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): February 21, 2025

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.

Nasdaq Minimum Bid Price Requirement Compliance

On February 21, 2025, Invivyd, Inc. (the "Company") received a letter from the Nasdaq Listing Qualifications Department of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it has regained compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Price Requirement") for continued listing on The Nasdaq Global Market.

As previously disclosed, on December 27, 2024, the Company received a letter from Nasdaq, notifying the Company that it was not in compliance with the Minimum Bid Price Requirement because the Company's common stock, $0.0001 par value per share (the "Common Stock"), had closed below the $1.00 per share minimum for 30 consecutive business days. To regain compliance with the Minimum Bid Price Requirement, the Common Stock was required to maintain a closing bid price of at least $1.00 per share for a minimum of ten consecutive business days.

In its letter dated February 21, 2025, Nasdaq indicated the Company has regained compliance with the Minimum Bid Price Requirement, and the matter is now closed.

Press Release

On February 24, 2025, the Company issued a press release entitled "FDA Declined Invivyd's Request to Expand Existing Emergency Use Authorization of PEMGARDA™ (pemivibart) to Include Treatment of Mild-to-Moderate COVID-19 For Immunocompromised Persons Who Have No Alternative Therapeutic Options; No Change to the Existing PEMGARDA EUA for Pre-Exposure Prophylaxis of COVID-19 in Certain Immunocompromised Patients." 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 February 24, 2025
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: February 24, 2025

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

Exhibit 99.1

FDA Declined Invivyd's Request to Expand Existing Emergency Use Authorization of PEMGARDA™ (pemivibart) to Include Treatment of Mild-to-Moderate COVID-19 For Immunocompromised Persons Who Have No Alternative Therapeutic Options; No Change to the Existing PEMGARDA EUA for Pre-Exposure Prophylaxis of COVID-19 in Certain Immunocompromised Patients

- FDA's reasoning appears to center on a belief that COVID-19 treatment immunobridging analyses for a monoclonal antibody (mAb) must meet a standard of superior antiviral activity rather than equivalent antiviral activity to past, highly effective, previously authorized and now inactive COVID-19 mAbs in a bridging analysis of sVNA[1] titer levels, otherwise the Agency is "unable to reasonably conclude that the known and potential benefits of pemivibart…outweigh the known and potential risks"
- Invivyd's submission to expand the PEMGARDA™ EUA to include COVID-19 treatment for certain immunocompromised patients who have no other therapeutic options provided the FDA with analyses demonstrating comparable antiviral activity between pemivibart and adintrevimab, the key antibody of interest for immunobridging, as well as analyses demonstrating predicted pemivibart clinical efficacy in-line with prior authorized mAb therapeutics, and well above currently authorized convalescent plasma
- In parallel with continuing efforts with the FDA to advance PEMGARDA as a COVID-19 treatment for certain immunocompromised patients, Invivyd plans to rapidly advance VYD2311 in collaboration with FDA given the ongoing and unacceptable burden of COVID-19 in America, including high rates of death, hospitalization, and Long COVID, reflective of the short and modest disease protection from the current standard of care for vulnerable patient populations
- The COVID-19 treatment opportunity for pemivibart was not contemplated in existing financial guidance

WALTHAM, Mass., February 24, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced that Invivyd's request to expand the existing emergency use authorization (EUA) for pre-exposure prophylaxis of COVID-19 EUA for PEMGARDA™ (pemivibart) to provide a treatment option for mild-to-moderate COVID-19 in adults and adolescents who have moderate-to-severe immune compromise due to certain medical conditions such as cancer and organ transplant, and for whom alternative COVID-19 treatment options are not accessible or clinically appropriate, was declined by the U.S. Food and Drug Administration (FDA). Existing PEMGARDA™ (pemivibart) EUA for pre-exposure prophylaxis of COVID-19 in certain immunocompromised patients remains in effect.

"This is a sad day for patients in need. Immunocompromised people who cannot access standard of care are once again left with no option for COVID-19 treatment. Pemivibart, in contrast to all other COVID-19 antibodies ever made, is active and in clinical use today in the U.S. as authorized. Pemivibart is safe

[1] sVNA stands for serum virus neutralizing antibody titers, the industry standard measurement of antibody antiviral activity

enough for certain immunocompromised patients who are not currently sick with COVID-19, but it is now being withheld from those same immunocompromised patients fighting active COVID-19 infection purportedly because its measured antiviral activity is in-line with, but does not clearly exceed, the activity of its key comparator antibody adintrevimab, as well as other comparative mAbs," commented Mark Wingertzahn, Invivyd's Senior Vice President of Clinical Development.

"It is disappointing that healthcare providers are unable to add the power of a mAb therapy for treatment of COVID-19 to our current therapeutic options. Current treatments such as PAXLOVID® may be contraindicated, clinically inappropriate, or not accessible for patients, especially among the immunocompromised who are most vulnerable and often have complex cases and medication regimens. We need tools like PEMGARDA™ immediately to lessen the ongoing, unacceptable burden of COVID-19 death and hospitalization," commented Dr. Alfred H. Kim, MD, PhD, Associate Professor of Medicine, Associate Professor of Pathology and Immunology, Washington University School of Medicine.

Invivyd plans in the near term to share detailed data and regulatory correspondence regarding pemivibart, VYD2311 and immunobridging of COVID-19 antibodies, so Americans can better appreciate the historic and recent governmental handling of these assets in contrast to COVID-19 vaccines and small molecule treatment.

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 the prevention and treatment of COVID-19. PEMGARDA has demonstrated in vitro neutralizing activity against major SARS-CoV-2 variants, including JN.1, KP.3.1.1 and XEC. 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 post-exposure prophylaxis of COVID-19. Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccinations, should receive COVID-19 vaccination. In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered at least 2 weeks after vaccination.

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. Further, 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. Additionally, certain SARS-CoV-2 viral variants may emerge that have substantially reduced susceptibility to PEMGARDA, and PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants.

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. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

About VYD2311

VYD2311 is a novel monoclonal antibody (mAb) candidate being developed for COVID-19 to continue to address the urgent need for new prophylactic and therapeutic options. The pharmacokinetic profile and antiviral potency of VYD2311 may offer the ability to deliver clinically meaningful titer levels through more patient-friendly means such as an intramuscular route of administration.

VYD2311 was engineered using Invivyd's proprietary integrated technology platform and is the product of serial molecular evolution designed to generate an antibody optimized for neutralizing contemporary virus lineages. VYD2311 leverages the same antibody backbone as pemivibart, Invivyd's investigational mAb granted emergency use authorization in the U.S. for the pre-exposure prophylaxis (PrEP) of symptomatic COVID-19 in certain immunocompromised patients, and 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 the prevention and treatment of COVID-19.

About Invivyd

Invivyd, Inc. (Nasdaq: IVVD) is a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2. Invivyd deploys a proprietary integrated technology platform unique in the industry designed to assess, monitor, develop, and adapt to create best in class antibodies. In March 2024, Invivyd received emergency use authorization (EUA) from the U.S. FDA for a monoclonal antibody (mAb) in its pipeline of innovative antibody candidates. 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,” “estimates,” “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 efforts with the FDA to advance PEMGARDA as a COVID-19 treatment for certain immunocompromised patients and plans to rapidly advance VYD2311 in collaboration with the FDA; expectations regarding the COVID-19 landscape and beliefs regarding limitations of current therapies for COVID-19; the potential of PEMGARDA™ to lessen the burden of COVID-19 death and hospitalization; the company’s plans to share detailed data and regulatory correspondence regarding pemivibart, VYD2311 and immunobridging of COVID-19 antibodies; the company’s ongoing research and development activities, as well as future potential research and development efforts; the potential of PEMGARDA as a mAb for PrEP of COVID-19 in certain adults and adolescents who have moderate-to-severe immune compromise; the potential of VYD2311 as a novel mAb candidate and the potential of VYD2311 to deliver clinically meaningful titer levels through more patient-friendly means; the company’s devotion to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2; 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 outcome of the company’s efforts with the FDA to advance PEMGARDA as a COVID-19 treatment for certain immunocompromised patients and VYD2311 in collaboration with the FDA; how long the EUA granted by the FDA for PEMGARDA for PrEP will remain in effect and whether the EUA is revised or revoked by the FDA; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for authorization or approval of the company’s product candidates; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of any product candidate following regulatory authorization or approval; changes in the regulatory environment; the timing, progress and results of the company’s discovery, preclinical and clinical development activities; the risk that results of nonclinical studies or clinical trials may not be predictive of future results, and interim data are subject to further analysis; 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 nonclinical studies; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; 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 and methods used to predict activity against SARS-CoV-2 variants; whether the epitope that pemivibart and VYD2311 targets remains structurally intact; whether the company’s product candidates are able to demonstrate and sustain neutralizing activity against major SARS-CoV-2 variants, particularly in the face of viral evolution; the company’s ability to maintain and expand sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; changes in expected or existing competition; 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, 2023 and the company’s Quarterly Report on

Form 10-Q for the quarter ended September 30, 2024, each 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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