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): July 6, 2026

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.)**

209 Church Street **New Haven, CT**	**06510**
(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 July 6, 2026, Invivyd, Inc. issued a press release entitled "Invivyd Announces Receipt of Twelve Months' Advanced Notice of Emergency Use Authorization (EUA) Termination for PEMGARDA® and Provides an Update on Next Steps with the U.S. FDA." A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated July 6, 2026
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: July 6, 2026

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

Exhibit 99.1

INVIVYD INC.

Invivyd Announces Receipt of Twelve Months' Advanced Notice of Emergency Use Authorization (EUA) Termination for PEMGARDA® and Provides an Update on Next Steps with the U.S. FDA

- *U.S. Department of Health and Human Services (HHS) announced advanced Notice of Termination of the COVID-19 EUA declaration, effective June 29, 2027*
- *Consequently, Invivyd received from the U.S. Food and Drug Administration (FDA) Notice of Termination of the PEMGARDA EUA, to be effective on June 29, 2027, after a twelve-month transition period*
- *Consistent with EUA transition processes, Invivyd is in dialogue with FDA about appropriate next steps for PEMGARDA*
- *Invivyd intends to pursue every avenue to secure permanent, high quality medical protection from COVID infection for immune-compromised and other vulnerable Americans*
- *PEMGARDA has demonstrated strong protection from COVID in a contemporary randomized clinical trial, has been growing in clinical use for more than two years, and is a critical non-vaccine option for vulnerable Americans that combines high antiviral activity and attractive safety demonstrated in clinical trials and post-authorization monitoring*

NEW HAVEN, Conn., July 06, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced that the U.S. Food and Drug Administration (FDA) has sent Invivyd a Notice of Termination for the PEMGARDA® (pemivibart) Emergency Use Authorization (EUA), following the U.S. Department of Health and Human Services' (HHS) announcement of advanced Notice of Termination of the COVID-19 EUA declaration on June 30, 2026 (link), with an effective date of June 29, 2027. Consequently, the EUA for PEMGARDA is set to terminate on June 29, 2027. PEMGARDA (pemivibart) is Invivyd's investigational monoclonal antibody authorized by the FDA under an EUA since March 2024 for the pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescents 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.

The Secretary of HHS is obligated by law under Section 564(b)(5) of the Federal Food, Drug, and Cosmetic Act, codified as 21 U.S.C. § 360bbb-3(b)(5), (link) to provide sponsors such as Invivyd written notice of potential obstacles for an EUA product's approval, including specific actions to

be taken by HHS and Invivyd to overcome the same. Invivyd is in active dialogue with FDA on next steps, although, to date, neither HHS nor FDA has expressly provided Invivyd with such written advice regarding a PEMGARDA regulatory approval pathway.

“The end of a formal emergency for COVID products is in many ways overdue,” commented Marc Elia, Chairman of Invivyd’s Board of Directors. “While an EUA designation granted to PEMGARDA by the U.S. FDA in March 2024 has allowed thousands of vulnerable Americans access to a non-vaccine COVID-prevention option for over two years, the EUA designation is not a product approval. At Invivyd, we believe PEMGARDA has sufficient clinical and post-authorization data to support Biologics License Application (BLA) submission and approval, and we regret that procedural uncertainty has needlessly intruded into our work on behalf of vulnerable Americans, who may find these headlines worrying and confusing.” Mr. Elia continued, “Our view at Invivyd is unchanged over years: Invivyd’s monoclonal antibodies for COVID prevention have generated more randomized clinical data than comparable COVID-19 vaccine boosts, which have all received full approval via BLA, and we feel as though a full approval of PEMGARDA is well-warranted at this time by the totality of demonstrated safety and efficacy data both from the CANOPY pivotal trial and from growing clinical practice. We are in dialogue with the FDA on appropriate next steps.”

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, XEC, LP.8.1 and XFG. 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 the treatment of COVID-19, Long COVID, or COVID-19 Post-Vaccination Syndrome, or for 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 reactions included systemic infusion-related reactions and hypersensitivity reactions, local infusion site reactions, and infusion site infiltration or extravasation. 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. 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.

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 authorization revoked sooner. On June 30, 2026, the U.S. Department of Health and Human Services (HHS) announced notice of the termination of the declaration, effective June 29, 2027.

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.

Trademarks are the property of their respective owners.

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,” “plans,” “potential,” “predicts,” “projects,” “future,” and “target” 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, expectations regarding the future termination of the EUA granted by the FDA for PEMGARDA and the transition process; the company’s intention to pursue every avenue to secure permanent, high quality medical protection from COVID infection for immune-compromised and other vulnerable Americans; the company’s belief that PEMGARDA has sufficient clinical and post-authorization data to support BLA submission and approval; expectations regarding potential development and regulatory pathways and dialogue between Invivyd and regulators; plans related to the company’s research and development activities; expectations regarding the COVID landscape and potential advantages of mAbs; the company’s business strategies and objectives; the company’s future prospects; 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: uncertainties regarding the impact of the future termination of the EUA granted by the FDA for PEMGARDA on the business of the company; uncertainties related to the transition period for PEMGARDA, regulatory authorization or approval processes, and available development and regulatory pathways; whether sufficient data is available to support BLA submission and approval for PEMGARDA, and the potential timing thereof; changes in the regulatory environment; the outcome of the company’s engagement with regulators; the timing, progress, and results of the company’s discovery, preclinical, and clinical development activities; unexpected safety or

efficacy data observed during preclinical studies or clinical trials; 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; the ability to maintain a continued acceptable safety, tolerability, and efficacy profile of any product candidate following regulatory authorization or approval; uncertainties regarding market acceptance, payor coverage, and reimbursement, or future revenue generated by any authorized or approved product; the success of the company's in-house sales force, and the company's ability to maintain and expand sales, marketing, and distribution capabilities to successfully commercialize any authorized or approved product; changes in expected or existing competition; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; variability of results in models and methods used to predict activity against SARS-CoV-2 variants; whether the epitope that pemivibart targets remains structurally intact and 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 risk that a lack of awareness of mAb therapies and regulatory scrutiny of mAb therapies may adversely impact the development or commercial success of the company's product candidates; the company's reliance on third parties; complexities of manufacturing mAb therapies; macroeconomic and political uncertainties; 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, 2025, as 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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