# 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): May 7, 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**<br>**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 May 7, 2024, Invivyd, Inc. issued a press release entitled "Invivyd to Pursue Rapid Immunobridging Pathway to Potential EUA for Treatment of COVID-19 in Moderately to Severely Immunocompromised People, Based on U.S. FDA Feedback." 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 May 7, 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: May 7, 2024

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

INVIVYD

**Invivyd to Pursue Rapid Immunobridging Pathway to Potential EUA for Treatment of COVID-19 in Moderately to Severely Immunocompromised People, Based on U.S. FDA Feedback**

- *Pathway leverages immunobridging approach via serum virus neutralizing antibody (sVNA) titers enabled by prior successful COVID-19 treatment clinical trial "STAMP" conducted with prototype antibody adintrevimab*
- *Company anticipates submitting a COVID-19 treatment EUA application for PEMGARDA™ (pemivibart) imminently*
- *COVID-19 treatment EUA pathway offers a novel, rapid pathway to potential second EUA for pemivibart*
- *Invivyd leaves 2024 net product revenue and year-end cash guidance unchanged although potential near-term COVID-19 treatment EUA and associated commercial dynamics were not considered*
- *Further details on upcoming 1Q 2024 results call on May 9, 2024*

WALTHAM, Mass., May 7, 2024 (GLOBE NEWSWIRE) — Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced its intention to submit an emergency use authorization (EUA) application to the U.S. Food and Drug Administration (FDA) for pemivibart for the treatment of mild to moderate symptomatic COVID-19 in certain immunocompromised people utilizing a rapid immunobridging pathway. This immunobridging pathway leverages a similar approach Invivyd used to achieve its current EUA for PEMGARDA™ (pemivibart) for pre-exposure prophylaxis (PrEP) of COVID-19 in certain immunocompromised people and was aligned in principle with the FDA. The immunobridging pathway for COVID-19 treatment is enabled by data from the Phase 2/3 clinical trial (STAMP) of adintrevimab, the prototype monoclonal antibody (mAb), for the treatment of COVID-19[1] and data from the ongoing CANOPY Phase 3 clinical trial of pemivibart for PrEP of COVID-19. The potential COVID-19 treatment EUA request would focus on the critical treatment needs of people in the U.S. who have moderate-to-severe immune compromise and for whom alternative COVID-19 treatment options are not clinically appropriate or accessible. Subsequent to the anticipated submission of an EUA request, Invivyd plans to initiate a compact clinical trial focused on confirmatory safety, pharmacokinetics (PK), and clinical virology.

"We are glad to once again align with the FDA on a rapid pathway towards addressing a critical unmet medical need among immunocompromised people who may benefit from alternative approaches to treating their symptomatic COVID-19. In the past, immunoglobulin G (IgG) mAbs targeting the receptor binding domain (RBD) of the SARS-CoV-2 spike protein have been highly effective therapeutic options for symptomatic COVID-19, and we are happy to leverage our prior success and proprietary technology with the aim to serve both prevention and now treatment of symptomatic disease for immunocompromised people as soon as possible," commented Marc Elia, Chairman of the Invivyd Board of Directors. "Our current manufacturing plan contemplates approximately one hundred thousand doses available through the second half of 2024 and anticipated seasonal uptick in circulating virus to serve both PrEP and potential treatment uses. We are currently considering options to expand and accelerate product availability."

“Treatment of active COVID-19 infection, which presents a substantial risk to immunocompromised patients, is a medical context well suited for an infused antibody therapy, as prior COVID-19 treatment mAbs were generally provided via intravenous (IV) infusion to enhance the speed at which antiviral titers are delivered to patients in need,” said Mark Wingertzahn, SVP of Clinical Development and Medical Affairs. “We are moving with considerable urgency as we believe that immunobridging provides us with a more rapid and efficient pathway to deliver an important COVID-19 treatment option, complementing our efforts with PrEP.”

Observational studies have demonstrated that people who are immunocompromised continue to be disproportionally impacted by COVID-19-related hospitalizations and death.[2-3] In addition to small molecule treatment options, where appropriate a monoclonal antibody may be a highly attractive option to alter the course of established infection.

“It’s important to remember that SARS-CoV-2 still poses a major threat to many people, such as those who are significantly immunocompromised and at higher risk for severe outcomes if they develop a COVID-19 infection,” said Brian Koffman, MDCM (retired), MS Ed, Co-Founder, Executive Vice President and Chief Medical Officer of the CLL (Chronic Lymphocytic Leukemia) Society. “For people who develop a COVID-19 infection, today’s treatment options are not always adequate or clinically appropriate, especially for those who are immunocompromised and may be taking other drugs that are contraindicated for use with certain antivirals. For this vulnerable population, it would be extremely helpful to have a new monoclonal antibody as an option for treatment, a therapeutic approach that was shown during the earlier days of the pandemic to be highly effective against previous variants.”

Invivyd is maintaining its existing guidance of $150-$200 million in anticipated 2024 PEMGARDA net product revenue and year end cash guidance of at least $75 million in cash and cash equivalents, although the previously issued guidance was based on PEMGARDA being authorized for PrEP of COVID-19 in certain immunocompromised people and did not contemplate any potential sales for COVID-19 treatment or inventory build that may be required to deliver medicine timely to patients in need.

**About PEMGARDA**

PEMGARDA™ (pemivibart) is a half-life extended investigational monoclonal antibody (mAb). PEMGARDA was engineered from adintrevimab, Invivyd’s investigational mAb that has a robust safety data package and provided evidence of clinical efficacy in global Phase 2/3 clinical trials for both the prevention and treatment of COVID-19. PEMGARDA has demonstrated in vitro neutralizing activity in pseudotyped virus-like particle and authentic virus neutralization assays against major SARS-CoV-2 variants, including JN.1. PEMGARDA targets the SARS-CoV-2 spike protein receptor binding domain (RBD), thereby inhibiting virus attachment to the human ACE2 receptor on host cells.

PEMGARDA (pemivibart) injection (4500 mg), for intravenous use is an investigational mAb that has not been approved, but has been authorized for emergency use by the U.S. FDA under an EUA for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2. PEMGARDA is not authorized for use for treatment of COVID-19 or post-exposure prophylaxis of COVID-19. Anaphylaxis has been observed with PEMGARDA and the PEMGARDA Fact Sheet for Healthcare Providers includes a boxed warning for anaphylaxis. The most common adverse events (all grades, incidence ≥2%) observed in participants who have moderate-to-severe immune compromise treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea. For additional information, please see the PEMGARDA full product Fact Sheet for Healthcare Providers, including important safety information and boxed warning.

To support the EUA for PEMGARDA, an immunobridging approach was used to determine if PEMGARDA may be effective for pre-exposure prophylaxis of COVID-19. Immunobridging is based on the serum virus neutralizing titer-efficacy relationships identified with other neutralizing human mAbs against SARS-CoV-2. This includes adintrevimab, the parent mAb of pemivibart, and other mAbs that were previously authorized for EUA. There are limitations of the data supporting the benefits of PEMGARDA. Evidence of clinical efficacy for other neutralizing human mAbs against SARS-CoV-2 was based on different populations and SARS-CoV-2 variants that are no longer circulating. Additionally, the variability associated with cell-based EC50 value determinations, along with limitations related to pharmacokinetic data and efficacy estimates for the mAbs in prior clinical trials, impact the ability to precisely estimate protective titer ranges.

The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

**About Invivyd**

Invivyd, Inc. (Nasdaq: IVVD) is a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, 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. INVYMAB is designed to facilitate the rapid, serial generation of new monoclonal antibodies (mAbs) to keep pace with evolving viral threats. In March 2024, Invivyd received emergency use authorization (EUA) from the U.S. FDA for its first mAb in a planned series of innovative antibody candidates. Visit https://invivyd.com/ to learn more.

**References**


1. Ison, Michael G et al. "Efficacy and Safety of Adintrevimab (ADG20) for the Treatment of High-Risk Ambulatory Patients With Mild or Moderate Coronavirus Disease 2019: Results From a Phase 2/3, Randomized, Placebo-Controlled Trial (STAMP) Conducted During Delta Predominance and Early Emergence of Omicron." Open forum infectious diseases vol. 10,6 ofad279. 24 May. 2023, doi:10.1093/ofid/ofad279.
2. Evans, Rachael A et al. "Impact of COVID-19 on immunocompromised populations during the Omicron era: insights from the observational population-based INFORM study." The Lancet regional health. Europe vol. 35 100747. 13 Oct. 2023.
3. Singson, Jason Robert C et al. "Factors Associated with Severe Outcomes Among Immunocompromised Adults Hospitalized for COVID-19 - COVID-NET, 10 States, March 2020-February 2022." MMWR. Morbidity and mortality weekly report vol. 71,27 878-884. 8 Jul. 2022.

**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 plans to pursue a rapid immunobridging pathway to potential EUA for treatment of COVID-19 in moderately to severely immunocompromised people, including the company's beliefs regarding the potential speed and efficiency of such pathway; the company's anticipated submission of a COVID-19 treatment EUA request to the FDA for PEMGARDA (pemivibart), and the anticipated timing and focus of such potential EUA request; the company's research and clinical development efforts, and the timing thereof, including the potential initiation of a compact clinical trial subsequent to the anticipated submission of a COVID-19 treatment EUA request; the company's manufacturing plans and strategies, including its anticipated supply through the second half of 2024, and the potential to expand and accelerate product availability; the potential benefits of a new COVID-19 treatment mAb, if authorized or approved, to certain vulnerable populations; the company's anticipated 2024 PEMGARDA net product revenue and the company's projected 2024 year end cash and cash equivalents balance; the company's EUA for PEMGARDA for PrEP of COVID-19 in certain immunocompromised people; the company's devotion to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2; the design of the company's INVYMAB platform approach to facilitate the rapid, serial generation of new mAbs to keep pace with evolving viral threats; the company's expectation that PEMGARDA is the first mAb in a planned series of innovative antibody candidates; 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 company's ability to effectively utilize an immunobridging pathway to potential EUA for treatment of symptomatic COVID-19; whether the company is able to successfully submit a COVID-19 treatment EUA request to the FDA in the future, and the timing, scope and outcome of any such EUA request; uncertainties related to the regulatory authorization or approval process; changes in the regulatory environment; the timing and progress of the company's discovery, preclinical and clinical development activities; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of the company's 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, and interim data are subject to further analysis; the company's reliance on third parties with respect to virus assay creation and product candidate testing and with respect to its clinical trials; how long the EUA granted by the FDA in March 2024 for PEMGARDA for PrEP of COVID-19 in certain immunocompromised people will remain in effect and whether such EUA is revoked or revised by the FDA; the company's ability to build and maintain sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; changes in expected or existing competition; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of PEMGARDA or any other product candidate following regulatory authorization or approval; whether PEMGARDA or any other product candidate is able to demonstrate and sustain neutralizing activity against major SARS-CoV-2 variants,

particularly in the face of viral evolution; variability of results in models used to predict activity against SARS-CoV-2 variants; the complexities of manufacturing mAb therapies; the company's dependence on third parties to manufacture, label, package, store and distribute clinical and commercial supplies of its product candidates; whether the company is able to provide sufficient commercial supply of PEMGARDA to meet market demand; whether the company can obtain and maintain third-party coverage and adequate reimbursement for PEMGARDA or any other product candidate; the company's ability to leverage its INVYMAB platform approach to facilitate the rapid, serial generation of new mAbs to keep pace with evolving viral threats; any litigation and other proceedings or government investigations relating to the company; the company's ability to continue as a going concern; the company's ability to optimize operating expenses; 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, 2023 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.

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

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