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 30, 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Departure of Jeremy Gowler as Interim Chief Executive Officer, Chief Operating Officer and Chief Commercial Officer

Jeremy Gowler, the Interim Chief Executive Officer, Chief Operating Officer and Chief Commercial Officer of Invivyd, Inc. (the "Company"), ceased serving as an executive officer and as the Company's "principal executive officer," effective as of May 30, 2024, with his employment terminating on June 29, 2024. The Board of Directors of the Company is continuing its search for a permanent Chief Executive Officer.

Upon Mr. Gowler executing a separation agreement, and subject to Mr. Gowler agreeing to a release of claims and complying with certain other continuing obligations contained therein, the Company will pay Mr. Gowler the amounts owed to him pursuant to Section 5 of that certain Employment Agreement, dated September 17, 2022, by and between the Company and Mr. Gowler, which was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission ("SEC") on December 6, 2022, as amended by that certain First Amendment, dated April 11, 2024, which was filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 12, 2024.

Appointment of William Duke, Jr. as Principal Executive Officer

Effective May 30, 2024, William Duke, Jr., the Company's Chief Financial Officer, will serve as the Company's "principal executive officer". Mr. Duke will continue to serve as "principal financial officer" and "principal accounting officer" of the Company.

Mr. Duke, 51, has served as the Company's Chief Financial Officer since September 2023. He brings more than 25 years of finance, accounting, and operations experience, including over a decade of senior leadership experience in the biotechnology industry. Prior to joining the Company, Mr. Duke served as the Chief Financial Officer of Apexigen, Inc. from June 2022 to August 2023 where he was responsible for all areas of finance and accounting and helped guide the company through its sale to Pyxis Oncology, Inc. Before Apexigen, Mr. Duke was Chief Financial Officer of Kaleido Biosciences, Inc. from November 2019 to April 2022, where he led the successful completion of multiple financings. Prior to Kaleido Biosciences, he was Chief Financial Officer of Pulmatrix, Inc. from June 2015 to November 2019, where he helped negotiate the company's first product partnership and led the successful completion of several public offerings. Prior to that, he held senior financial leadership roles at Valeritas, Inc. and Genzyme Corporation, where he helped in the sale of the company to Sanofi. Mr. Duke is a certified public accountant and holds a B.S. in Business Administration from Stonehill College and an M.B.A. from Bentley College.

There are no arrangements or understandings between Mr. Duke and any other persons pursuant to which Mr. Duke was designated as the "principal executive officer" of the Company. There are also no family relationships between Mr. Duke and any director or executive officer of the Company and Mr. Duke has no direct or indirect interest in any transaction or proposed transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Item 8.01. Other Events.

On May 31, 2024, the Company issued a press release announcing changes to its management team, including the appointment of Timothy Lee as the Chief Commercial Officer of the Company. A copy of the press release is being filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in this Item 8.01.

On May 31, 2024, the Company issued a press release announcing general alignment with the U.S. Food and Drug Administration on an expedient, repeatable immunobridging pathway to future potential emergency use authorizations for serial, novel monoclonal antibodies for the prevention and treatment of symptomatic COVID-19. A copy of the press release is being filed as Exhibit 99.2 to this Current Report on Form 8-K 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 31, 2024
99.2	Press Release, dated May 31, 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 31, 2024

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

Invivyd Announces the Appointment of Timothy Lee as Chief Commercial Officer

- *Mr. Lee joins Invivyd with a history of high-quality commercial execution at Alexion, Biohaven and Amylyx*
- *Appointment intended to accelerate the addition of commercial capabilities associated with orphan medicines to the ongoing PEMGARDA™ commercial launch*
- *William Duke, Jr., Chief Financial Officer, appointed as Principal Executive Officer*

WALTHAM, Mass., May 31, 2024 (GLOBE NEWSWIRE) — Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced that Timothy Lee will be appointed Invivyd's Chief Commercial Officer and will join the company's executive leadership team. Mr. Lee's appointment follows the decision by the Board of Directors to eliminate the Chief Operating Officer role as part of its ongoing efforts to reallocate resources to support the launch of PEMGARDA, resulting in Jeremy Gowler's departure. In the ongoing transitional period, Invivyd's Chief Financial Officer, William Duke, Jr. will assume the role of Principal Executive Officer, and the Board of Directors will continue its ongoing search for a permanent Chief Executive Officer.

"Invivyd is off to an impressive start serving populations vulnerable to COVID-19. The company has a unique technology platform, industrial strategy and a commercial phase asset in PEMGARDA to show for their rapid and thoughtful approach to addressing the ongoing risk of COVID-19. COVID-19 represents intolerable medical risk for large immunocompromised and high-risk populations that, taken together, resemble very large orphan-style, highly motivated and vulnerable populations. Working together with the dedicated Invivyd team, I look forward to leveraging my network, experience and expertise to accelerate the company's execution over the long term as we aim to provide durable protection to this population through serial innovation of best-in-class medicines," said Tim Lee.

"Now is the right time to focus our leadership on commercial excellence, and Tim's demonstrated track record of leading sales growth and successfully launching multiple global products in rare disease and general medicine markets makes him exceptionally well-suited to accelerate Invivyd's growth trajectory. I am confident that Tim is the right commercial leader to advance Invivyd's evolution," said Marc Elia, Chairman of the Invivyd Board of Directors. "On behalf of the Board, I would like to thank Jeremy for his valuable contributions to our company's operations over the past year and a half."

Tim Lee is a highly experienced commercial leader with an extraordinary track record of building commercial teams, leading successful product launches, and delivering strong results. Under his recent sales leadership at Amylyx, the commercial organization generated $390 million in net product revenue in 14 months and was on track to be in the top five orphan drug launches. Tim also previously held key commercial leadership roles across a variety of life science companies including Biohaven Pharmaceuticals and Alexion Pharmaceuticals.

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 address 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.

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 a global Phase 2/3 clinical trial for 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.

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 anticipated benefits of the company's management transition; the company's plans and expectations related to the commercial launch of PEMGARDA; the company's potential growth trajectory and anticipated evolution; the future of the COVID-19 landscape; the company's aim to provide durable protection to certain populations through serial innovation of best-in-class medicines; the company's EUA for PEMGARDA for pre-exposure prophylaxis (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: potential challenges or disruptions to the business as a result of the company's management transition; how long the EUA granted by the FDA for PEMGARDA for COVID-19 PrEP in certain adults and adolescents with moderate-to-severe immune compromise will remain in effect and whether such EUA is revoked or revised by the FDA; the company's ability to maintain and expand sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; changes in expected or existing competition; 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 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 ability to maintain a continued acceptable safety, tolerability and efficacy profile of PEMGARDA or any other product candidate following regulatory authorization or approval; 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; variability of results in models used to predict activity against SARS-CoV-2 variants; 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; 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 address 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.

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INVIVYD

Invivyd Announces General Alignment with U.S. FDA on a Repeatable, Expedient Emergency Use Authorization Pathway for the Prevention and Treatment of Symptomatic COVID-19, Based on Compact Clinical Programs to Establish Safety and Immunobridging for Serial Monoclonal Antibodies

- *Newly outlined pathway provides a practical, expedient, repeatable immunobridging approach to potential emergency use authorization of serial, novel monoclonal antibodies (mAbs) to prevent and treat COVID-19*
- *Pathway provides for the establishment of a master, registrational clinical trial protocol that is anticipated to streamline the evaluation of new mAbs in compact clinical programs*
- *Utilizing this framework, Invivyd plans to rapidly move towards a registrational clinical trial of VYD2311 that evaluates intravenous (IV) and potentially other routes of administration*

WALTHAM, Mass., May 31, 2024 (GLOBE NEWSWIRE) — Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced general alignment with the U.S. Food and Drug Administration (FDA) on an expedient, repeatable immunobridging pathway to future potential emergency use authorizations (EUAs) for serial, novel monoclonal antibodies (mAbs) for the prevention and treatment of symptomatic COVID-19. Coupled with Invivyd's proprietary mAb technology platform and engineering capabilities, this pathway provides the company with the opportunity to rapidly, efficiently, and durably deliver high value medicines that prevent and treat symptomatic COVID-19 in vulnerable populations.

This pathway provides for the establishment of a master, registrational clinical trial protocol that could obviate the need to submit a new protocol for the evaluation of each new mAb, streamlining the process required to evaluate new mAbs in compact clinical programs envisioned to include hundreds of participants (e.g., 300-600) exposed to a new mAb, with the specific number of exposures to be determined in consultation with the FDA. This compact, repeatable immunobridging pathway is similar to the approach Invivyd used to obtain an EUA for PEMGARDA™ for pre-exposure prophylaxis (PrEP) but would leverage a more efficient route to obtaining the safety and pharmacokinetics (PK) data that could support future potential EUA requests. The direct clinical cost of generating the safety and PK data contemplated in this pathway is estimated at $25-40 million.

"We are pleased to gain general alignment with the FDA on a repeatable, rapid pathway toward addressing the ongoing, critical unmet need for novel options for the prevention and treatment of symptomatic COVID-19. As the speed of SARS-CoV-2 viral evolution has become the defining feature that limits antibody development and commercialization, our work over the last two years has focused on driving novel development pathways to allow our technology to match or exceed the pace of viral evolution," commented Marc Elia, Chairman of the Invivyd Board of Directors. "We look forward to discussing this approach with global regulators outside the U.S., as it represents a potentially transformational pathway to bring high value medicines to patients in need in a repeatable fashion, apace with rapid viral evolution."

"Our alignment on a defined pathway to potential future EUAs represents an important step forward for unlocking this unique class of medicines that can potentially both treat and prevent COVID-19," said Mark Wingertzahn, SVP of Clinical Development and Medical Affairs.

“The central challenge for advancing this COVID-19 mAb field has been the need for rapid discovery innovation combined with a rapid, clear, and reliable pathway for establishing the clinical evidence that can bring molecules to patients in need in an efficient manner. We are looking forward to innovating within this defined pathway as we seek to improve the patient and system-friendliness of our molecules by exploring, for example, intramuscular and other presentations that may have access advantages for both PrEP and treatment of COVID-19.”

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timing and progress of the company's discovery, preclinical and clinical development activities; the company's ability to streamline the evaluation of new mAbs in compact clinical programs through establishment of a master, registrational clinical trial protocol; 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; 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; 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.

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