

**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): September 6, 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 8.01. Other Events.

On September 6, 2024, Invivyd, Inc. posted an updated corporate presentation on its website at www.invivyd.com. A copy of the presentation is filed herewith as Exhibit 99.1 and is incorporated by reference in this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation, dated September 6, 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: September 6, 2024

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

INVIVYD

Corporate Overview

September 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™ (pemivibart) 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; the potential of our platform, including with respect to our mAb engineering capabilities, anticipated future immunobridging studies, and the potential commercial opportunity for our product candidates; the company’s general alignment with the U.S. Food and Drug Administration (FDA) on a repeatable immunobridging pathway to future potential Emergency Use Authorization (EUA) for serial, novel mAbs for the prevention and treatment of symptomatic COVID-19, including the company’s beliefs regarding the potential benefits, certain anticipated costs, and possible outcomes of utilizing such pathway; the company’s EUA amendment request to the FDA for PEMGARDA for COVID-19 treatment in certain immunocompromised patients; the company’s expectation that, if authorized, PEMGARDA would represent the first and only mAb authorized in PrEP and treatment of COVID-19 in certain immunocompromised patients; the potential of pemivibart for clinical protection from symptomatic COVID-19 based on the 180-day exploratory clinical efficacy data from the CANOPY clinical trial; the future of the COVID-19 landscape; our beliefs regarding the sufficiency of certain other COVID-19 therapies; our expectations about the potential market opportunity for mAbs, 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 improved drug profiles; our expectations regarding the biophysical properties and development of VYD2311; our beliefs regarding potential adjacent opportunities; 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; the outcome of the company’s EUA amendment request for PEMGARDA for COVID-19 treatment in certain immunocompromised patients, and the timing thereof; our ability to effectively utilize an immunobridging pathway to potential EUA for serial, novel mAbs for the prevention and treatment of COVID-19; 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, and available development and regulatory pathways for authorization or approval of the company’s product candidates; 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 any 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; variability of results in models used to predict activity against SARS-CoV-2 variants; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; whether pemivibart, VYD2311, 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; whether we are able to achieve high potency and/or variation resistance with our future 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 Annual Report on Form 10-K for the year ended December 31, 2023 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, each 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

▶ What We Do

How We Do It

Where We Are

What Comes Next

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

INVIVYD 4

SO, WHILE YOU WERE...

Getting ready in
the morning

15 minutes

2

Having lunch
with your colleague

60 minutes

7

Watching a
movie on Netflix

2 hours

14

Sleeping

8 hours

56

PEOPLE IN THE U.S. DIED WITH COVID-19*

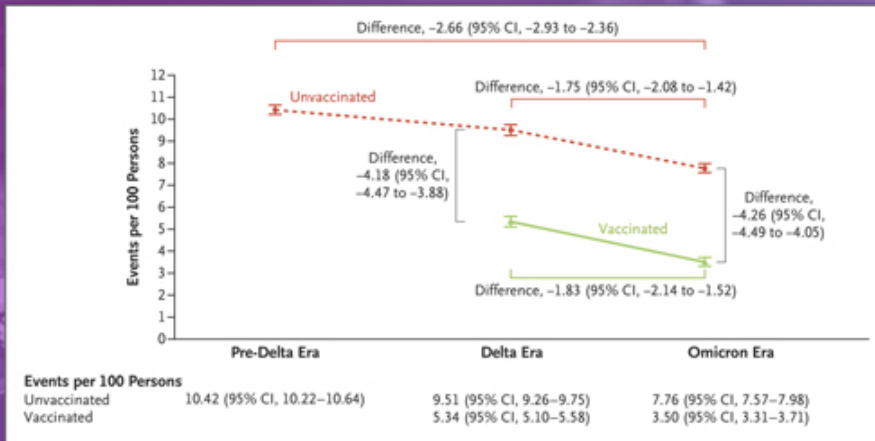
COVID-19=coronavirus disease 2019.

*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

MOREOVER, COVID-19 PLAYS NEVERENDING ROULETTE WITH OUR OVERALL HEALTH

Cumulative Incidence of Post-acute Sequelae ("Long COVID") of COVID-19 Infection¹





- 3.5% to 7.8% chance of developing Long COVID¹
- Reinfection may be the norm^{2*}

COVID-19=coronavirus disease 2019; PCR=polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.
^{*}COVID-19 reinfection defined as a positive SARS-CoV-2 PCR or antigen test that occurred 60 or more days after a COVID-19 infection index date. The date of the test was considered the first COVID-19 reinfection index date. Subsequent reinfections were defined as a new positive SARS-CoV-2 PCR or antigen test that occurred 60 or more days after each reinfection index date.
References: 1. Xie Y, et al. *N Engl J Med*. Published online July 17, 2024. doi:10.1056/NEJMoa2403211. 2. Hadley E, et al. *Commun Med*. 2024; doi: 10.1038/s43856-024-00539-2.

COVID-19 IS THE MOST DAMAGING AND DEADLY OF PREVALENT RESPIRATORY VIRUSES

COVID-19 is the leading cause of hospitalizations and death from respiratory viruses in the U.S. (2023-2024 data)*

	 Hospitalizations ^{1*}	 Deaths [*]
COVID-19	460,000	45,200²
INFLUENZA	272,000	9,900 ³
RSV	179,000	~6,000-10,000 ^{4†}

COVID-19=coronavirus disease 2019; RSV=respiratory syncytial virus.

*From Oct 1, 2023, through June 15, 2024; hospitalizations for all 3 viruses calculated based on 334.9 million US Census Bureau estimate of US population size and CDC reported rates of hospitalizations. RSV death data are an estimate from the CDC prior to the COVID-19 pandemic.

[†]Estimate in adults aged ≥65 years prior to the COVID-19 pandemic. Mortality data for the 2023-2024 season are not currently available.

References: **1.** CDC. RESP-NET. Accessed July 8, 2024. <https://www.cdc.gov/resp-net/dashboard/?CDC> **2.** CDC. COVID Data Tracker. Accessed July 8, 2024. https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00 **3.** CDC. FluView. Accessed July 8, 2024. <https://gis.cdc.gov/grasp/fluview/mortality.html> **4.** CDC. Readout of Advisory Committee on Immunization Practices Meeting Held June 26 - 28, 2024. Accessed July 8, 2024. <https://www.cdc.gov/media/releases/2024/s-0627-immunization-practices-meeting.html>

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 US. 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

CBS NEWS

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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COVID-19 BURDEN RESTS DISPROPORTIONATELY ON THE IMMUNOCOMPROMISED

Updated INFORM study data from England (1H 2023) found that in a sample of nearly 12 million people¹:

Immunocompromised people represented only **4% of the study population...**



Immunocompromised

YET

Immunocompromised people accounted for:



~23% of COVID-19 hospitalizations



~22% of COVID-19 deaths

Even though almost **73% of the immunocompromised population had received ≥ 4 COVID-19 vaccine doses**

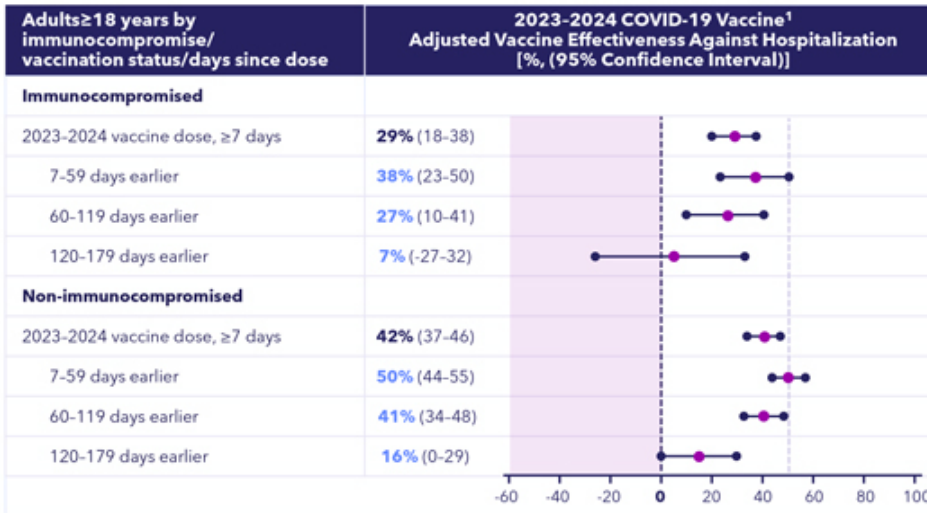
EPOCH 2022 analysis²

Immunocompromised people accounted for ~30% of total costs for first COVID-19 hospitalization despite accounting for only ~3% of the study population

COVID-19=coronavirus disease 2019; EPOCH=Emerging Populations and Outcomes associated with COVID-19-Health Conditions in the United States; INFORM=INvestigation of cOvid-19 Risk among Immunocompromised populations.

References: **1.** Dube S, et al. Continued increased risk of COVID-19 hospitalisation and death in immunocompromised individuals despite receipt of ≥ 4 vaccine doses: updated 2023 results from INFORM, a retrospective health database study in England. Presented at ECCMID 2024 [posterP0409]; Barcelona, Spain; **2.** Ketkar A, et al. *Adv Ther.* 2024;41(3):1075-1102.

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

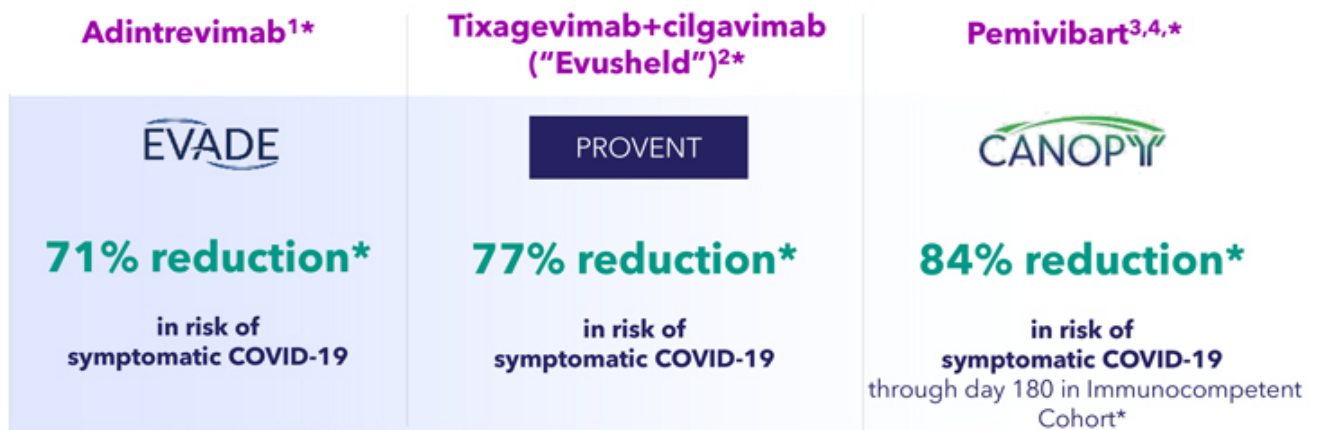


The sole 2023-24 Vaccine Effectiveness (VE) estimate data available for Immunocompromised (IC) persons presented to ACIP shows VE at max ~38% reduction in hospitalization over the short term (when vaccine dose is given 7-59 days earlier)¹

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>

WHEREAS ANTIBODIES HAVE BEEN SHOWN TO PROTECT PEOPLE FROM GETTING SICK WITH COVID-19






COVID-19= COVID-19=coronavirus disease 2019.

*Figures provided represent relative risk reduction versus placebo.

References: **1.** Ison MG, et al. *Open Forum Infect Dis.* 2023 Jun 13;10(7):ofad314. **2.** Levin MJ, et al. *N Engl J Med.* 2022;386(23):2188-2200. **3.** Invivyd. Data on File. **4.** Symptomatic COVID-19 event collection in the CANOPY clinical trial is an exploratory endpoint and not part of the primary immunobridging endpoint of the CANOPY clinical trial.

Adintrevimab is an investigational monoclonal antibody that has not been approved for use by any regulatory authorities; the safety and efficacy of adintrevimab have not been established. No head-to-head clinical trials have been conducted between adintrevimab, pemivibart, and/or tixagevimab+cilgavimab, and comparative conclusions cannot be made between antibodies.

WE SEE THE COVID-19 "STANDARD OF CARE" AS SUB-STANDARD, CREATING IMMENSE OPPORTUNITY FOR MONOCLONAL ANTIBODIES

Prevention (Vaccines)		<p>~38% vaccine effectiveness against hospitalization in IC for 2023-2024 vaccine¹</p> <p>Potential strain mismatch for 2024-2025 vaccine^{2,3}</p>	<p>>\$10B</p> <p>2024 Estimated Revenue⁸</p>
Outpatient Treatment		<p>Paxlovid™ is standard of care, but prominent drug-drug interaction issues and potential for rebound^{4,5*}</p> <p>Lagevrio™ is associated with viral mutagenicity⁶</p>	
Inpatient/ Outpatient Treatment		<p>Veklury® requires daily infusions over multiday treatment period⁷</p>	

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 IC=immunocompromised; mAb=monoclonal antibody; WBC=white blood cell.
 *Primary objective of the trial was to compare the efficacy of nirmatrelvir-ritonavir with that of placebo for the treatment of COVID-19, as measured by the difference in time to sustained alleviation of all targeted COVID-19 signs and symptoms through day 28.
References: 1. FDA, Effectiveness of COVID-19 (2023-2024 Formula) vaccines, June 2024. Accessed July 1, 2024. <https://www.fda.gov/media/179140/download> 2. FDA, Updated COVID-19 Vaccines for Use in the United States Beginning in Fall 2024. Accessed July 8, 2024. <https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2024> 3. Novavax Press Release. Accessed July 8, 2024. <https://ir.novavax.com/press-releases/2024-06-14-Novavax-Submits-Application-to-US-FDA-for-Updated-Protein-based-2024-2025-Formula-COVID-19-Vaccine> 4. PAXLOVID [Fact Sheet for Healthcare Providers]. Pfizer, 2023. 5. Hammond J, et al. *N Engl J Med*. 2024;390(13):1186-1195. 6. IDSA. Trial Shows Increased SARS-CoV-2 Mutations, Delayed Viral Clearance With Molnupiravir Treatment. Accessed July 31, 2024. https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/trial-shows-increased-sars-cov-2-mutations-delayed-viral-clearance-with-molnupiravir-treatment/#/*/0/publishedDate_na_dt/desc/ 7. Veklury (remdesivir) [Prescribing Information]. Gilead Sciences; February 2024. 8. Company Form 10-Qs, Earnings Releases, and Guidances.

AGENDA

What We Do

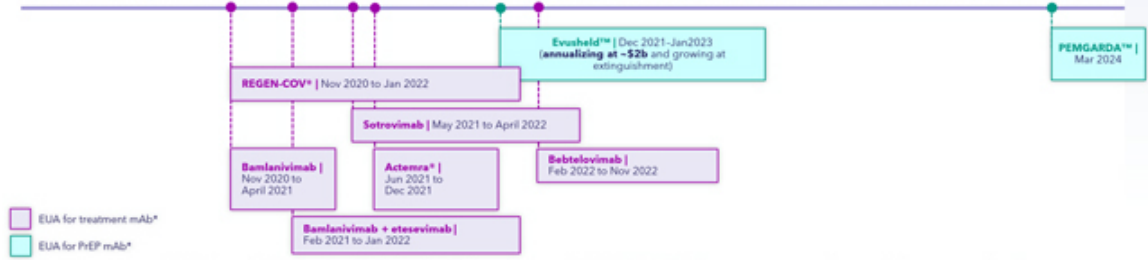
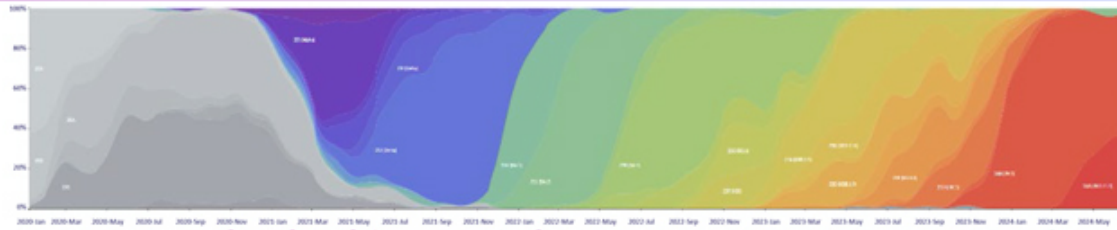
▶ How We Do It

Where We Are

What Comes Next

THE REALITY: SARS-COV-2 CONTINUES TO EVOLVE¹, AND SO MUST WE

Others have tried with mAbs, but succumbed to inevitable viral evolution²



EUA=emergency use authorization; mAb=monoclonal antibody; PrEP=Pre-exposure prophylaxis; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. All trademarks are the property of their respective owners.

References: 1. Nextstrain. Accessed July 1, 2024. <https://nextstrain.org/ncov/gisaid/global/all-time> 2. CMS. Accessed July 1, 2024. <https://www.cms.gov/monoclonal>

*See respective Healthcare Professional Fact Sheets for product-specific information. As it relates to PEMGARDA, please see the PEMGARDA full product Fact Sheet for Healthcare Providers, including Important Safety Information and Boxed Warning.

“I mourned the loss of monoclonal antibodies as the virus evolved their utility away.”
 - Jason Gallagher, PharmD, FCCP, FIDP, BCPS at Temple University

ADDRESSING REALITY: INVIVYD'S PROPRIETARY PLATFORM

We are working to raise the bar on the standard of care by continually staying ahead of viral evolution



Rapid mAb Engineering

- Privileged epitopes
- Rapid affinity maturation
- Surveillance-informed metrics for greater variation resistance



Rapid Immunobridging Studies

- Master clinical trial protocol anticipated to streamline evaluation of serial mAbs
- Compact clinical programs to evaluate new mAbs expected to rapidly generate data for treatment and prevention use cases



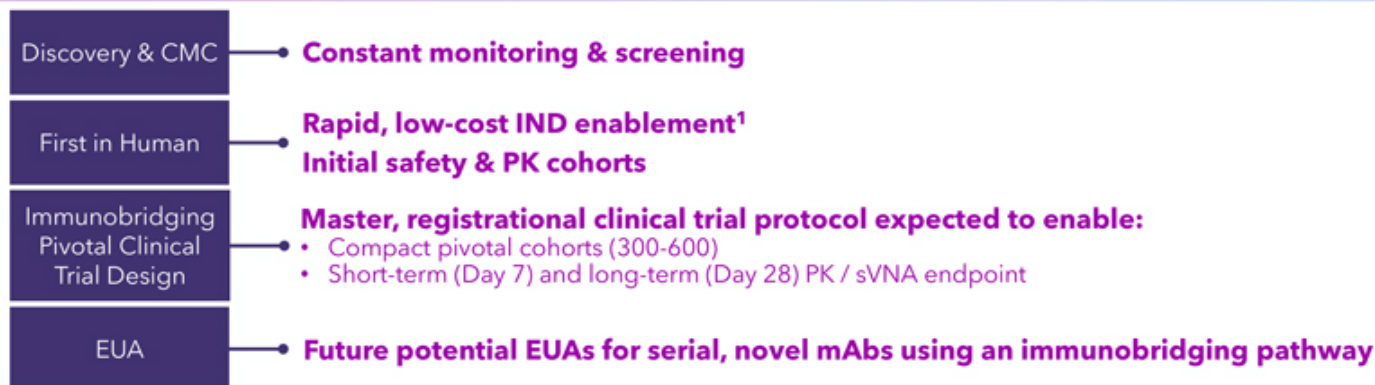
Commercial Opportunity

- Multiple profiles anticipated to be generated for specific molecules and use cases
- We intend to consider diverse routes of administration (e.g., IV, IM, SC) for future mAb candidates

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

OUR PLATFORM OFFERS HIGH SPEED, HIGH CONFIDENCE INNOVATION

General alignment reached with the U.S. FDA on a repeatable, expedient EUA pathway for the prevention and treatment of COVID-19, based on compact clinical programs to establish safety and immunobridging for serial mAbs



Key efficacy endpoint for COVID-19 Treatment and PrEP is sVNA titers: a simple calculation of mAb plasma concentration / IC₅₀

CMC=chemistry, manufacturing, and controls; COVID-19=coronavirus disease 2019; EUA= emergency use authorization; FDA=U.S. Food and Drug Administration; IND=investigational new drug; mAb=monoclonal antibody; PK=pharmacokinetics; PrEP=pre-exposure prophylaxis; sVNA=serum viral neutralizing antibody.

Reference: 1. Invivyd. Data on File, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8516790/>

EUA regulatory pathway for COVID-19 therapies is subject to FDA's 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).



**No competitor has currently
demonstrated the technology or
strategy to compete in serial mAb
development**

mAb=monoclonal antibody.

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AGENDA

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PEMGARDA™ REPRESENTS THE REBIRTH OF MABS FOR IMMUNOCOMPROMISED PATIENTS AND A DEBUT FOR INVIVYD

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.

Please see below

PEMGARDA has not been approved but has been authorized for emergency use by the 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.

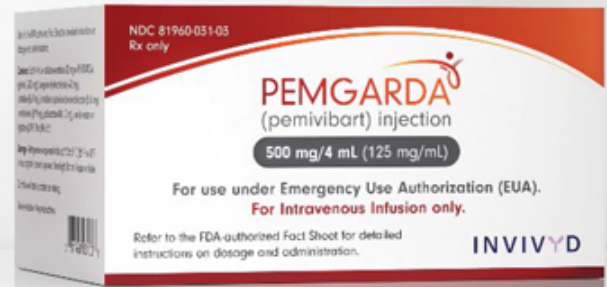
Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccinations, should receive COVID-19 vaccination. In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered at least 2 weeks after vaccination.

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. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

For additional information, please see the PEMGARDA full product Fact Sheet for Healthcare Providers, including Important Safety Information and Boxed Warning.

COVID-19=coronavirus disease 2019; mAb=monoclonal antibody.

Reference: PEMGARDA [Fact Sheet for Healthcare Providers]. Invivyd; August 2024.



THE PEMGARDA™ LAUNCH IS UNDERWAY - KEY 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 Blue Shield Plans

AGENDA

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▶ What Comes Next

POTENTIAL PEMGARDA™ TREATMENT EUA WOULD EXPAND COMMERCIAL REACH



Despite its limitations, ongoing use of Paxlovid for COVID-19 treatment¹ demonstrates a **strong market for treatment options**



If authorized, PEMGARDA **would represent the first and only mAb authorized for use in PrEP and treatment** of COVID-19 in certain immunocompromised patients



We plan to **leverage infrastructure** built with field team for PEMGARDA PrEP to gain traction for treatment if authorized

An EUA amendment request for PEMGARDA has been submitted to FDA for COVID-19 treatment

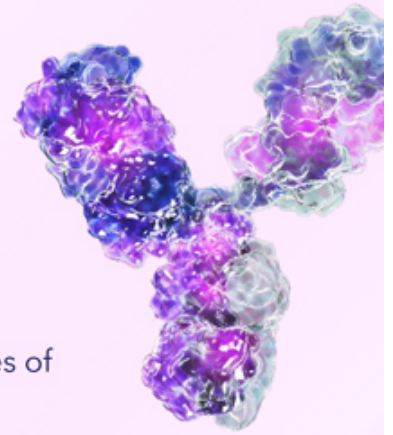
COVID-19=coronavirus disease 2019;EUA=emergency use authorization; FDA=U.S. Food and Drug Administration; mAb=monoclonal antibody; PrEP=pre-exposure prophylaxis.
Reference: 1. PAXLOVID [Fact Sheet for Healthcare Providers], Pfizer, 2023.

NEXT UP: VYD2311, A MAB WITH IN VITRO HIGH 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, including KP.3.1.1 and LB.1

Development:

- First-in-human (FIH) trial initiated in Summer 2024
- Development program for VYD2311 designed to evaluate diverse routes of administration (e.g., IV, IM) **for treatment and PrEP**



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

POTENTIAL FOR ADJACENT OPPORTUNITIES

RSV		Blockbuster category; validated mAbs
HBV/HDV		Malignant orphan; emerging mAb / RNAi doublet
Influenza		Pandemic potential

HBV=hepatitis B virus; HDV=hepatitis D virus; mAb=monoclonal antibody; RNAi=RNA interference.; RSV=respiratory syncytial virus.
Image sources: CDC (RSV, <https://phil.cdc.gov/Details.aspx?pid=2175>; HBV, <https://phil.cdc.gov/Details.aspx?pid=10755>; influenza <https://phil.cdc.gov/Details.aspx?pid=10073>)

SUMMARY

COVID-19 is here to stay—it's how we stay ahead that matters



mAbs are powerful and Invivyd is the virology mAb company



Our platform is designed to power best-in-class mAbs, unrivalled by our competitors



For COVID-19 and pandemic threats, we aim to be perpetually ready

MANAGEMENT TEAM WITH RELEVANT EXPERTISE AND TRACK RECORD OF SUCCESS



Robert Allen, Ph.D.
Chief Scientific Officer



Jill Andersen, J.D.
Chief Legal Officer & Corporate Secretary



William Duke, M.B.A.
Chief Financial Officer



Julie Green, M.B.A.
Chief Human Resources Officer



Timothy Lee
Chief Commercial Officer



Stacy Price, M.S.
Chief Technology & Manufacturing Officer



Mark Wingertzahn, Ph.D.
Senior Vice President of Clinical Development and Medical Affairs



INVIVYD

THANK YOU