort A participants received VYD222 administered via intravenous (IV) infusion.

Cohort B enrolled approximately 450 participants at risk of exposure to SARS-CoV-2. Participants were randomized 2:1 to receive VYD222 or placebo administered via IV infusion. The primary endpoints include safety and tolerability and the proportion of participants with RT-PCR-confirmed symptomatic COVID-19 through 6 months.

Invivyd is evaluating the 4500 mg dose of VYD222 in the CANOPY clinical trial.

About VYD222

VYD222 is a broadly neutralizing, half-life extended monoclonal antibody (mAb) candidate in development for the prevention of symptomatic COVID-19 in vulnerable populations, such as immunocompromised people. Globally, there are millions of immunocompromised people, with more than 9 million in the U.S. alone who may not adequately respond to COVID-19 vaccination, increasing their risk for severe outcomes from COVID-19. Currently, there are no monoclonal antibodies authorized or approved in the U.S. for the prevention of symptomatic COVID-19. VYD222 was designed for broad activity and has demonstrated *in vitro* neutralizing activity in pseudovirus assays against various pre-Omicron and Omicron variants, such as JN.1, HV.1, BA.2.86, XBB.1.5.10/EG.5, and HK.3. VYD222 was engineered from adintrevimab, Invivyd's investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 2/3 clinical trials for both the prevention and treatment of COVID-19.

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 SARS-CoV-2. The company's proprietary INVYMAB™ platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering. Leveraging its INVYMAB platform approach, 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 company's ongoing research and clinical development plans for VYD222 or any other product candidate, and the timing thereof, including with respect to the ongoing CANOPY phase 3 pivotal clinical trial and other research and development plans for VYD222; the company's regulatory and commercialization plans for VYD222 or any other product candidate, and the timing thereof; the potential of VYD222 for strong clinical protection from symptomatic COVID-19 based on early signals observed in the CANOPY clinical trial; the company's belief that the initial results from the CANOPY clinical trial are supportive of an immunobridging approach for the development of VYD222; the ability of the company to determine the sVNA titer levels against new SARS-CoV-2 variants as they emerge using *in vitro* VYD222 potency data; the continued and ongoing *in vitro* neutralization activity of VYD222 against relevant and major SARS-CoV-2 variants; the company's belief that the demonstrated durability of VYD222 is reflective of its strategy to select antibody candidates that target conservative epitopes to achieve its stated goal of keeping pace with viral evolution; the company's belief that VYD222 holds the potential to be an important preventive option for immunocompromised populations; the potential scope of an EUA for VYD222, if granted, including disease state and patient population; the potential for VYD222 to maintain an EUA, if granted, through evolution of SARS-CoV-2 variants; the company's continued preparations and plans for commercial launch of VYD222 and the ability to have VYD222 commercially available rapidly, if EUA is granted; 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 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 timing and progress of the company's discovery, preclinical and clinical development activities; the company's ability to generate the clinical data needed from the CANOPY clinical trial to support a potential EUA for VYD222; the company's interactions with the U.S. FDA regarding the EUA submission for VYD222; the outcome of the VYD222 EUA submission and timing thereof; the development and regulatory pathways for authorization or approval of VYD222 or other product candidates; 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; the company's reliance on third parties with respect to virus assay creation and product candidate testing and with respect to its clinical trials; variability of results in models used to predict activity against SARS-CoV-2 variants of concern; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory authorization or approval process; whether VYD222 or any other product candidate is able to demonstrate and sustain neutralizing activity against relevant, major or predominant SARS-CoV-2 variants, particularly in the face of viral evolution; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of VYD222 or any other product candidate following EUA or approval, if granted; whether the company's product candidates will be high-quality, long-lasting antibodies that resist viral escape; whether the company is able to successfully submit an EUA for any other product candidate in the future, and the outcome and timing of any such EUA submission; the company's ability to manufacture sufficient commercial quantities of VYD222; the complexities of manufacturing monoclonal antibody therapies and the company's reliance on contract manufacturers to do so; the company's ability to establish a sales, marketing and distribution infrastructure to commercialize VYD222 or any other product candidates for which the company may obtain regulatory approval or EUA; whether the company can obtain and maintain third-party coverage and adequate reimbursement for VYD222 or any other product candidate; 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; the company's ability to continue as a going concern; 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. 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.

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