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): June 14, 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 June 14, 2024, Invivyd, Inc. issued a press release entitled "Invivyd Announces Antiviral Activity of VYD222 (pemivibart) Against SARS-CoV-2 KP.1.1 FLiRT & KP.3 Variants." 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 June 14, 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: June 14, 2024

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

Exhibit 99.1

Invivyd Announces Antiviral Activity of VYD222 (pemivibart) Against SARS-CoV-2 KP.1.1 FLiRT & KP.3 Variants

- *Pseudovirus in vitro neutralization data show continued neutralizing activity of VYD222 (pemivibart) against the KP.1.1 FLiRT and KP.3 SARS-CoV-2 variants, virus selections representative of current dominant strains and the most recent FLiRT-containing viruses*
- *Invivyd's new data is broadly concordant with preliminary pseudovirus data showing neutralizing activity of VYD222 against KP.2 FLiRT and KP.3 variants recently publicized by an independent academic lab*
- *Invivyd's next anticipated SARS-CoV-2 monoclonal antibody (mAb) candidate, VYD2311, also shows continued in vitro neutralization activity in pseudovirus assays against these predominant strains to date*

WALTHAM, Mass., June 14, 2024 (GLOBE NEWSWIRE) – Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced that VYD222 (pemivibart), a half-life extended investigational monoclonal antibody (mAb), shows continued in vitro neutralization activity in pseudovirus assays designed to represent the predominant emerging variants of SARS-CoV-2, including the KP.1.1 FLiRT and KP.3 variants. FLiRT variants account for over half of circulating SARS-CoV-2 variant sequences for the two-week period ending June 8, 2024, with KP.3 prevalence increasing and the Centers for Disease Control and Prevention (CDC) predicting it will become the most dominant SARS-CoV-2 lineage nationally in the near term. Of note, VYD222 has previously demonstrated antiviral in vitro neutralization activity against ancestral XBB lineage viruses that also encoded mutations described in the FLip and FLiRT nomenclature.

"The VYD222 epitope has remained stable with a calculated 99.8% of sequences submitted to Global Initiative on Sharing All Influenza Data (GISAID) in 2024 demonstrating strict conservation at positions within five angstroms of the VYD222 binding interface," said Dr. Robert Allen, Chief Scientific Officer of Invivyd. "Of note, there have been no observed changes to residues within this defined VYD222:RBD binding interface for the spike proteins encoded by the KP.1.1 FLiRT and KP.3 variants. We remain pleased with the continued demonstrated in vitro neutralization activity of VYD222 and VYD2311 and will continue monitoring and assessing going forward."

Invivyd continually monitors the SARS-CoV-2 variant landscape using VivydTools, its in-house proprietary software that tracks virus variation across SARS-CoV-2, towards enabling early detection and characterization of neutralization activity of emergent variants, including FLiRT variants.

About VYD222
VYD222 is a half-life extended monoclonal antibody (mAb) candidate being investigated for the pre-exposure prophylaxis (prevention) of COVID-19 and the treatment of mild to moderate symptomatic COVID-19 in certain immunocompromised adults and adolescents. VYD222 has demonstrated in vitro neutralizing activity in pseudotyped virus-like particle and authentic virus neutralization assays against various pre-Omicron and Omicron variants, including JN.1. VYD222 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. VYD222 has not been approved by the U.S. FDA or any other regulatory authority.

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.

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," "predicts," "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 continued neutralization activity of VYD222 and VYD2311 against dominant SARS-CoV-2 variants, including KP.1.1 and KP.3; predictions regarding the future of the SARS-CoV-2 variant landscape and the company's plans to monitor such landscape using its in-house proprietary software designed towards enabling early detection and characterization of neutralization activity of emerging variants; 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 plans for a 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: whether VYD222, VYD2311 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; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; whether the company is able to successfully submit any future EUA request to the FDA, 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 ability to maintain a continued acceptable safety, tolerability and efficacy profile of any product candidate

following regulatory authorization or approval; 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; 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; changes in expected or existing competition; the complexities of manufacturing mAb therapies; 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; 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.

Contacts:
Media Relations
(781) 208-1747
media@invivyd.com

Investor Relations
(781) 208-1747
investors@invivyd.com