

**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): August 14, 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 2.02. Results of Operations and Financial Condition.

On August 14, 2024, Invivyd, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 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 August 14, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated August 14, 2024
99.2	Corporate Presentation, dated August 14, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 14, 2024

INVIVYD, INC.

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



INVIVYD REPORTS SECOND QUARTER 2024 FINANCIAL RESULTS AND RECENT BUSINESS HIGHLIGHTS

- *PEMGARDA™ launched commercially in Q2 2024 with \$2.3 million of net product revenue*
- *Notable acceleration of commercial results in early Q3 2024, with the anticipated peak fall/winter respiratory virus season approaching*
- *New commercial leadership with Chief Commercial Officer, Tim Lee, an experienced biopharmaceutical leader with demonstrated commercial success*
- *Achieved Medicare and Medicaid coverage, rapid growth in commercial coverage across national and regional plans, and strong growth in infusion center utilization*
- *Submitted Emergency Use Authorization (EUA) amendment request to U.S. FDA for PEMGARDA for the treatment of mild-to-moderate COVID-19 in certain immunocompromised patients*
- *Next generation molecule VYD2311 first-in-human clinical trial dosing scheduled to begin late August*
- *Ended Q2 2024 with cash and cash equivalents of \$147.9 million*
- *Management to host conference call today at 8:30AM ET*

WALTHAM, Mass., August 14, 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 June 30, 2024, and recent business highlights.

Shortly after the PEMGARDA Emergency Use Authorization (EUA) was issued by the U.S. Food and Drug Administration (FDA) for pre-exposure prophylaxis (PrEP) of COVID-19 in certain immunocompromised patients, Invivyd transitioned its commercial strategy to reflect the novel features of a newly commercial COVID-19 PrEP antibody marketplace. This commercial transition was designed to increase the company's capabilities and accelerate awareness and education about PEMGARDA across multiple stakeholders in the field including healthcare professionals (HCPs), academic and major community medical institutions, and high-volume infusion centers. Under new commercial leadership, the company has onboarded multiple, highly experienced biopharmaceutical commercial leaders with an eye toward activating the marketplace in the coming respiratory virus season.

“Against the backdrop of rising, persistent COVID-19 disease, we are pleased with our progress in the quarter establishing a robust infrastructure to support PEMGARDA demand, access and utilization. We believe our early revenues reflect just the beginning of a unique, fast growing, medically critical prophylactic category in infectious disease. As we enter the peak fall/winter respiratory virus season, we aim to substantially increase PEMGARDA awareness and activation among HCPs, institutions, and vulnerable populations. Our expectation is that our ongoing commercial work can build a broad, high medical value category starting with PEMGARDA and continuing through novel pipeline molecules that may offer step changes in patient- and system-friendliness,” said Marc Elia, Chairperson of the Invivyd Board of Directors.

In addition, Invivyd expects to initiate in late August dosing a first-in-human clinical trial for VYD2311, a next generation anti-RBD monoclonal antibody (mAb) with substantially increased measured in vitro potency to date and other potentially favorable biophysical properties. While Invivyd has secured more than 100,000 total doses of PEMGARDA, expected potency and associated potential improvements to dose may result in substantially greater commercial quantities of VYD2311 should the molecule achieve regulatory authorization.

“Over two months at Invivyd, my appreciation for the company’s unique technology platform and ability for PEMGARDA to address the significant COVID-19 unmet need for certain immunocompromised people has grown tremendously,” said Tim Lee, Chief Commercial Officer of Invivyd. “We are excited about the positive commercial momentum we’ve seen, doubling available infusion sites from the end of May to the end of June, and again doubling from the end of June to the end of last week. We are enthusiastic about our efforts to drive awareness of PEMGARDA in the HCP community, expand reach to additional infusion centers, and add new programs to support patients. The fall will be here in weeks and the team is ready for action.”

Recent Business Highlights

- Reported PEMGARDA net product revenue of \$2.3 million in the second quarter of 2024.
- Announced general alignment with the FDA on an immunobridging pathway to future potential EUAs for serial, novel mAbs for the prevention and treatment of symptomatic COVID-19. This pathway, similar to the approach used to obtain EUA for PEMGARDA, provides for the establishment of a master, registrational clinical trial protocol that could obviate the need to submit a new protocol for the evaluation of each new mAb, streamlining the process required to evaluate new mAbs in compact clinical programs envisioned to include hundreds of participants (e.g., 300-600) exposed to a new mAb, with the specific number of exposures to be determined in consultation with the FDA.
- Expanded organizational expertise adding new Chief Commercial Officer and two new independent directors to the company’s Board of Directors.
 - Timothy Lee joined in June 2024 as Invivyd’s new Chief Commercial Officer. While at Amylyx, the commercial organization generated \$390 million in net product revenue in 14 months and was on track to be in the top five orphan drug launches. Tim also previously held key commercial leadership roles across a variety of life science companies including Biohaven Pharmaceuticals and Alexion Pharmaceuticals. Tim’s appointment is intended to accelerate the addition of commercial capabilities associated with orphan medicines to the ongoing PEMGARDA commercial launch.
 - Srishti Gupta, M.D. joined the company’s Board of Directors in May 2024 and is an experienced physician leader with over 20 years of experience in health and a global career spanning various sectors, including private, public, and non-profit.
 - Kevin F. McLaughlin joined the company’s Board of Directors in May 2024 bringing with him more than 40 years of financial and operating management experience spanning the biotech, high-tech and education industries.
- Submitted EUA amendment request to FDA for PEMGARDA for the treatment of mild-to-moderate COVID-19 in certain immunocompromised patients. The submission is based on immunobridging analyses of pemivibart versus comparator mAbs and safety data from the CANOPY Phase 3 clinical trial. The immunobridging pathway for COVID-19 treatment was previously aligned in principle with FDA, similar to the approach utilized for the EUA of PEMGARDA for PrEP of COVID-19 in certain immunocompromised patients granted in March 2024. If authorized, we anticipate PEMGARDA would be the only mAb available for both PrEP of moderate to severe COVID-19 and treatment of mild-to-moderate COVID-19 in certain immunocompromised patients.

- Invivyd was added to the Russell 2000® and Russell 3000® Indexes.

Recent Pipeline Highlights

- Announced antiviral activity of VYD222 (pemivibart) and VYD2311 against SARS-CoV-2 KP.1.1 FLiRT and KP.3 variants: Initial data demonstrated continued in vitro neutralization activity of VYD222 and VYD2311 in pseudovirus assays designed to represent the predominant emerging variants of SARS-CoV-2, including the KP.1.1 FLiRT and KP.3 variants. FLiRT variants are predicted to become the most dominant SARS-CoV-2 lineage nationally in the near term and accounted for over half of circulating SARS-CoV-2 variant sequences for the two-week period ending June 8, 2024, with KP.3 prevalence increasing per the Centers for Disease Control and Prevention.

Second Quarter 2024 Financial Results:

- Revenue: Reported \$2.3 million of net product revenue following the launch of PEMGARDA in the second quarter of 2024.
- Cash Position: Cash and cash equivalents were \$147.9 million as of June 30, 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 moderate to severe 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 \$30.3 million for the quarter ended June 30, 2024, compared to \$43.8 million for the comparable period of 2023. This decrease is primarily attributable to a decrease in commercial manufacturing costs of PEMGARDA and partially offset by an increase in VYD2311 manufacturing.
- Selling, General & Administrative (SG&A) Expenses: SG&A expenses were \$21.1 million for the quarter ended June 30, 2024, compared to \$10.1 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 launch of PEMGARDA.
- Net Loss and Net Loss per Share: Net loss was \$47.2 million for the quarter ended June 30, 2024, compared to \$50.2 million for the comparable period in 2023. Basic and diluted net loss per share was \$0.40 for the quarter ended June 30, 2024, compared to \$0.46 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 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 $\geq 2\%$) 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 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 immunocompromised patients; the company's plans, strategies, goals and expectations related to the commercialization of PEMGARDA; the company's EUA amendment request to the FDA for PEMGARDA for the treatment of mild-to-moderate COVID-19 in certain immunocompromised patients; the company's general alignment with the FDA on a immunobridging pathway to future potential EUAs for serial, novel mAbs for the prevention and treatment of symptomatic COVID-19, including the company's beliefs regarding the potential benefits of utilizing such pathway; the company's research and clinical development efforts, and the timing thereof, including with respect to a first-in-human clinical trial for VYD2311; the company's expectation that PEMGARDA is the first mAb in a planned series of innovative antibody candidates; the company's aim to build a broad, high medical value category starting with PEMGARDA and continuing through novel pipeline molecules; the future of the COVID-19 landscape, including the anticipated fall/winter respiratory virus season; 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 immunocompromised patients 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 outcome of the company's EUA amendment request for PEMGARDA for treatment of mild-to-moderate COVID-19 in certain immunocompromised patients, and the timing thereof; 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 any product candidate following regulatory authorization or approval; the predictability of clinical success of the company's product candidates based on neutralizing activity in nonclinical studies; the risk that results of nonclinical 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; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; 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 can obtain and maintain third-party coverage and adequate reimbursement for PEMGARDA or any other product candidate; the company's ability to build a broad, high medical value category starting with PEMGARDA and continuing through novel pipeline molecules; the company's ability to leverage its INVYTAB platform approach to facilitate the rapid, serial generation of new mAbs to address evolving viral threats; any legal proceedings or investigations relating to the company; the company's ability to continue as a going concern; and whether the company has adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause the company's actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission (SEC), and in the company's other filings with the SEC, and in its future reports to be filed with the SEC and available at www.sec.gov. Forward-looking statements contained in this press release are made as of this date, and Invivyd undertakes no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

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INVIVYD, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 147,881	\$ 200,641
Accounts receivable, net	2,888	—
Inventory, net	5,333	—
Prepaid expenses and other current assets	16,909	24,240
Total current assets	173,011	224,881
Property and equipment, net	1,772	1,896
Operating lease right-of-use assets	782	2,229
Other non-current assets	1,781	175
Total assets	<u>\$ 177,346</u>	<u>\$ 229,181</u>
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,499	\$ 7,953
Accrued expenses	26,822	40,860
Deferred revenue	1,681	—
Operating lease liabilities, current	681	1,443
Other current liability	21	35
Total current liabilities	36,704	50,291
Operating lease liabilities, non-current	—	722
Other non-current liability	—	700
Total liabilities	36,704	51,713
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock (undesignated), \$0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, \$0.0001 par value; 1,000,000,000 shares authorized, 119,442,635 shares issued and outstanding at June 30, 2024; 110,160,684 shares issued and outstanding at December 31, 2023	12	11
Additional paid-in capital	963,454	909,539
Accumulated other comprehensive loss	(12)	(13)
Accumulated deficit	(822,812)	(732,069)
Total stockholders' equity	140,642	177,468
Total liabilities, preferred stock and stockholders' equity	<u>\$ 177,346</u>	<u>\$ 229,181</u>

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

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Revenue:				
Product revenue, net	\$ 2,264	\$ —	\$ 2,264	\$ —
Total revenue	<u>2,264</u>	<u>—</u>	<u>2,264</u>	<u>—</u>
Operating costs and expenses:				
Cost of product revenue	88	—	88	—
Research and development ⁽¹⁾	30,334	43,618	61,494	70,819
Acquired in-process research and development ⁽²⁾	—	150	—	975
Selling, general and administrative	21,089	10,107	36,018	21,152
Total operating costs and expenses	<u>51,511</u>	<u>53,875</u>	<u>97,600</u>	<u>92,946</u>
Loss from operations	<u>(49,247)</u>	<u>(53,875)</u>	<u>(95,336)</u>	<u>(92,946)</u>
Other income:				
Other income, net	2,000	3,647	4,593	7,397
Total other income, net	<u>2,000</u>	<u>3,647</u>	<u>4,593</u>	<u>7,397</u>
Net loss	<u>(47,247)</u>	<u>(50,228)</u>	<u>(90,743)</u>	<u>(85,549)</u>
Other comprehensive income (loss)				
Unrealized gain on available-for-sale securities, net of tax	—	93	1	250
Comprehensive loss	<u>\$ (47,247)</u>	<u>\$ (50,135)</u>	<u>\$ (90,742)</u>	<u>\$ (85,299)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.40)</u>	<u>\$ (0.46)</u>	<u>\$ (0.77)</u>	<u>\$ (0.78)</u>
Weighted-average common shares outstanding, basic and diluted	<u>119,362,670</u>	<u>109,450,071</u>	<u>117,490,439</u>	<u>109,119,630</u>

(1) Includes related-party amounts of \$1,131 and \$2,266 for the three and six months ended June 30, 2024, respectively, and \$2,258 and \$5,218 for the three and six months ended June 30, 2023, respectively.

(2) Includes no related-party amounts for both the three and six months ended June 30, 2024, and \$0 and \$375 for the three and six months ended June 30, 2023, respectively.

INVIVYD Q2 2024 FINANCIAL RESULTS & BUSINESS HIGHLIGHTS

August 14, 2024

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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 immunocompromised patients; our plans, strategies, goals and expectations related to the commercialization of PEMGARDA; potential evolution of PEMGARDA fact sheet; the future of the COVID-19 landscape, including the anticipated fall/winter respiratory virus season; our belief about the sufficiency of certain other COVID-19 therapies; our belief that mAbs may be critical for managing endemic virus over the long term; 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; our expectations regarding advancement of our pipeline and anticipated potential improved clinical and commercial profiles; our business strategies and objectives, and ability to execute on them; our future prospects; the company’s anticipated 2024 net product revenue and projected 2024 year-end cash position; 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 immunocompromised patients 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; whether we are able to successfully submit any future EUA request to the FDA, and the timing, scope and outcome of any such EUA request; uncertainties related to the regulatory authorization or approval process; changes in the regulatory environment; the timing, 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 nonclinical studies; the risk that results of nonclinical 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; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; 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 can obtain and maintain third-party coverage and adequate reimbursement for PEMGARDA or any other product candidate; whether we are able to achieve improved clinical and commercial profiles with our product pipeline; any legal proceedings or investigations relating to the company; our ability to continue as a going concern; 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.

▶ Executive Summary

Commercial Update

Pipeline

Virology

Finance

Q&A

A QUARTER OF BUSINESS PREPARATION, EVOLUTION & ACCELERATION

- **PEMGARDA™ uptake accelerating nicely after a slow start early in the quarter**
- **Key respiratory disease season approaching; activation preparations underway**
- **Pipeline offering improved clinical & commercial profile advancing**
- **Ongoing evolution of *in vitro* virology, anticipated PEMGARDA Fact Sheet evolution, and future opportunities**
- **CANOPY 180-day data anticipated to be released soon**

IT'S **2024** AND YET...

Approximately every

8 MINUTES,

a person in the U.S. **DIES**
with COVID-19*



COVID-19=coronavirus disease 2019.
*Calculation based on provisional CDC data (from Oct 1, 2023 start date of RESP-NET, through June 15, 2024, ~45,200 people in the U.S. died with COVID-19).
Reference CDC. COVID Data Tracker. Accessed July 8, 2024. https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00

THE VIRUS WILL NEVER GO AWAY

2021



Delta variant makes up 10% of new COVID cases in the US. Should Americans be worried?

June 11, 2021



The delta variant: Everything you need to know

The coronavirus variant is on track to become the dominant version of the virus in the U.S. Here's what you need to know about it and the delta plus variant.

July 2, 2021

The Washington Post

Spread of delta variant ignites covid hot spots in highly vaccinated parts of the U.S., Post analysis finds

August 12, 2021

2022-2023



Life expectancy in the U.S. continues to drop, driven by COVID-19

August 31, 2022



Are COVID-19 symptoms still the same? What to know about this winter's JN.1 wave

December 22, 2023



With a new Covid-19 variant on the rise, here's how to stay safe this holiday season

December 22, 2023

2024



Why are 1,500 Americans still dying from COVID every week?

January 10, 2024



US to Face Another Summer COVID-19 Wave in 2024?

June 19, 2024

Stateline

Wastewater tests show COVID infections surging, but pandemic fatigue limits precautions

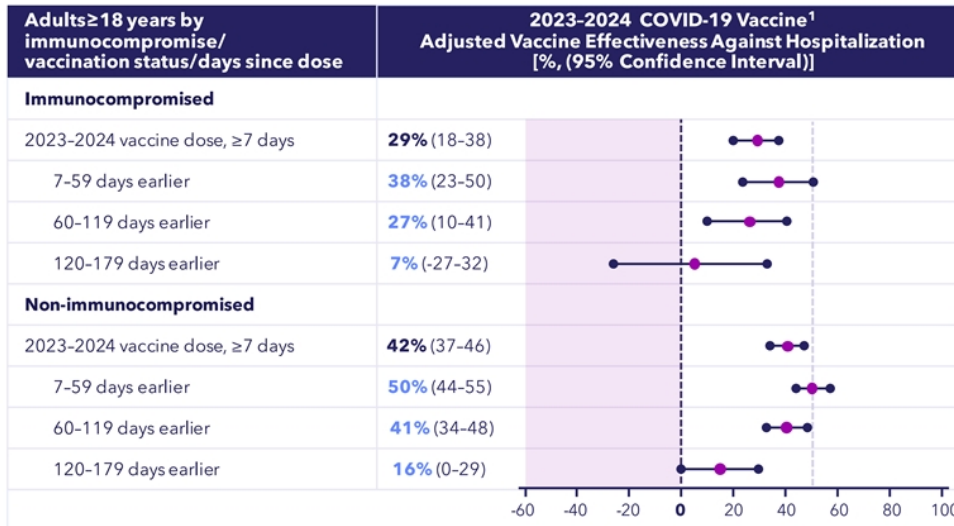
January 23, 2024

EVERY YEAR, THE SAME STORY: COVID-19 IS IN NONSTOP EVOLUTION

COVID-19—coronavirus disease 2019.

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WE BELIEVE COVID-19 VACCINES ARE INSUFFICIENT FOR REAL PROTECTION, ESPECIALLY FOR IMMUNOCOMPROMISED PEOPLE



The sole 2023-24 Vaccine Effectiveness (VE) estimate data available for Immunocompromised (IC) persons presented to ACIP shows VE at max ~38% reduction in hospitalization over the short term (when vaccine dose is given 7-59 days earlier)¹

Perhaps not surprisingly, the CDC recommends IC populations boost no more than every 2 months, or no more than 6 times per year²

CDC=U.S. Centers for Disease Control and Prevention; COVID-19=coronavirus disease 2019; IC=immunocompromised.
References: **1.** FDA. Effectiveness of COVID-19 (2023-2024 Formula) vaccines, presented to the Advisory Committee on Immunization Practices (ACIP), June 2024. Accessed July 1, 2024. <https://www.fda.gov/media/179140/download> **2.** CDC. Interim 2023-2024 COVID-19 Immunization Schedule for Persons 6 Months of Age and Older. Accessed July 19, 2024. <https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf>

WE BELIEVE MABS MAY BE CRITICAL FOR MANAGING ENDEMIC VIRUS OVER THE LONG TERM

- COVID-19 disease remains a pervasive human health threat, with particular burden imposed on immunocompromised people.
- Vaccinations, infections, and the associated immunologic imprinting have left humans with measurable baseline immune experience but continued risk and a potential benefit associated with increasing protective antibody titers
- Upcoming **CANOPY** and **Supernova** (AZN) clinical trial results will yield important insights into the potential role of mAbs in immunologically experienced populations. We plan to leverage these insights, along with our work on VYD2311, to expand the scope of our business.

References: FDA. Effectiveness of COVID-19 (2023-2024 Formula) vaccines, presented to the Advisory Committee on Immunization Practices (ACIP), June 2024. Accessed July 1, 2024., Invivyd data on file

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COMMERCIAL OVERVIEW: RAPID EVOLUTION TO GROWTH

Situation at Start of Q2

- Legacy leadership & strategy
- Low ambient COVID-19 in the US*
- Low PEMGARDA awareness
- Strong HCP perception of COVID-19 seasonality
- Observable underlying demand



Today

- Best-in-class biopharma commercial team



- High ambient COVID-19*
- Significantly expanded PEMGARDA awareness
- Substantial growth in access
- Substantial acceleration in sales
- Preparing for respiratory season & activation

References: *CDC NWSS, Invivyd data on file

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KEY LAUNCH METRICS

	As of May 1	As of June 30	As of July 31
HCP Interactions Logged	34	1,338	2,029
Unique Accounts Called On	33	679	909
Accounts Ordered	7	115	208

- Centers for Medicare and Medicaid Services (CMS) had issued product specific HCPCS codes for PEMGARDA drug and administration with no copay for Medicare patients
- Rapid growth in commercial coverage across national and regional plans, including United Health Care, Aetna, Cigna, and Regional Blue Cross Plans

Source: Invivyd data on file

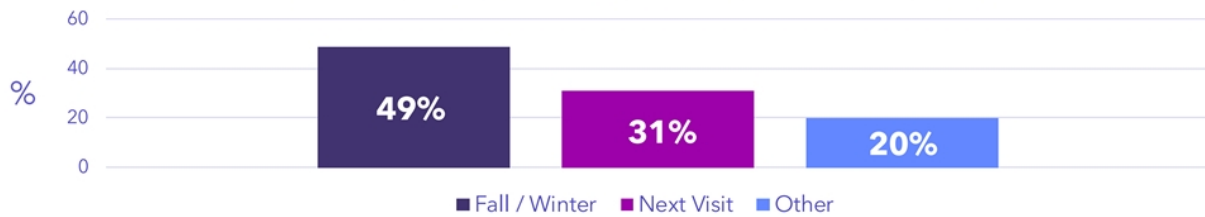
RESEARCH SHOWS HCP PERCEPTION OF COVID-19 SEASONALITY DESPITE CONSTANT THREAT

Select Highlights from Survey of Transplant Surgeons, Hematologists-Oncologists (n=45)
Conducted Over April → May 2024*

HCP Feedback On Risk COVID-19 Poses to their Patients



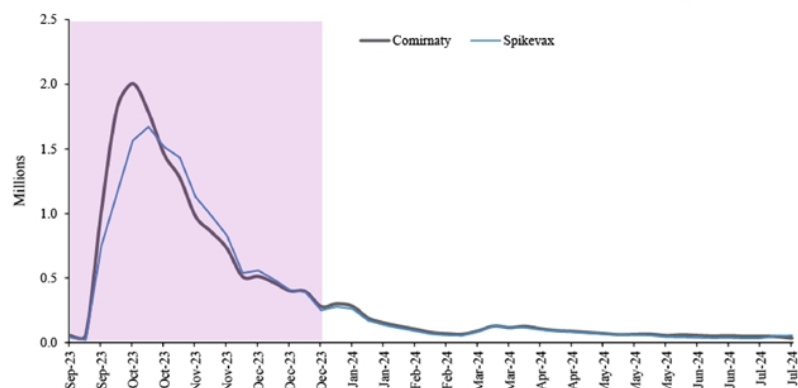
HCP Intended Timing of PEMGARDA Utilization



* Third Party non-scientific survey conducted by Guidepoint provided to Invivyd in 2Q 2024, analyzed by Invivyd. Target HCPs include transplant surgeons, hematologists-oncologists

IMPENDING RESPIRATORY SEASON: POST-LABOR DAY PUSH

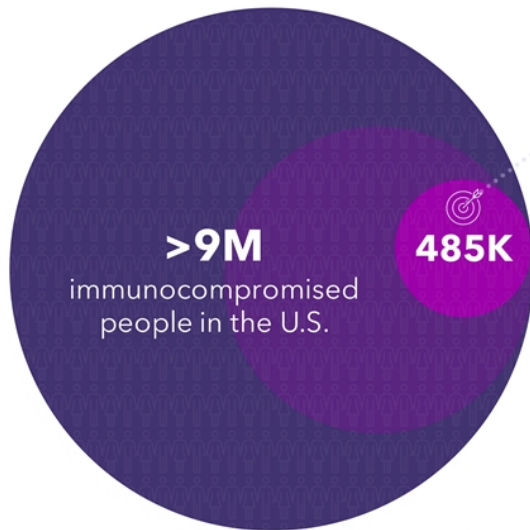
2023-2024 Season Historical COVID-19 Vaccine Utilization Trends



- COVID-19 prophylaxis habits shaped by vaccine conventions
- Majority of vaccine utilization in the preventative "season", despite:
 - ✓ Clear persistence of COVID-19 outside of the season
 - ✓ Short durability of vaccine effectiveness
- Millions of Americans per week have reached for COVID-19 boosts during the last COVID-19 vaccination "season"

Source: JPM Biotech - Large Cap | MRNA / BNTX / BGNE / INCY / ITCI / ALKS / AMRN / ESPR: Latest Rx Trends. 2 August 2024.

THIS IS OUR OPPORTUNITY TO OFFER ADDITIONAL PROTECTION TO THE VULNERABLE



Lower  Higher
Risk of severe COVID-19 based on HCP surveys

Reference: Estimates based on Invivyd-sponsored market research and internal analysis.

Commercial focus:

- **~485K who are moderately to severely immunocompromised and at highest risk for severe COVID-19:**
 - 67K: stem cell transplants
 - 86K: solid organ transplants (liver/lung/kidney)
 - 332K: hematologic cancers
- Care for these populations is often associated with specialized centers
- These groups are often receiving other IV infusions as part of their care
- Invivyd revenue guidance contemplates 30-40K doses of PEMGARDA sold by year-end

INVIVYD FALL ACTIVATION PLAN

- Digital campaign on disease awareness & antibody therapies
- Hiring and deploying Regional Clinic Specialists
- Developing updated corporate positioning and awareness
- Developing a class of trade strategy to increase access to infusion sites
- Educational HCP webinars and presence & educational events at National Congresses (ID Week, ACR, ASH, and ATC)
- Inside sales team (high efficiency telephonic sales)

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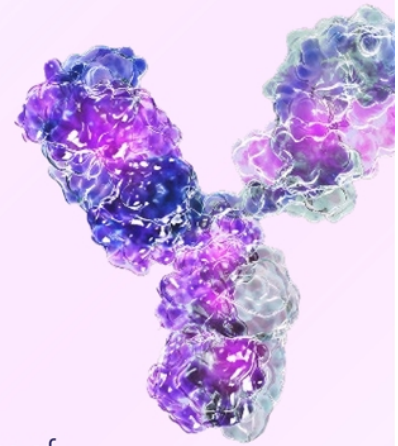
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NEXT UP: VYD2311, A MAB WITH HIGH IN VITRO POTENCY SHOWN AGAINST POST-OMICRON COVID-19 VARIANTS TESTED TO DATE

Our next-generation mAb, VYD2311, improves biophysical properties; shows continued *in vitro* neutralization activity in pseudovirus assays against KP1.1 FLiRT, KP.2 FLiRT, and KP.3 variants

Development:

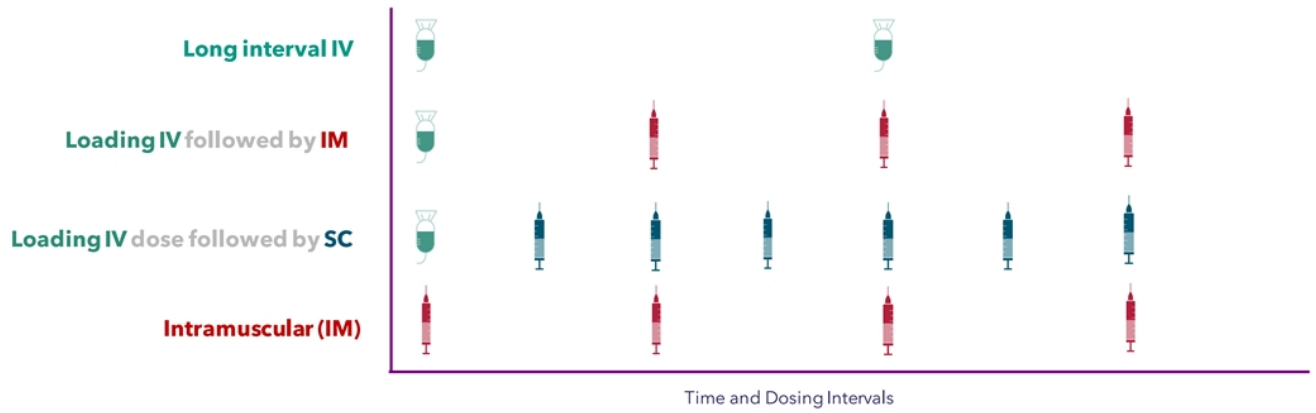
- Next generation molecule VYD2311 first-in-human clinical trial dosing scheduled to begin late August
- Development program for VYD2311 designed to evaluate diverse routes of administration (e.g., IV, IM, SC) **for treatment and PrEP**



COVID-19= COVID-19=coronavirus disease 2019; IM=intramuscular; IV=intravenous; mAb=monoclonal antibody; PrEP=pre-exposure prophylaxis; SC=subcutaneous.
Reference: Invivyd. Data on File.

VYD2311 OPEN FIH PROTOCOL WITH IV AND INTRAMUSCULAR FORMULATIONS; SUBCUTANEOUS FOLLOWING SHORTLY

Depending on the target clinical SVNA titer, VYD2311 pharmacokinetic profile, and antiviral potency (IC50), there may be many ways to achieve and hold attractive titers for PrEP



IM=intramuscular; IV=intravenous; mAb=monoclonal antibody; SC=subcutaneous; FIH = First In Human
Reference: Invivyd. Data on File.

NEAR TERM VYD2311 GOALS

- Determine first-in-human safety at escalating doses
- Determine pharmacokinetic profile (PK), including in vivo half-life
- Explore Safety and PK across posologies / routes of administration
- Determine authorization pathways and titer thresholds with regulators going forward

Reference: Invivyd. Data on File.

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COVID-19 IMMUNOBRIDGING ENDPOINTS REQUIRE A TITER POINT ESTIMATE BASED ON VIROLOGY

Pemivibart Titer Bridge Calculation

Calculated titer for adintrevimab against Delta

- 12 total EVADE study clinical events: 71% relative risk reduction against Delta through Day 90
- AVNA estimated adintrevimab potency EC50 value: 7 ng/ml vs Delta

Calculated titer for pemivibart against JN.1

- AVNA estimated pemivibart potency EC50 value: 63.6 ng/ml
- Calculated titer for pemivibart reflecting EC50, dose, and estimated PK

Resulting Ratio & Sensitivity

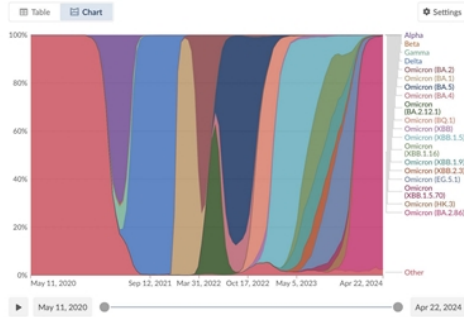
- AVNA to AVNA estimated titer bridge = 0.82
- PVNA to PVNA estimated titer bridge = 0.35

*"Immunobridging is based on the serum neutralization titer-efficacy relationships identified with other neutralizing monoclonal antibodies against SARS-CoV-2... this highlights the impact of even modest differences in EC50 values on the results of the primary endpoint" - **PEMGARDA Fact Sheet***

SINGLE SVNA TITER POINT ESTIMATES ARE OBSOLETE BY CONSTANT VIRUS EVOLUTION...

SARS-CoV-2 variants in analyzed sequences, United States

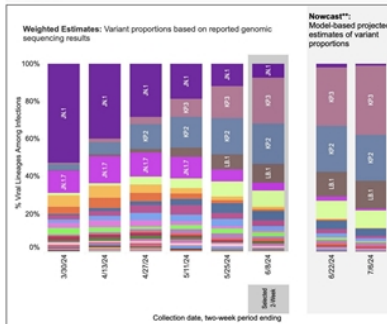
The number of analyzed sequences in the preceding two weeks that correspond to each variant group. This number may not reflect the complete breakdown of cases since only a fraction of all cases are sequenced.



Data source: GISAID, via CoVariants.org - Last updated 3 May 2024 - [Learn more about this data](#)
 Note: Recently-discovered or actively-monitored variants may be overrepresented, as suspected cases of these variants are likely to be sequenced preferentially or faster than other cases.
 OurWorldinData.org/coronavirus-1-CC-BY

Weighted Estimates in United States for 2-Week Periods in 3/17/2024 – 7/6/2024

Hover over (or tap in mobile) any lineage of interest to see the amount of uncertainty in that lineage's estimates.



Weighted Estimates in United States for 5/26/2024 – 6/8/2024

These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates.

WHO label	Lineage #	%Total	95%CI
Omicron	KP.3	24.5%	18.4-31.6%
	KP.2	21.5%	17.5-25.9%
	LB.1	10.0%	5.2-17.0%
	KP.1.1	8.9%	4.8-15.2%
	JN.1	7.4%	4.8-10.9%
	JN.1.16.1	4.8%	2.5-8.2%
	JN.1.7	4.0%	1.7-7.9%
	JN.1.16	3.1%	1.6-6.4%
	JN.1.18	2.2%	1.2-3.7%
	JN.1.15.1	2.1%	1.1-3.7%
	XDIV.1	1.4%	0.2-4.0%
	KP.4.1	1.3%	0.4-3.4%
	JN.1.13.1	1.2%	0.3-3.0%
	KS.1	1.1%	0.4-2.6%
	KQ.1	1.1%	0.1-3.7%
	JN.1.8.1	1.0%	0.3-2.4%
	JN.1.32	0.8%	0.0-4.4%
	KW.1.1	0.8%	0.2-2.2%
	XDP	0.6%	0.1-1.8%
	KV.2	0.3%	0.0-1.2%
	JN.1.4.3	0.3%	0.0-1.5%
	BA.2	0.0%	0.0-0.4%

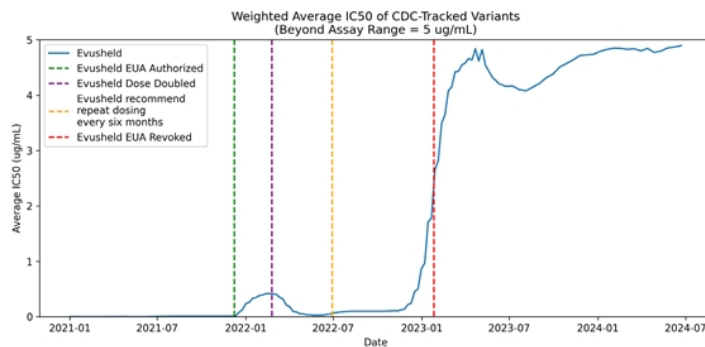
... So what is the **average IC50** over any given time for a specific mAb?

Source: CDC and Our World In Data

ARITHMETIC OF AVERAGE IC50 AND AUTHORIZATION

- Calculated **weighted average PVNA IC50s** for past antibodies authorized under EUA against prior mixes of circulating viruses
- Studied regulatory withdrawal actions and associated potencies
- Imputed **ancestral removal thresholds** (reliant on data prior to acquisition of population immunity e.g. CANOPY / Supernova)

Evusheld



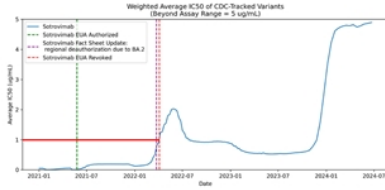
- Authorized 12/8/21
- 2/24/22, dose doubled
- 6/29/22, fact sheet updated to recommend dosing every 6 months
- 1/26/23 EUA revoked

Source: ClinicalTrials.gov Identifier: NCT06039449; IV, intravenous; SAEs, serious adverse events; AEs, adverse events

AVERAGE IC50 DEAUTHORIZATION THRESHOLD

~Average IC50
at deauthorization:

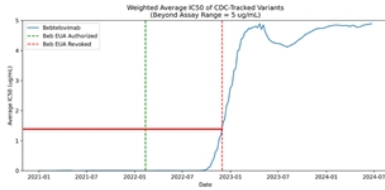
sotrovimab
(GSK/VIR)



1.0 ug/mL

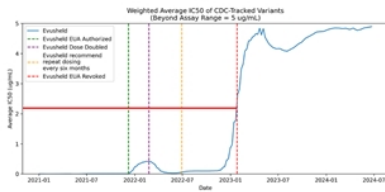
Recent **treatment** mAbs have lost EUA at an average of 1.2 ug/ml

bebtelovimab
(LLY)



1.3 ug/mL

Evusheld
(AZN)

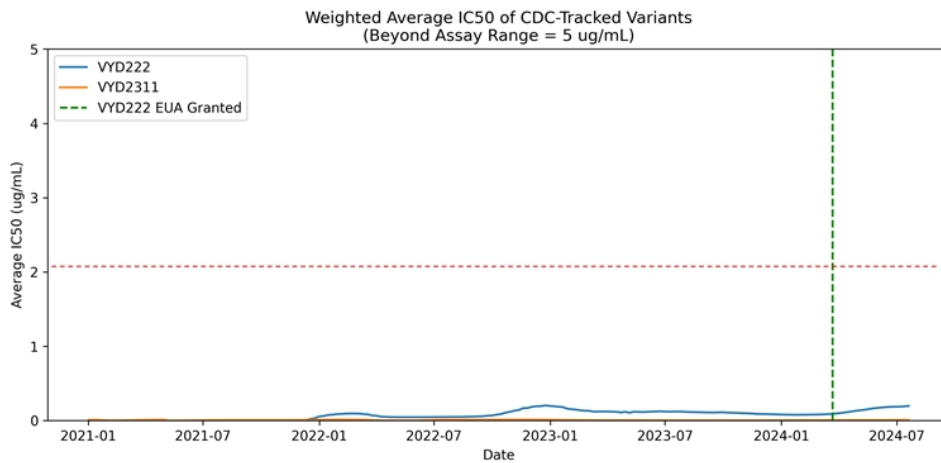


2.1 ug/mL

PrEP mAb combo Evusheld lost EUA at approximately 2 ug/mL

Source: Published data and Invivyd analysis.

VYD222 (PEMIVIBART) AND VYD2311 IC50 VALUES APPEAR ESSENTIALLY STABLE, AS A STABLE EPITOPES MIGHT PREDICT



- VYD222 / pemivibart has not experienced a major deviation from the average IC50 baseline
- VYD2311 has shown greater potency/stability (orange line at bottom of graph)
- Pemivibart epitope structure (5 angstrom cloud) remains stable post-Omicron through KP.3

Source: Published data and Invivyd analysis.

A POTENTIAL VENDOR CONTAMINATION EVENT REQUIRES REGENERATION OF ONE AVNA VALUE

- In mid-July, Invivyd learned and promptly notified the FDA of a potential contamination event at a vendor that provides authentic viral neutralization assay (AVNA) testing services to the industry, including Invivyd
- Invivyd is in the process of generating new JN.1 AVNA values at multiple labs, which may impact the estimated AVNA value for JN.1
- The JN.1 pseudovirus (PVNA) value is reassuringly similar to the AVNA value now in question (63.6 ng/ml AVNA vs. 74.6 ng/ml PVNA)
- As required by the PEMGARDA EUA, Invivyd provides the FDA with continuous virology updates, including PVNA and AVNA values, which along with the aforementioned event, will likely result in revisions to the PEMGARDA fact sheet
- FDA is also in receipt of preliminary CANOPY 180-day data, including exploratory efficacy endpoints

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FINANCIALS

- Ended Q2 2024 with cash and cash equivalents of \$147.9 million
- Revenue and cash guidance re-iterated (\$150-\$200m in revenue), \$75m in year-end cash
- Previously announced operating efficiencies began to take effect in Q2
- VYD2311 clinical and launch material production; meaningful quantities expensed to R&D already
- Continuing to evaluate multiple sources of additional capital

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