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 9, 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 2.02. Results of Operations and Financial Condition.

On May 9, 2024, Invivyd, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024, and recent business highlights. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 2.02.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any of the Company's filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On May 9, 2024, the Company posted an updated corporate presentation on its website at www.invivyd.com. A copy of the presentation is filed as Exhibit 99.2 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 May 9, 2024
99.2	Corporate Presentation, dated May 9, 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 9, 2024

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

INVIVYD

Invivyd Reports First Quarter 2024 Financial Results and Recent Business Highlights

- *Launched PEMGARDA™ in the U.S. for COVID-19 pre-exposure prophylaxis (PrEP) in certain adults and adolescents with moderate-to-severe immune compromise*
- *Reported interim exploratory COVID-19 clinical event data from CANOPY Phase 3 clinical trial of VYD222*
- *Received product-specific reimbursement codes covering PEMGARDA from the U.S. Centers for Medicare & Medicaid Services (CMS), covering approximately half of target population*
- *Announced plans to pursue rapid immunobridging pathway to potential EUA for COVID-19 treatment in certain immunocompromised people, based on U.S. FDA feedback*
- *Continued to advance VYD2311, the company's next monoclonal antibody candidate engineered with the company's state-of-the-art technologies for variant monitoring, predictive modeling and antibody engineering*
- *Ended Q1 2024 with cash and cash equivalents of $189.4 million*
- *Company expects to end 2024 with at least $75 million in cash and cash equivalents, based on anticipated 2024 net product revenue of $150-$200 million and recent resource realignment*
- *Management to host conference call today at 4:30pm ET*

WALTHAM, Mass., May 9, 2024 (GLOBE NEWSWIRE) — Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced financial results for the quarter ended March 31, 2024, and recent business highlights.

"The recent months have been incredibly productive for Invivyd. Moving into the commercial phase is a critical step for the company and we are executing on the PEMGARDA launch with maximum focus across the company," said Marc Elia, Chairman of the Invivyd Board of Directors. "In addition, we look forward to sharing on today's quarterly update call more of the scientific underpinnings of our plans going forward, including detail on the innovative engine we believe can deliver meaningful product-level advancements with associated medical and economic value creation."

Recent Business Highlights

- **Launched PEMGARDA, the company's first monoclonal antibody (mAb) in a planned series of innovative antibodies, in the U.S.:** On March 22, 2024, PEMGARDA (pemivibart) received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the pre-exposure prophylaxis (PrEP) of COVID-19 in certain adults and adolescents with moderate-to-severe immune compromise. At the beginning

of April, Invivyd announced that PEMGARDA is available for purchase in the U.S. through a network of authorized specialty distributors. At the end of April, Invivyd's market access and sales, as well as medical affairs, teams were fully operational across the U.S. The company will begin reporting PEMGARDA net product revenue with its second quarter 2024 financial results.

- **Received product-specific reimbursement codes covering PEMGARDA from the U.S. Centers for Medicare & Medicaid (CMS):** In April 2024, Invivyd announced that CMS has granted a Healthcare Common Procedure Coding System (HCPCS) Q code (Q0224) covering product reimbursement and a product specific M code (M0224) covering the administration of PEMGARDA. The company estimates that CMS provides coverage for nearly half of the moderately to severely immunocompromised people at highest risk for severe COVID-19 that the company is initially targeting.
- **Reported interim exploratory COVID-19 clinical event data from CANOPY Phase 3 clinical trial of VYD222:** In March 2024, Invivyd announced interim exploratory data from the ongoing CANOPY Phase 3 clinical trial that reflect and add further to the initial potential signal of clinical protection from symptomatic COVID-19 shared in December 2023. While not part of the primary immunobridging endpoint of the CANOPY clinical trial, the interim exploratory data may be hypothesis generating for future discovery and development work.

Recent Pipeline Highlights

- **Announced plans to pursue rapid immunobridging pathway to potential EUA for COVID-19 treatment in certain immunocompromised people, based on U.S. FDA feedback:** In May 2024, Invivyd announced that it anticipates imminently submitting an EUA application to the FDA for pemivibart for the treatment of mild to moderate symptomatic COVID-19 in certain immunocompromised people utilizing a rapid immunobridging pathway. This immunobridging pathway leverages a similar approach Invivyd used to achieve its current EUA for PEMGARDA for COVID-19 PrEP in certain immunocompromised people and was aligned in principle with the FDA.
- **Continued to advance VYD2311, the company's next anticipated mAb candidate:** In March 2024, Invivyd announced that it expects that VYD2311 will be the next anti-SARS-CoV-2 mAb candidate that it advances into clinical development. VYD2311 is optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1. The design of VYD2311 leverages Invivyd's state-of-the-art technologies for variant surveillance, predictive modeling, and antibody engineering.

First Quarter 2024 Financial Results:

- **Cash Position:** Cash and cash equivalents were $189.4 million as of March 31, 2024.

- **Projected 2024 Year-End Cash Position:** Based on current operating plans, Invivyd expects to end 2024 with at least $75 million in cash and cash equivalents, based on anticipated 2024 net product revenue of $150 million to $200 million and recent resource realignment. Invivyd is maintaining its existing guidance, although the previously issued guidance was based on PEMGARDA being authorized for PrEP of COVID-19 in certain immunocompromised people and did not contemplate any potential sales for COVID-19 treatment, if authorized, or inventory build that may be required to deliver medicine timely to patients in need.
- **Research & Development (R&D) Expenses (including In-Process R&D):** R&D expenses were $31.2 million for the quarter ended March 31, 2024, compared to $28.0 million for the comparable period of 2023. This increase is primarily attributable to an increase in commercial manufacturing costs of PEMGARDA and an increase in clinical trial costs related to the ongoing monitoring of our CANOPY Phase 3 clinical trial.
- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were $14.9 million for the quarter ended March 31, 2024, compared to $11.0 million for the comparable period of 2023. This increase is primarily attributable to an increase in personnel-related costs and commercial costs driven by the preparation for launch of PEMGARDA.
- **Net Loss and Net Loss per Share:** Net loss was $43.5 million for the quarter ended March 31, 2024, compared to $35.3 million for the comparable period in 2023. Basic and diluted net loss per share was $0.38 for the quarter ended March 31, 2024, compared to $0.32 for the comparable period in 2023.

Conference Call & Webcast

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 via the company's investor website approximately two hours after the call's conclusion. 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 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.

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.

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, PEMGARDA as a mAb for COVID-19 PrEP in certain adults and adolescents with moderate-to-severe immune compromise; the company's plans and expectations related to the commercialization of PEMGARDA; the company's intention to pursue a rapid immunobridging pathway to potential EUA for COVID-19 treatment in certain immunocompromised people; the company's anticipated submission of a COVID-19 treatment EUA request to the FDA for pemivibart, and the timing thereof; the company's research and clinical development efforts, and the timing thereof; the potential of VYD222 for clinical protection from symptomatic COVID-19 based on interim exploratory data from the CANOPY Phase 3 clinical trial; the company's expectation that PEMGARDA is the first mAb in a planned series of innovative antibody candidates and VYD2311 will be the next mAb candidate to advance into clinical development; the future of the COVID-19 landscape; the company's belief that its innovative engine can deliver meaningful product-level advancements with associated medical and economic value creation; the company's anticipated 2024 net product revenue and projected 2024 year-end cash position; the company's commitment 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 address evolving viral threats; 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 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; the company's ability to effectively utilize an immunobridging pathway to potential EUA for pemivibart for COVID-19 treatment in certain immunocompromised people; whether the company is able to successfully submit a COVID-19 treatment 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 deliver meaningful product-level advancements with associated medical and economic value creation; 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; 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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INVIVYD, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 189,388	$ 200,641
Inventory	109	—
Prepaid expenses and other current assets	20,386	24,240
Total current assets	209,883	224,881
Property and equipment, net	1,901	1,896
Operating lease right-of-use assets	1,827	2,229
Other non-current assets	1,857	175
Total assets	$ 215,468	$ 229,181
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,168	$ 7,953
Accrued expenses	34,003	40,860
Operating lease liabilities, current	1,134	1,443
Other current liability	40	35
Total current liabilities	36,345	50,291
Operating lease liabilities, non-current	625	722
Other non-current liability	—	700
Total liabilities	36,970	51,713
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 119,221,230 shares issued and outstanding at March 31, 2024; 110,160,684 shares issued and outstanding at December 31, 2023	12	11
Additional paid-in capital	954,063	909,539
Accumulated other comprehensive loss	(12)	(13)
Accumulated deficit	(775,565)	(732,069)
Total stockholders' equity	178,498	177,468
Total liabilities, preferred stock and stockholders' equity	$ 215,468	$ 229,181

INVIVYD, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Operating expenses:		
Research and development[1]	$ 31,160	$ 27,201
Acquired in-process research and development[2]	—	825
Selling, general and administrative	14,929	11,045
Total operating expenses	46,089	39,071
Loss from operations	(46,089)	(39,071)
Other income:		
Other income, net	2,593	3,750
Total other income, net	2,593	3,750
Net loss	(43,496)	(35,321)
Other comprehensive income (loss)		
Unrealized gain on available-for-sale securities, net of tax	1	157
Comprehensive loss	$ (43,495)	$ (35,164)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.38)	$ (0.32)
Weighted-average common shares outstanding, basic and diluted	115,618,209	108,785,519

(1) Includes related-party amounts of $1,135 and $2,960 for the three months ended March 31, 2024 and 2023, respectively.
(2) Includes related-party amounts of $0 and $375 for the three months ended March 31, 2024 and 2023, respectively.

Exhibit 99.2

INVIVYD Q1 2024 FINANCIAL RESULTS & BUSINESS HIGHLIGHTS

May 9, 2024

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

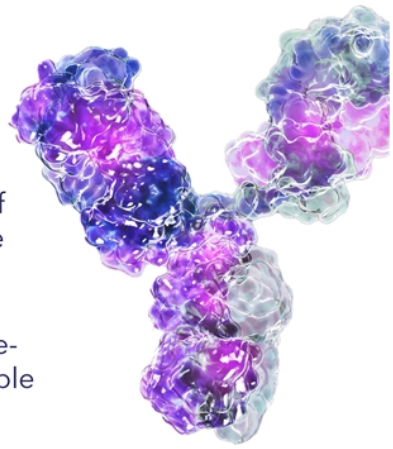
This presentation contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Statements in this presentation that are not statements of historical fact are forward-looking statements. Words such as "may," "will," "should," "expect," "plan," "anticipate," "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, PEMGARDA™ as a monoclonal antibody (mAb) for pre-exposure prophylaxis (PrEP) of COVID-19 in certain adults and adolescents with moderate-to-severe immune compromise; our plans, strategy and expectations related to the launch and commercialization of PEMGARDA; our intention to pursue a rapid immunobridging pathway to potential Emergency Use Authorization (EUA) for COVID-19 treatment in certain immunocompromised people; our anticipated submission of a COVID-19 treatment EUA request to the U.S. Food and Drug Administration (FDA) for pemivibart, and the timing thereof; our belief that pemivibart has the potential to offer Invivyd's first, one-time, outpatient, long-acting COVID-19 treatment, if authorized; the potential of VYD222 for clinical protection from symptomatic COVID-19 based on interim exploratory data from the CANOPY Phase 3 clinical trial; the future of the COVID-19 landscape; our expectations about the size of target patient populations and the potential market opportunity for our product candidates, as well as our market position; our research and clinical development efforts, including statements regarding initiation or completion of studies or trials, the time-frame during which results may become available, and the potential utility of generated data; potential alignment of our strategy and the evolving U.S. regulatory landscape; our expectation regarding a repeatable, low-cost pathway for novel molecules with anticipated improved profiles over pemivibart; the potential of our SARS-CoV-2 variant tracking and analysis capabilities; our expectations regarding advancement of our pipeline and anticipated improved pharmaceutical profiles; the company's anticipated 2024 net product revenue and projected 2024 year-end cash position; 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 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; our ability to maintain and expand sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; changes in expected or existing competition; our ability to effectively utilize an immunobridging pathway to potential EUA for pemivibart for COVID-19 treatment in certain immunocompromised people; whether we are able to successfully submit a COVID-19 treatment 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, progress and results of our 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 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; 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; our dependence on third parties to manufacture, label, package, store and distribute clinical and commercial supplies of our product candidates; whether we are able to provide sufficient commercial supply of PEMGARDA to meet market demand; whether we can obtain and maintain third-party coverage and adequate reimbursement for PEMGARDA or any other product candidate; the ability of our SARS-CoV-2 variant tracking and analysis capabilities to effectively enable epitope surveillance and intelligent mAb selection in addition to surveillance of emergent SARS-CoV-2 lineages; whether we are able to achieve high potency and/or variation resistance with our future product pipeline; 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

- Introduction/Overview
- Financials
- PEMGARDA™ EUA & Commercial Launch
- CANOPY Clinical Data
- Pathway to Potential Treatment EUA
- Variant Monitoring & Predictive Modeling
- Product Pipeline
- Q&A

INVIVYD HAS ENTERED A TRANSFORMATIONAL PERIOD OF GROWTH

- Invivyd has been **built to address the unique challenges presented by SARS-CoV-2**, and potentially other viruses in the future
- We are **pioneering a still brand-new approach to antibody therapeutics and prophylactics**, starting with SARS-CoV-2
- Our strategy is to combine the potential for high efficacy and attractive safety of monoclonal antibodies (mAbs) targeting the SARS-CoV-2 spike protein with the **opportunity for product evolution** commonly seen in the vaccine space
- The U.S. FDA's recent emergency use authorization (EUA) of PEMGARDA for pre-exposure prophylaxis (PrEP) of COVID-19 in certain immunocompromised people and our opportunity to pursue a rapid immunobridging pathway to a potential EUA for treatment of mild-to-moderate COVID-19 in certain immunocompromised people, represent **growing alignment between our strategy and the evolving U.S. regulatory landscape**



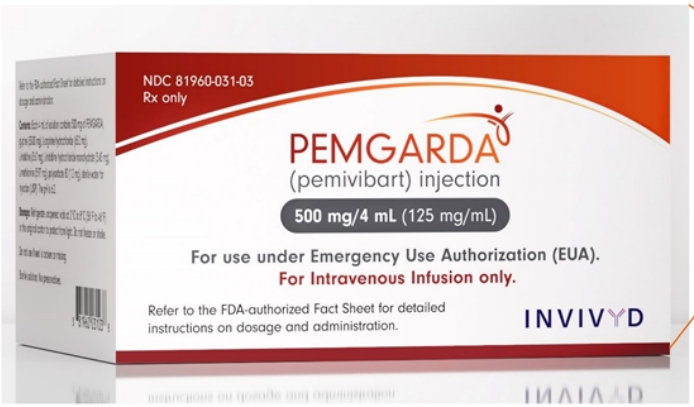
FINANCIALS

Cash and cash equivalents were $189.4 million as of March 31, 2024

Invivyd is maintaining its existing guidance of **$150-$200 million in anticipated 2024 PEMGARDA net product revenue and year-end cash guidance of at least $75 million in cash and cash equivalents**

- Previously issued guidance was based on PEMGARDA being authorized for PrEP of COVID-19 in certain immunocompromised people and did not contemplate any potential sales for COVID-19 treatment, if authorized, or inventory build that may be required to deliver medicine timely to patients in need

PEMGARDA EUA MAKES AN IMPORTANT THERAPY AVAILABLE TO CERTAIN PATIENTS & PROVIDES PROOF-OF-CONCEPT FOR PLATFORM



1 EMERGENCY USE AUTHORIZATION FOR PEMGARDA

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product PEMGARDA (pemivibart) for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
- Who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** are unlikely to mount an adequate response to COVID-19 vaccination.

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 IS RAPIDLY EXECUTING ON ITS COMMERCIAL STRATEGY

1 Product Availability

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

2 Securing Reimbursement & Access

- ✓ Deploy national account managers focused on payor engagement
- ✓ Obtain HCPCS code from CMS and associated coverage
- IP Secure inclusion in institutional formularies, as needed
- IP Obtain coverage from major commercial payors

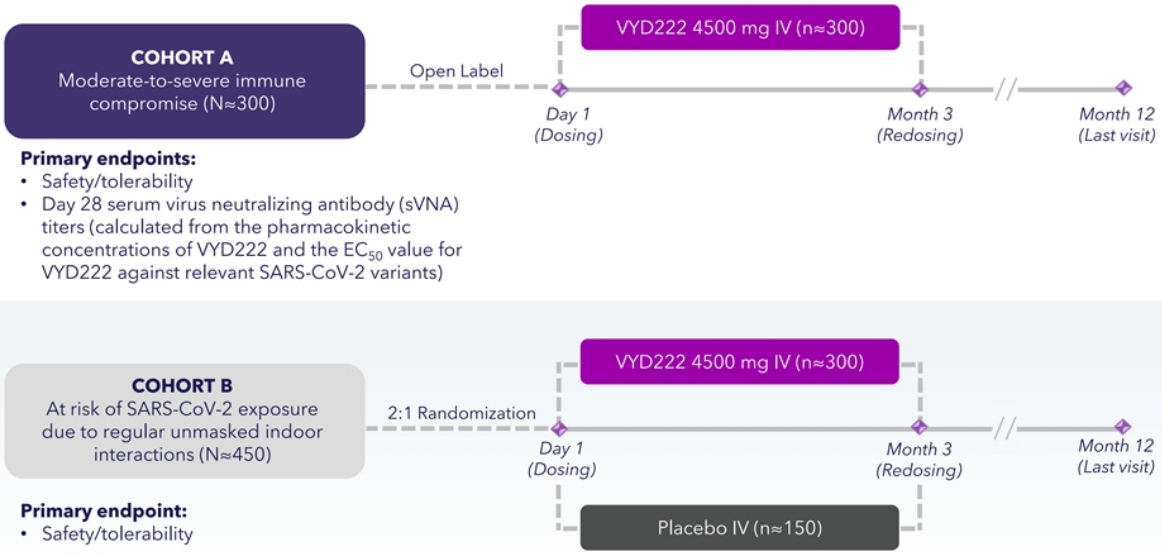
3 Full Commercial Implementation

- ✓ Fully deploy contracted Key Account Managers (KAMs)
- ✓ Activate targeted awareness campaigns
- ✓ Account reordering
- ☐ Expand utilization within authorized population

WAC: Wholesale acquisition cost; HCPCS: Healthcare Common Procedure Coding System; CMS: U.S. Centers for Medicare & Medicaid Services; IP: In process

THE PEMGARDA EUA FOR PRE-EXPOSURE PROPHYLAXIS IS BASED ON AN IMMUNOBRIDGING CLINICAL TRIAL (CANOPY)

CANOPY CLINICAL TRIAL OVERVIEW



Primary endpoints:

- Safety/tolerability
- Day 28 serum virus neutralizing antibody (sVNA) titers (calculated from the pharmacokinetic concentrations of VYD222 and the EC_{50} value for VYD222 against relevant SARS-CoV-2 variants)

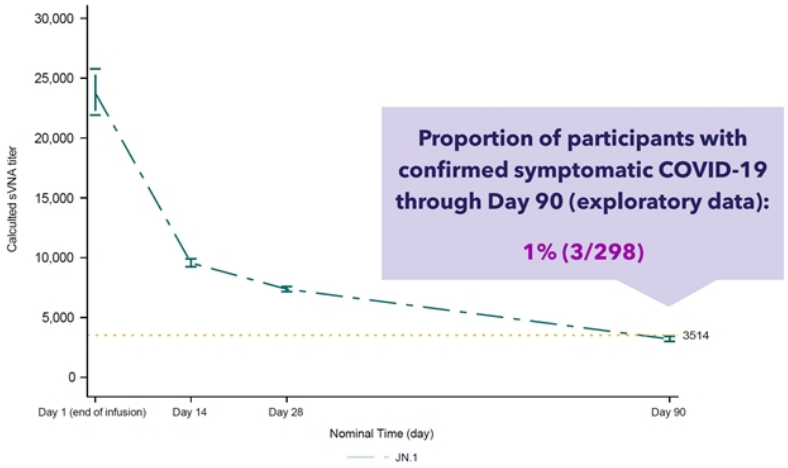
Primary endpoint:

- Safety/tolerability

Source: F: NCT06039449; IV, intravenous; SAEs, serious adverse events; AEs, adverse events

SVNA TITERS & EXPLORATORY EFFICACY DATA FROM IMMUNOCOMPROMISED COHORT IN CANOPY CLINICAL TRIAL

Cohort A - Calculated VYD222 sVNA titers against JN.1 based on observed PK concentration by timepoints



Proportion of participants with confirmed symptomatic COVID-19 through Day 90 (exploratory data):

1% (3/298)

Additional exploratory COVID-19 clinical event data anticipated mid-year 2024

While the PEMGARDA EUA was based on immunobridging data from Cohort A, the exploratory event data are expected to be hypothesis generating for future studies in terms of dose and titers

Notes: The interim exploratory COVID-19 clinical event data shown were not used for the basis of the EUA nor referenced in the PEMGARDA Fact Sheet. Beyond this interim update, additional cases of confirmed symptomatic COVID-19 have occurred in Cohort A post Day 90.

INTERIM EXPLORATORY DATA FROM CANOPY CLINICAL TRIAL

While not part of the primary immunobridging endpoint of the CANOPY clinical trial, interim exploratory data may be hypothesis generating for future Invivyd discovery and development work

Cohort B (Randomized, placebo-controlled cohort *without* moderate-to-severe immune compromise at risk of acquiring SARS-CoV-2 due to regular unmasked face-to-face interactions) – Proportion of participants with RT-PCR-confirmed symptomatic COVID-19:

	As of Dec 1, 2023 (median 67 days follow-up)	**Through Day 90**
Pemivibart	0% (0/322)	0.3% (1/314)
Placebo	3% (5/162)	5% (8/159)
Relative Risk Reduction	**100%**	**94%**

Cohort A (Open-label cohort *with* moderate-to-severe immune compromise) – Proportion of participants with RT-PCR-confirmed symptomatic COVID-19:

	As of Dec 1, 2023 (median 35 days follow-up)	**Through Day 90**
Pemivibart	0% (0/306)	1% (3/298)

Notes: These are exploratory endpoints; these data were not used for the basis of the EUA nor referenced in the PEMGARDA Fact Sheet. Beyond this interim update, additional cases of confirmed symptomatic COVID-19 have occurred in Cohort A and Cohort B post Day 90. These data will be analyzed and presented at a later timepoint.

RAPID REGULATORY PATHWAY TO A POTENTIAL COVID-19 TREATMENT EUA REFLECTS THE DEMONSTRATED UTILITY OF MONOCLONAL ANTIBODIES

Old therapy vs old variants
(known clinical efficacy)

STAMP clinical trial of adintrevimab

Immunobridging approach

New therapy vs new variants
(Unknown clinical efficacy)

PEMGARDA (pemivibart)

- **Invivyd anticipates submitting a treatment EUA application for PEMGARDA (pemivibart) imminently**
- Pathway leverages immunobridging approach via serum virus neutralizing antibody (sVNA) titers enabled by prior successful COVID-19 treatment clinical trial (STAMP) conducted with prototype antibody adintrevimab
- COVID-19 treatment EUA pathway offers a novel, rapid pathway to potential second EUA for pemivibart

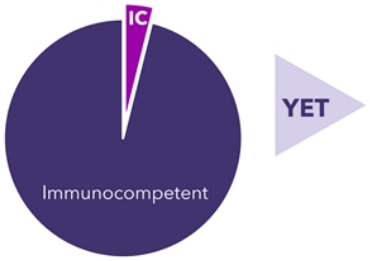
Repeatable, low-cost pathway could also be used for possible follow-on novel molecules with anticipated improved profiles over pemivibart

RBD: Receptor binding domain

DESPITE VACCINATION, IMMUNOCOMPROMISED PEOPLE ARE DISPROPORTIONALLY IMPACTED BY SEVERE COVID-19 OUTCOMES

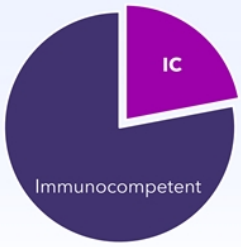
The recent INFORM[1] study, conducted during the Omicron period, found that in a sample of nearly 12 million people:

Immunocompromised (IC) people represented only **3.9% of the study population...**

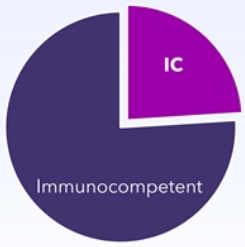


YET

IC individuals accounted for **22% of COVID-19 hospitalizations**



IC individuals accounted for **24% of COVID-19 deaths**



Even though **>80% of the IC population had received ≥3 COVID-19 vaccines**

References: 1. Evans Lancet Reg 2023

NO ONE-TIME OUTPATIENT COVID-19 TREATMENT CURRENTLY EXISTS BUT MAY BE AN IMPORTANT THERAPEUTIC OPTION

	Dosing	Indication or Authorized Use for Treatment (Abbreviated)	Treatment Setting	Select Limitations
PAXLOVID™ (nirmatrelvir/ritonavir)[1-2]	Oral dose twice daily for 5 days	Mild-to-moderate COVID-19 in adults and pediatrics at high risk for progression to severe COVID-19	Studied in non-hospitalized	Significant drug-drug interactions
LAGEVRIO™ (molnupiravir)[3]	Oral dose twice daily for 5 days	Adults with mild-to-moderate COVID-19 at high-risk for progression to severe COVID-19 and for whom alternative treatment options are not accessible or clinically appropriate	Non-hospitalized	Low efficacy reported from MOVE-OUT (31%)[4]
VEKLURY® (remdesivir)[5]	IV infusions for 3 consecutive days (for non-hospitalized patients)	Adults and pediatric patients who are hospitalized or not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19	Non-hospitalized or hospitalized	Requires 3 consecutive days of IV infusions (for non-hospitalized patients)

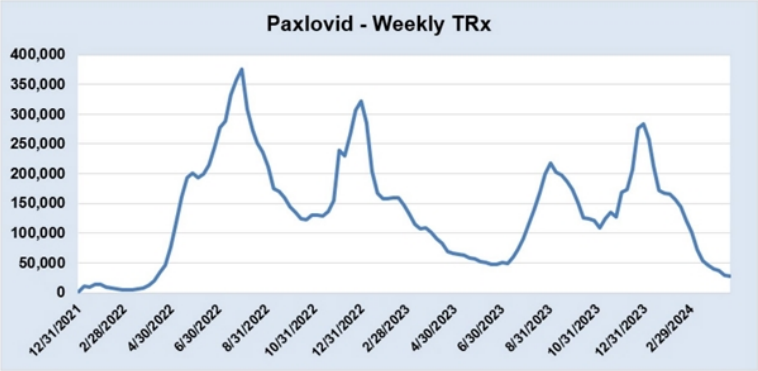
Pemivibart has the potential to offer Invivyd's first, one-time, outpatient, long-acting COVID-19 treatment, if authorized

See the following materials for additional information: 1. PAXLOVID Full Prescribing Information (Revised 5/2023); 2. Paxlovid Fact Sheet for Healthcare Providers (Revised 4/2024); 3. LAGEVRIO Fact Sheet for Healthcare Providers (Revised 10/2023); 4. Bernal N Engl J Med 2022; 5. VELKURY Prescribing Information (Revised 2/204)

No head-to-head clinical trials have been conducted between PEMGARDA (pemivibart) and any other COVID-19 treatment. Comparative conclusions regarding the safety and efficacy of PEMGARDA (pemivibart) relative to other COVID-19 treatment therapies cannot be made. All trademarks are the property of their respective owners.

COVID-19 TREATMENT REPRESENTS A LARGE OPPORTUNITY

Paxlovid script data reflects ongoing need for COVID-19 treatments[1]

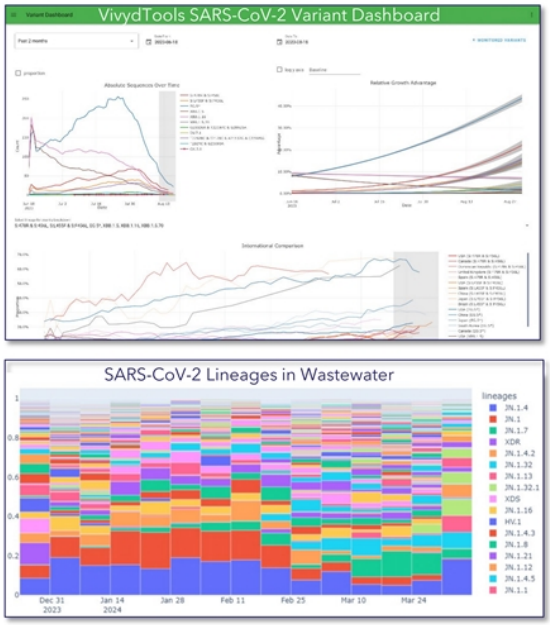


Recent reporting underscores the compelling potential opportunity in COVID-19 treatment:

- Pfizer reported **$2 billion in Paxlovid revenues for 1Q 2024, with $1.8 billion from the U.S.**; Pfizer anticipates $3 billion in Paxlovid full year 2024 revenue[2]
- Gilead reported **$555 million in Veklury sales for 1Q 2024**[3]

Reference: 1. Jefferies Equity Research Report: Pfizer (May 1, 2024); 2. Pfizer First-Quarter 2024 Results; 3. Gilead First Quarter 2024 Financial Results

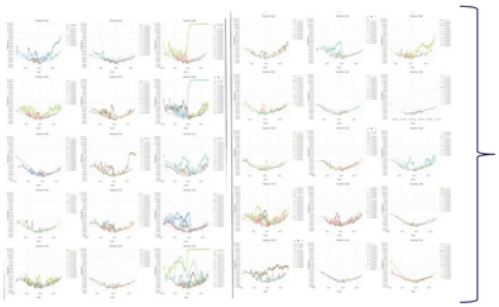
INVIVYD'S SARS-COV-2 VARIANT INSIGHTS ARE POWERED BY VIVYDTOOLS ANALYTICS



- Variant tracking and analysis is automated using proprietary bioinformatics
- Clinical sequence data is supplemented with wastewater data
- Internal analysis provides a detailed view of SARS-CoV-2 evolution across the U.S.
- VivydTools enable **epitope surveillance** and intelligent mAb selection in addition to surveillance of emergent SARS-CoV-2 lineages

EPITOPIC ANALYSIS IS BUILT FROM INDIVIDUAL RESIDUE ANALYSIS

SARS-CoV-2 spike protein evolution is tracked at the residue (amino acid) level

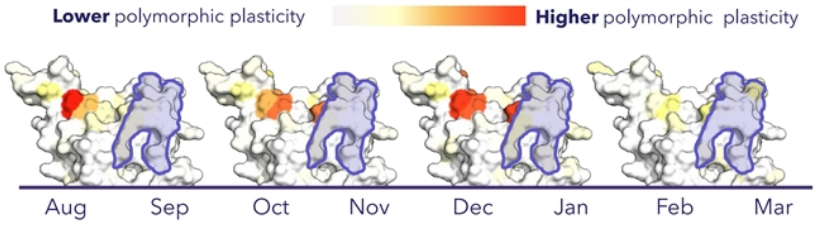


Each graph represents the frequency of different substitutions observed at one specific amino acid position in the receptor binding domain (RBD) of the spike

Individual residue analysis yields two observations

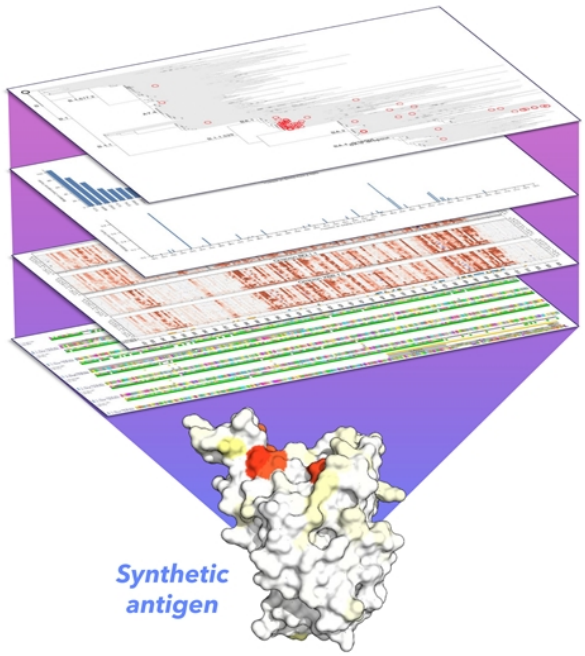
1. Observed mutational potential at individual amino acid positions or for a complete epitope are increasingly informative of future divergence

2. To date, the VYD222 epitope (area of RBD outlined in blue below) has been stable



Note: Epitope is defined as all residues within 5 angstroms of VYD222 binding interface determined via co-crystal analysis.

VIRAL ANALYSIS ENABLES SYNTHETIC ANTIGEN DESIGN AND INCREASINGLY INTELLIGENT ANTIBODIES



SARS-CoV-2 Phylogeny: Cov2tree.org, DMS data: Tyler Starr

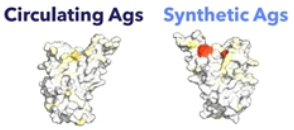
Analysis of convergent evolution yields patterns of prediction regarding spike / RBD mutations

Predictive data is computationally combined with deep mutational scanning data specific for our mAbs to inform **synthetic antigen design (spike antigen variations that may dominate the viral landscape in the future)**

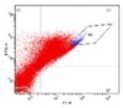
Synthetic antigens screened via Invivyd technology using unique Boolean antibody optimization process

INVIVYD DISCOVERY PROCESS NOW INCORPORATES SYNTHETIC EVOLUTIONARY INTELLIGENCE

EVOLUTIONARY INTELLIGENCE

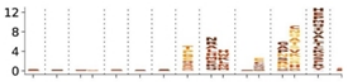


BOOLEAN MAB DISCOVERY SCREENS



PREDICTIVE VARIANT NEUTRALIZATION

INTELLIGENT MAB SELECTION



Proprietary incorporation of probabilistic future evolution into today's mAb discovery and qualification

Ags: Antigen

INVIVYD'S PIPELINE IS RAPIDLY ADVANCING TOWARD HIGHER INTELLIGENCE AND ANTICIPATED IMPROVED PHARMACEUTICAL PROFILES

Adintrevimab (ADG20)

- First generation, mined from SARS-CoV-1 survivor serum and optimized against Wuhan
- Optimized on one dimension (ACE2:RBD affinity)

↳ **PEMGARDA (pemivibart)**

- 2nd generation, engineered from ADG20 to recover activity against BA.2
- Engineered for single dimension (ACE2:RBD breadth), constraining potency

↳ **VYD2311**

- 3rd generation, optimized for post-Omicron two-dimensional problem (ACE2:RBD, immune evasion)
- **Highly potent** and demonstrated post-Omicron variant resistance

↳ **VYDXXXX**

- **Leverages evolutionary intelligence** from VivydTools analysis and predictive synthetic antigens
- Expected high potency and designed for high variation resistance

SUMMARY: KEY ELEMENTS OF STRATEGY

Variant Monitoring

- Virus is in constant motion
- Individual residue mutations and combinations are under constant analysis and direct observation; data are routinely shared with the US FDA
- Invivyd monitors, analyzes, and tests constantly, but will not update except through the PEMGARDA Fact Sheet
- Neutralization assays exhibit wide variances by system and laboratory, but have questionable meaning in the context of **ongoing pharmaceutical activity**

Pipeline Development & Commercial Opportunity

- Pemivibart reflects Invivyd's first generation technology
- Invivyd now almost two years into analytics and technology development and corresponding discovery strategies
- More evasion resistant, more potent antibodies can enable more elegant ROAs and doses that improve access and the medical value associated with protection and treatment
- Rapid, highly efficient development pathways could unlock rapid profile improvements

Overall aim is to maximize the medical value of high-quality protection from symptomatic disease (PrEP) and adverse outcomes (treatment) in the broadest possible populations over time

ROA: routes of administration

INVIVYD

Q&A


INVIVYD