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): April 4, 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 April 4, 2024, Invivyd, Inc. (the "Company") issued a press release entitled "Invivyd Provides PEMGARDA™ Launch Update and Announces 2024 Net Product Revenue Guidance in the Range of $150 Million to $200 Million". A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference in this Item 8.01.

On April 4, 2024, the Company also posted an updated corporate presentation on its website at www.invivyd.com. A copy of the presentation is filed herewith as Exhibit 99.2 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 April 4, 2024
99.2	Corporate Presentation, dated April 4, 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: April 4, 2024

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

Exhibit 99.1

Invivyd Provides PEMGARDA™ Launch Update and Announces 2024 Net Product Revenue Guidance in the Range of $150 Million to $200 Million

- PEMGARDA now commercially available in the U.S. for pre-exposure prophylaxis (PrEP) of COVID-19 in certain adults and adolescents with moderate-to-severe immune compromise
- Based on anticipated net product revenue and continued optimization of operational expenses, company expects to end 2024 with at least $55 million in cash and cash equivalents
- Conference call today at 5 pm ET to discuss PEMGARDA launch progress

WALTHAM, Mass., April 4, 2024 (GLOBE NEWSWIRE) — Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company on a mission to protect the vulnerable from serious viral infectious diseases, today announced that PEMGARDA™ is now available for purchase in the U.S.

On March 22, 2024, PEMGARDA (pemivibart) injection, for intravenous use, received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) 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.

“I am very pleased to announce that, in less than two weeks from receiving EUA, PEMGARDA is now commercially available for order across the U.S.,” said Dave Hering, Chief Executive Officer. “This is a remarkable achievement for our organization and for the immunocompromised individuals we serve. With product now available, today we are providing initial PEMGARDA net product revenue guidance in the range of $150 million to $200 million for the full year 2024. Based on this anticipated net product revenue and our continued optimization of operating expenses, we expect to end 2024 with at least $55 million in cash and cash equivalents.”

PEMGARDA is available by prescription through a network of authorized specialty distributors. Healthcare professionals seeking to obtain PEMGARDA for their patients should contact their primary vendor for ordering information or contact Invivyd at 1-800-890-3385 for more information. For additional information about PEMGARDA, please see the full product Fact Sheet for Healthcare Providers, including important safety information and boxed warning.

Conference Call & Webcast

Invivyd will host a conference call and webcast today, Thursday, April 4 at 5 pm ET. A live audio webcast will be available at https://investors.invivyd.com/. Listeners can register for the webcast via this link. Analysts wishing to participate in the question-and-answer session should use this link. A replay of the webcast will be available in the investor section of the company’s website approximately two hours after the end of the call. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 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, the dominant variant in the U.S. currently according to estimates from the Centers for Disease Control and Prevention. 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 EC_{50} 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 commercial-stage company on a mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, 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," "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 potential of PEMGARDA as a mAb for pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescents (12 years of age and older weighing at least 40 kg) with moderate-to-severe immune compromise; the company's plans related to the commercialization of PEMGARDA, including expectations regarding availability of PEMGARDA; 2024 financial guidance, including the company's anticipated net product revenue and projected cash and cash equivalents balance; the company's anticipated continued optimization of operating expenses; the company's ongoing research and clinical development efforts, and the timing thereof; the company's mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, 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: how long the EUA granted by the FDA for PEMGARDA will remain in effect and whether the 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 timing and progress of the company's discovery, preclinical and clinical development activities; the uncertainties and timing of the regulatory authorization or approval process, and available development and regulatory pathways for authorization or approval of the company's product candidates; changes in the regulatory environment; 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 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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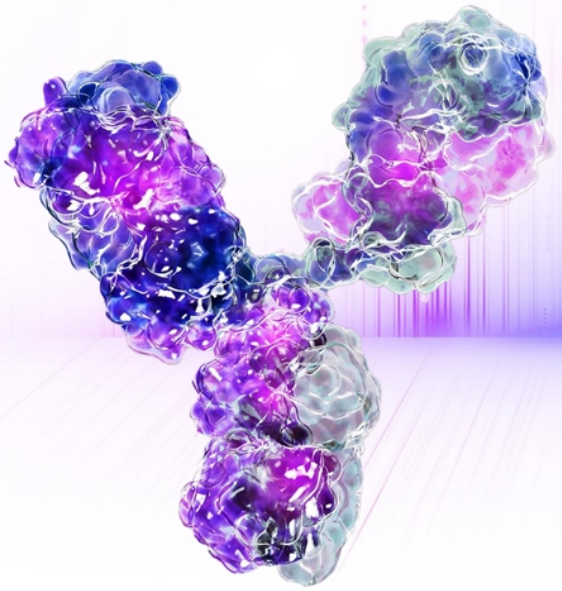
Exhibit 99.2

INVIVYD



PEMGARDA™ LAUNCH UPDATE

April 4, 2024

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Statements in this presentation that are not statements of historical fact are forward-looking statements. Words such as "may," "will," "should," "expect," "plan," "anticipate," "seek," "could," "intend," "target," "aim," "project," "designed to," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. Forward-looking statements include statements concerning, among other things, the potential of PEMGARDA™ as a monoclonal antibody (mAb) for pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescents (12 years of age and older weighing at least 40 kg) with moderate-to-severe immune compromise; our plans and strategy related to the launch and commercialization of PEMGARDA, including expectations regarding availability of PEMGARDA; 2024 financial guidance, including the company's anticipated net product revenue and projected cash and cash equivalents balance; the company's anticipated continued optimization of operational spend; our plans to share launch metrics in the future; our expectations about the size of target patient populations and the potential market opportunity for our product candidates, as well as our market position; the future of the COVID-19 landscape; the progress and timing of our ongoing research and clinical development activities and future plans; the potential of our INVYMAB™ platform approach to enable the rapid, serial generation new mAbs; our business strategies and objectives, and ability to execute on them; our future prospects; and other statements that are not historical fact. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: how long the Emergency Use Authorization (EUA) granted by the U.S. Food and Drug Administration (FDA) for PEMGARDA will remain in effect and whether the EUA is revoked or revised by the FDA; our ability to build and maintain sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; whether we are able to provide sufficient commercial supply of PEMGARDA to meet market demand; whether we can timely obtain and maintain third-party coverage and adequate reimbursement for PEMGARDA or any other product candidate; 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; changes in expected or existing competition; the timing and progress of our discovery, preclinical and clinical development activities; our ability to leverage our INVYMAB platform approach to enable the rapid, serial generation of new mAb candidates; the uncertainties and timing of the regulatory authorization or approval process, and available development and regulatory pathways for authorization or approval of our product candidates; changes in the regulatory environment; 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; whether we are able to successfully submit an EUA for any other product candidate in the future, and the outcome and timing of any such EUA submission; the predictability of clinical success of our 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; our reliance on third parties with respect to virus assay creation and product candidate testing and with respect to our clinical trials; variability of results in models used to predict activity against SARS-CoV-2 variants; the complexities of manufacturing mAb therapies; our dependence on third parties to manufacture, label, package, store and distribute clinical and commercial supplies of our product candidates; any litigation and other proceedings or government investigations relating to the company; our ability to continue as a going concern; our ability to optimize operating expenses; and whether we have adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause our actual results to differ materially from those expressed or implied in the forward-looking statements in this presentation are described under the heading "Risk Factors" in our most recent Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission (SEC), and in our other filings with the SEC, and in our future reports to be filed with the SEC and available at www.sec.gov. Forward-looking statements contained in this presentation are made as of this date, and we undertake no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

AGENDA

1. **Opening remarks & business updates**
   - **Dave Hering**, Chief Executive Officer
2. **Commercial progress and plans**
   - **Jeremy Gowler**, Chief Operating & Commercial Officer
3. **Financial summary and updates**
   - **Bill Duke**, Chief Financial Officer
4. **Q&A**

LESS THAN 2 WEEKS AFTER RECEIVING AN EUA FOR PEMGARDA, EXCITING PROGRESS HAS BEEN MADE

- PEMGARDA is now available for order in the U.S. through major distributors
- **Based on anticipated 2024 net product revenue in the range of $150-200 million and continued optimization of operational spend, company expects to end 2024 with at least $55 million in cash and cash equivalents**

$5,775 wholesale acquisition cost (WAC)

PEMGARDA has not been approved, but has been authorized for emergency use by FDA under an emergency use authorization (EUA), for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents (12 years of age and older weighing at least 40 kg) with moderate-to-severe immune compromise.

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 is revoked sooner.

For additional information, please see the PEMGARDA full product Fact Sheet for Healthcare Providers, including important safety information and boxed warning.

INVIVYD CONTINUES TO RAPIDLY EXECUTE TO PLAN

Our commercial strategy is built around 3 main phases

1 Product Availability

- [x] Publish WAC in pricing compendia
- [x] Make product available for order through major distributors
- [ ] Receive and ship first order

2 Securing Reimbursement & Access

- [x] Deploy national account managers focused on payor engagement
- [ ] Obtain HCPCS code from CMS
- [ ] Secure inclusion in institutional formularies, as needed
- [ ] Obtain coverage from major commercial payors

3 Full Commercial Implementation

- [ ] Fully deploy contracted Key Account Managers (KAMs)
- [ ] Activate targeted awareness campaigns
- [ ] Expand utilization within authorized population

WAC: Wholesale acquisition cost; HCPCS: Healthcare Common Procedure Coding System; CMS: Centers for Medicare & Medicaid Services

WE PLAN TO SHARE SEVERAL LAUNCH METRICS TO PROVIDE VISIBILITY INTO OUR PROGRESS

PEMGARDA
(pemivibart) injection

Anticipated metrics:

- Patient lives covered by CMS & commercial payors
- Progress reaching/calling on top 200 institutions identified
- Number of accounts that have ordered product
- Number of accounts placing reorders
- Number of new accounts ordering product

CMS: Centers for Medicare & Medicaid Services

FINANCIAL SUMMARY & UPDATES

Financial summary:

- Cash and cash equivalents of $200.6M as of Dec 31, 2023
- Anticipated 2024 net product revenue in the range of $150M-$200M
- Plans to continue optimization of operational spend
- **We expect to end 2024 with at least $55M in cash and cash equivalents**, based on existing cash and cash equivalents, $40.5M in gross proceeds raised from ATM facility in Feb 2024, anticipated 2024 net product revenue, and continued optimization of operational spend

Insights on anticipated margins:

- We expect to begin reporting PEMGARDA net product revenue and associated COGS in Q2 2024 earnings update
- Notably, in connection with receiving an EUA from the FDA, we began capitalizing inventory costs in March 2024
- Prior to receiving an EUA, such costs were recorded as R&D expenses in the period incurred
  - As a result, initial gross margins will be anomalous; however, had our pre-EUA manufacturing costs been capitalized, our expected margins would be in line with other biologics products, approaching 80%

ATM: At-the-market; COGS: cost of goods sold; R&D: Research and development

INVIVYD

Q&A

INVIVYD

THANK YOU!