

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 11, 2024

Invivyd, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40703
(Commission
File Number)

85-1403134
(IRS Employer
Identification No.)

1601 Trapelo Road, Suite 178
Waltham, MA
(Address of Principal Executive Offices)

02451
(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 Chief Executive Officer and Director

David Hering, the Chief Executive Officer of Invivyd, Inc. (the “Company”), ceased serving as an executive officer and as the Company’s “principal executive officer”, effective as of April 11, 2024, with his employment terminating on May 11, 2024. The Board of Directors of the Company (the “Board”) is instituting a search for Mr. Hering’s successor as permanent Chief Executive Officer.

Upon Mr. Hering executing a separation agreement, and subject to Mr. Hering agreeing to a release of claims and complying with certain other continuing obligations contained therein, the Company will pay Mr. Hering the amounts owed to him pursuant to Section 5 of that certain Employment Agreement, dated July 5, 2022, by and between the Company and Mr. Hering, 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 July 5, 2022, as amended by that certain First Amendment, dated June 15, 2023, filed as Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q filed with the SEC on August 10, 2023 (as amended, the “Hering Employment Agreement”).

In connection with Mr. Hering ceasing to serve as Chief Executive Officer, Mr. Hering has also resigned from the Board pursuant to the terms of the Hering Employment Agreement. The Board also reduced the size of the Board from nine (9) members to eight (8) members.

Appointment of Jeremy Gowler as Interim Chief Executive Officer

On April 11, 2024, the Board appointed Jeremy Gowler, the Company’s current Chief Operating Officer and Chief Commercial Officer, as the Company’s Interim Chief Executive Officer and designated him as the Company’s “principal executive officer”, effective immediately. Mr. Gowler will remain as the Company’s Chief Operating Officer and Chief Commercial Officer while serving as Interim Chief Executive Officer. In connection with the management transition and until a permanent Chief Executive Officer is named, Mr. Gowler will work in collaboration with an executive committee of the Board led by Marc Elia, the Chairperson of the Board, which committee, along with the Board, will provide oversight and strategic guidance on the business and affairs of the Company.

Mr. Gowler, 47, has served as the Company’s Chief Operating Officer and Chief Commercial Officer since December 2022. Most recently, Mr. Gowler held the role of Global Head of Commercial for the Biopharmaceutical business of Sandoz (a division of Novartis) from April 2020 until his departure in 2022 to join the Company. Mr. Gowler began his career at Novartis in 2002 and progressed through roles of increasing responsibility in the areas of marketing, sales, medical affairs and operations in Canada, the U.S. and in Switzerland until his departure in 2014. He then joined PaxVax, a private equity backed biotechnology company, where he held the role of VP, Global Commercial from 2014 until October 2018. PaxVax was sold to Emergent Biosolutions in 2018, where Mr. Gowler became VP of Global Commercial for Emergent’s vaccine business unit until his departure for Sandoz in March 2020. Mr. Gowler holds a BSc with a double major in Biology and Environmental Studies from the University of Victoria and a Dipl T in Marketing Management from the British Columbia Institute of Technology.

In connection with Mr. Gowler’s appointment as Interim Chief Executive Officer, the Company and Mr. Gowler entered into an amendment (the “Gowler Amendment”) to that certain employment agreement, dated September 17, 2022, 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 SEC on December 6, 2022 (the “Gowler Employment Agreement”). Pursuant to the Gowler Amendment, the Company will pay Mr. Gowler an additional monthly payment of \$5,000 while Mr. Gowler serves as Interim Chief Executive Officer. In addition, for calendar year 2024, Mr. Gowler’s annual bonus will be calculated as follows: (i) for the period during which Mr. Gowler serves only as Chief Operating Officer and Chief Commercial Officer, Mr. Gowler’s target bonus will be forty percent (40%) of Mr. Gowler’s actual base salary for the calendar year 2024; and (ii) for the period during which Mr. Gowler serves as Interim Chief Executive Officer, his target bonus will be fifty-five percent (55%) of an assumed annualized base salary of \$525,000 (calculated using Mr. Gowler’s base salary of \$465,000 plus the additional amounts payable as Interim Chief Executive Officer on an annualized basis). The Gowler Amendment also provides, among other things, that neither the removal of Mr. Gowler’s Interim Chief Executive Officer title, nor the diminution of or removal of the interim related duties, will constitute grounds for “Good Reason” pursuant to Section 3(e) of the Gowler Employment Agreement.

There are no arrangements or understandings between Mr. Gowler and any other persons pursuant to which Mr. Gowler was appointed as Interim Chief Executive Officer of the Company. There are also no family relationships between Mr. Gowler and any director or executive officer of the Company and Mr. Gowler 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.

The foregoing description of the Gowler Amendment is only a summary and is qualified in its entirety by reference to the complete terms and conditions of the Gowler Amendment, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On April 12, 2024, the Company issued a press release announcing changes to its management team. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 7.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
10.1	First Amendment to the Employment Agreement of Jeremy Gowler, dated April 11, 2024, by and between Invivyd, Inc. and Jeremy Gowler
99.1	Press Release, dated April 12, 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 12, 2024

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

**FIRST AMENDMENT TO THE
EMPLOYMENT AGREEMENT OF JEREMY GOWLER**

This FIRST AMENDMENT TO THE EMPLOYMENT AGREEMENT OF JEREMY GOWLER (the "*Amendment*") is entered into this April 11, 2024 (the "*Amendment Effective Date*"), by and between JEREMY GOWLER (the "*Executive*") and INVIVYD, INC. (the "*Company*").

RECITALS

WHEREAS, the Company and Executive have entered into that certain Employment Agreement dated September 17, 2022 (the "*Executive Agreement*"); and

WHEREAS, the Company desires to continue to employ Executive as its Chief Operating Officer and Chief Commercial Officer of the Company and to employ Executive as its Interim Chief Executive Officer, and Executive desires to accept such employment and to perform the duties to the Company on the terms and conditions hereinafter set forth in this Amendment; and

WHEREAS, the Company and Executive wish to amend the Executive Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other valid consideration, the sufficiency of which is acknowledged, the parties hereto agree as follows:

AGREEMENT

1. **Amendment to Section 1(b)**. Section 1(b) of the Executive Agreement is hereby amended by replacing Section 1(b) in its entirety with the following:

(b) **Position and Duties**. Executive shall serve as the Chief Operating Officer and Chief Commercial Officer of the Company and shall have such powers and duties as customarily associated with the office of the Chief Operating Officer and Chief Commercial Officer, and as may from time to time be prescribed by the Chief Executive Officer of the Company (the "*CEO*") or the Company's Board of Directors (the "*Board*"). Executive shall report to the CEO and shall be subject to the direction and control of the CEO and the Board. Nothing in this Agreement shall prohibit Executive from reasonably delegating parts of the responsibilities set forth in or contemplated by this Section 1(b) to other employees of the Company or its subsidiaries.

As of April 11, 2024 (the "*Amendment Effective Date*"), Executive shall additionally serve as the Interim Chief Executive Officer of the Company and shall have such powers and duties as customarily associated with the office of Interim Chief Executive Officer, and as may from time to time be prescribed by the Board or a designated committee thereof, subject to the direction and control of the Board or a designated committee thereof. In his service as Interim Chief Executive Officer, Executive shall report to the Board or a designated committee thereof.

2. **Amendment to Section 2(a).** Section 2(a) of the Executive Agreement is hereby amended by replacing Section 2(a) in its entirety with the following:
 - (a) **Base Salary.** The Company will continue to pay Executive, as compensation for the performance of Executive's duties and obligations hereunder, salary at the rate of \$465,000 per year, less applicable deductions. Executive's salary shall be subject to annual review not later than March 31st of each year for possible increase by the Board or the Compensation Committee of the Board (the "**Compensation Committee**"), which may be adjusted from time to time. The base salary in effect at any given time is referred to herein as "**Base Salary**." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for its executive officers. As of the Amendment Effective Date, and while Executive serves as Interim Chief Executive Officer, Executive shall receive an additional monthly payment of \$5,000, less applicable deductions.
3. **Amendment to Section 2(c).** Section 2(c) of the Executive Agreement is hereby amended by inserting the following sentence immediately following the end of the third sentence in Section 2(c):

Subject to the foregoing, as of the Amendment Effective Date and while Executive serves as Interim Chief Executive Officer, the Target Bonus will be fifty-five percent (55%) of the Base Salary. For the calendar year 2024, the Annual Bonus shall be calculated as follows: (i) for the period during which Executive serves only as Chief Operating Officer and Chief Commercial Officer, the Target Bonus will be forty percent (40%) of Executive's actual Base Salary for the calendar year 2024; and (ii) for the period during which Executive serves as Interim Chief Executive Officer, the Target Bonus will be fifty-five percent (55%) of an assumed base salary of \$525,000.
4. The Company and Executive further agree that this Amendment does not constitute grounds for "Good Reason" pursuant to Section 3(e) of the Executive Agreement, or otherwise constitute any trigger for the Company's payment of any severance benefits to Executive pursuant to the Executive Agreement. The Company and Executive further agree that Executive's title of Interim Chief Executive Officer is temporary, and neither the removal of the Interim Chief Executive Officer title, nor the diminution of or removal of the interim related duties, will constitute grounds for "Good Reason" pursuant to Section 3(e) of the Executive Agreement.

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5. Except as modified or amended in this Amendment, no other term or provision of the Executive Agreement is amended or modified in any respect. Executive remains employed "at will." The Executive Agreement and its exhibits, the Employee Proprietary Information and Inventions Assignment Agreement, and this Amendment, set forth the entire understanding between the parties with regard to the subject matter hereof and supersedes any prior oral discussions or written communications and agreements. This Amendment cannot be modified or amended except in writing signed by Executive and an authorized officer of the Company.

The parties have executed this First Amendment to the Employment Agreement of Jeremy Gowler on the day and year first written above.

INVIVYD, INC.

/s/ Marc Elia

Marc Elia

Chairperson of the Board

EXECUTIVE

/s/ Jeremy Gowler

Jeremy Gowler

I hereby acknowledge and reaffirm my obligations pursuant to the Employee Proprietary Information and Inventions Assignment Agreement.

/s/ Jeremy Gowler

Jeremy Gowler

Date: April 11, 2024

Invivyd Announces CEO Transition***Jeremy Gowler appointed Interim CEO***

WALTHAM, Mass., April 12, 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 the company's Board of Directors has appointed Jeremy Gowler as Interim Chief Executive Officer (CEO), effective immediately, while the Board institutes a search for a permanent CEO. Mr. Gowler succeeds Dave Hering.

"The Invivyd Board of Directors is positioning the company for its next phase of growth," said Marc Elia, Chairperson. "Invivyd is poised to lead a brand-new paradigm in delivering novel, impactful monoclonal antibody (mAb) therapies for the pre-exposure prophylaxis (PrEP) of COVID-19, and we wish to fully unlock this capability and associated value creation. In the interim, we are pleased to align the day-to-day leadership of the company with Jeremy, who is primarily responsible for our commercial execution, and I personally look forward to partnering with him on the success of the company. With PEMGARDA™, our novel pipeline mAb candidates for COVID PrEP, and our strong balance sheet, we believe we have a highly attractive and undervalued base on which to build a class-leading company in virology. The Board would like to thank Dave for his contributions in bringing the company from the research phase through first emergency use authorization."

"I am eager to work closely with the Invivyd Board and strengthen engagement with key internal and external stakeholders, while remaining focused on delivering a successful launch of PEMGARDA. Invivyd has tremendous potential to reach and support vulnerable populations and their caregivers with PEMGARDA and beyond," said Mr. Gowler.

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 $\geq 2\%$) 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.

About Invivyd

Invivyd, Inc. (Nasdaq: IVVD) is a 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 anticipated benefits of the company’s management transition; the company’s anticipated next phase of growth, future prospects, and potential value creation; the company’s expectations for the commercial launch of PEMGARDA; the potential of the company to reach and support vulnerable populations and their caregivers; the company’s ongoing research and clinical development efforts; 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 INVYTAB 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, novel, impactful 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 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 INVYTAB 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.

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