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 11, 2023

Invivyd, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-40703**	**85-1403134**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1601 Trapelo Road, Suite 178 **Waltham, MA**	**02451**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 819-0080

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	IVVD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On September 11, 2023, 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

Exhibit No.	Description
99.1	Corporate Presentation, dated September 11, 2023
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 11, 2023

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

Exhibit 99.1

INVIVYD

CORPORATE OVERVIEW

September 2023

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, our mission to rapidly deliver antibodies that protect vulnerable populations from viral threats; the future of the COVID-19 landscape; our expectations regarding the size of target patient populations and the potential market opportunity for our product candidates, as well as our market position; our beliefs regarding the clinical utility of anti-SARS-CoV-2 monoclonal antibodies (mAbs) and our product candidates; the potential of our platform-based approach to continuously discover and optimize mAb candidates that can perpetually protect the vulnerable from serious viral threats; the anticipated broad activity and prolonged utility of VYD222; our ongoing research and clinical development plans and the timing thereof, including with respect to VYD222; the possibility of a unique, rapid development pathway to potential emergency use authorization (EUA) in the U.S. for mAbs using immunobridging via serum neutralizing titers; the anticipated CANOPY clinical trial design, including our plans to use an immunobridging approach comparing data obtained in the CANOPY clinical trial to certain historical adintrevimab data; our expectation to rapidly generate clinical data in the CANOPY clinical trial for a potential VYD222 EUA submission, and the timing of anticipated initial primary endpoint data from the CANOPY clinical trial; our plans to generate a robust pipeline of product candidates which, if authorized or approved, could be used in prevention or treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications; our belief that our existing cash resources will be sufficient to support operating runway into the fourth quarter of 2024; 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: the timing and progress of our discovery, preclinical and clinical development activities; our ability to rapidly generate the clinical data needed from the CANOPY clinical trial to support a potential EUA submission for VYD222; clinical trial site activation or enrollment rates that are lower than expected; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of VYD222 or other 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 in connection with current or future clinical trials; variability of results in models used to predict activity against SARS-CoV-2 variants of concern; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; whether our platform-based approach enables us to continuously discover and optimize mAb candidates that can perpetually protect the vulnerable from serious viral threats; whether VYD222 or any other product candidate is able to demonstrate and sustain neutralizing activity against predominant SARS-CoV-2 variants, particularly in the face of viral evolution; whether we are able to successfully submit an EUA in the future, and the outcome of any such EUA submission; whether our research and development efforts will identify and result in safe and effective therapeutic options for infectious diseases other than COVID-19; 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, 2022 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.

INVIVYD IS ON A MISSION TO RAPIDLY DELIVER ANTIBODIES THAT PROTECT VULNERABLE POPULATIONS FROM VIRAL THREATS, STARTING WITH COVID-19

8-18M

immunocompromised people in the U.S. alone who may not adequately respond to COVID-19 vaccination[1-4]

Zero

authorized or approved monoclonal antibodies (mAbs) in the U.S. to prevent symptomatic COVID-19

Near-Term Opportunity

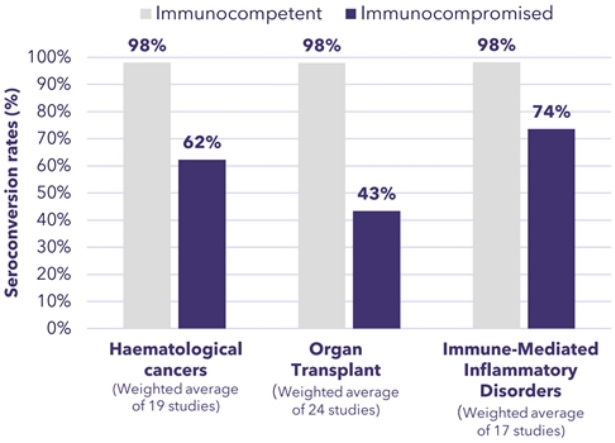
EUA pathway provides the opportunity to rapidly bring a much needed therapeutic to immunocompromised people

References: 1. Harpaz JAMA 2016; 2. Patel Emerg Infect Dis 2020; 3. U.S. 2020 Census Bureau Data; 4. Lee BMJ 2022

MANY IMMUNOCOMPROMISED PEOPLE HAVE AN IMPAIRED RESPONSE TO VACCINES AND LESS PROTECTION AGAINST SEVERE COVID-19 OUTCOMES

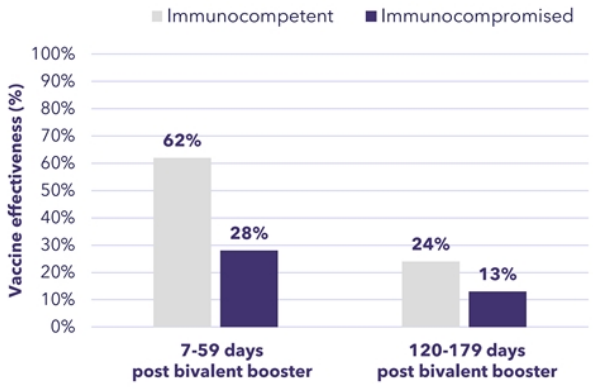
Immunocompromised people are less likely to have detectable SARS-CoV-2 antibodies following vaccination than immunocompetent people

Seroconversion rates (detectable Abs) in immunocompromised people vs. immunocompetent controls after two COVID-19 vaccine doses[1] [*pre-Omicron*]



Immunocompromised people generate less protection against severe outcomes than immunocompetent people after bivalent boosters

Vaccine effectiveness against COVID-19-associated hospitalizations after bivalent booster compared with no vaccination[2]



References: 1. Lee BMJ 2022 ; 2. Centers for Disease Control and Prevention, Estimates of Bivalent mRNA Vaccine Durability in Preventing COVID-19–Associated Hospitalization and Critical Illness Among Adults with and Without Immunocompromising Conditions — VISION Network, September 2022–April 2023; Abs, antibodies

EVEN IN PRIMARILY IMMUNOCOMPETENT POPULATIONS, COVID-19 VACCINE EFFECTIVENESS (VE) HAS WANED

Monovalent boosters provided 90% VE against symptomatic Delta infection vs. 46% VE against symptomatic Omicron infection

VE against symptomatic COVID-19 in primarily immunocompetent[1]

Monovalent (BNT162b2)	**≥10 wks** from monovalent booster (following two doses of monovalent vaccine)
Delta B.1.617.2	90%
Omicron B.1.1.529	46%

Bivalent boosters have shown 4-29% VE against infection with more recent Omicron variants

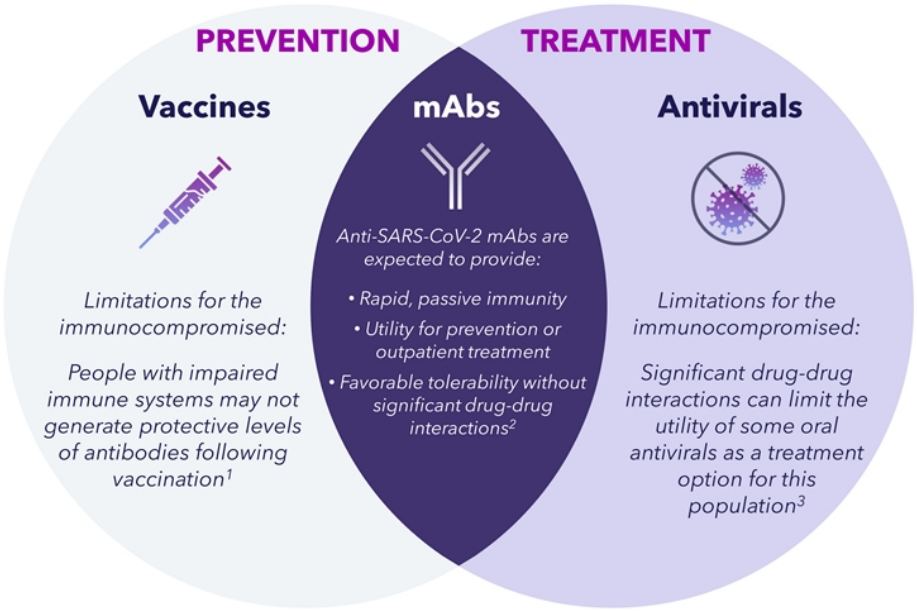
VE against SARS-CoV-2 infection in primarily immunocompetent[2]

Bivalent Booster	**Up to 26 wks** from bivalent booster
Omicron BA.4/5 dominant phase	29%
Omicron BQ dominant phase	20%
Omicron XBB dominant phase	4%

A mAb therapeutic that offers more robust protection against current variants would be an important addition to the COVID-19 medicine cabinet, especially for vulnerable populations

References: 1. Andrews N Engl J Med 2022; 2. Shrestha Open Forum Infectious Diseases 2023

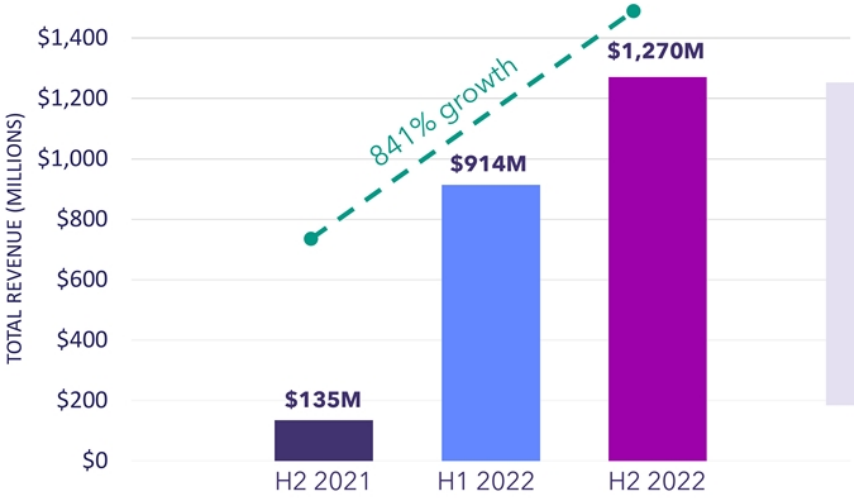
IN ADDITION TO PREVENTION, MONOCLONAL ANTIBODIES ALSO HAVE COMPELLING POTENTIAL IN THE TREATMENT OF COVID-19



References: 1. Lee BMJ 2022; 2. McCreary JAMA Netw Open 2023; 3. Marzolini Clin Pharmacol Ther 2022

PREVENTION OF COVID-19 IN VULNERABLE POPULATIONS PRESENTS A COMPELLING, POTENTIAL LONG-TERM VALUE PROPOSITION

$2.2B in total revenue of Evusheld® in 2022, a mAb previously authorized to protect vulnerable populations from COVID-19[1]



In a 2023 survey of U.S. physicians who treat immunocompromised people, **76% said they would be 'extremely likely' or 'somewhat likely' to use Evusheld® if it were still available and relevant to circulating SARS-CoV-2 strains**[2]

References: 1. Results publicly reported by AstraZeneca; 2. Invivyd-sponsored survey of HCPs in the U.S. (N=197) (2023)

SUMMER UPTICK FORESHADOWS POTENTIAL FALL AND WINTER WAVES AND HIGHLIGHTS ONGOING NEED FOR COVID-19 THERAPEUTICS

The New York Times

Not Over Yet: Late-Summer Covid Wave Brings Warning of More to Come

Hospitalizations are still low but have been rising in recent weeks, according to the Centers for Disease Control and Prevention.

August 28, 2023

STAT

Covid hospitalizations on the rise, Humana says

More older adults have been hospitalized for Covid-19 over the past several weeks, according to data reviewed by health insurer Humana.

September 6, 2023

THE WALL STREET JOURNAL.

An Unwelcome Visitor Returns This Summer. Hint: It's Covid.

Hearing about a smattering of Covid cases again? There's a reason

July 27, 2023

The New York Times

How Bad Is a Second (or Third or Fourth) Case of Covid?

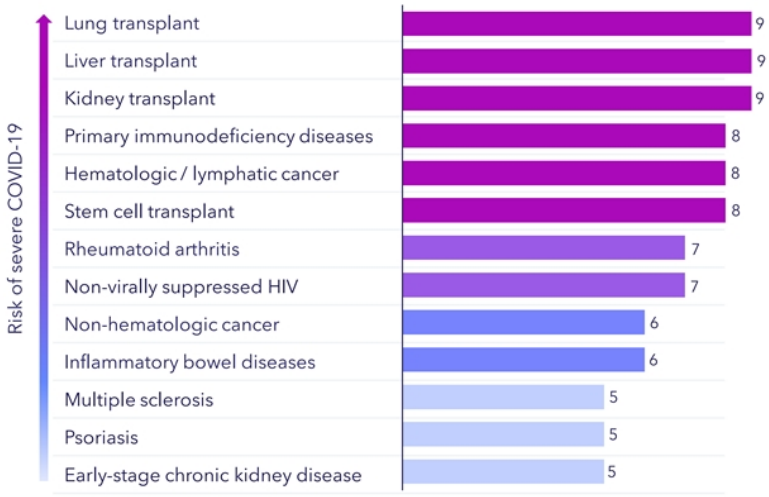
Reinfections are becoming more common. Experts are still unsure about how damaging they can be.

August 17, 2023

HCPs CONTINUE TO REPORT THAT A SIGNIFICANT SUBSET OF IMMUNOCOMPROMISED PEOPLE ARE AT HIGH-RISK OF SEVERE COVID-19

Risk of severe COVID-19 for select immunocompromised populations according to July 2023 survey of specialty HCPs in the U.S.[1]

1 = No greater risk compared to the general population; 10 = Extremely high risk



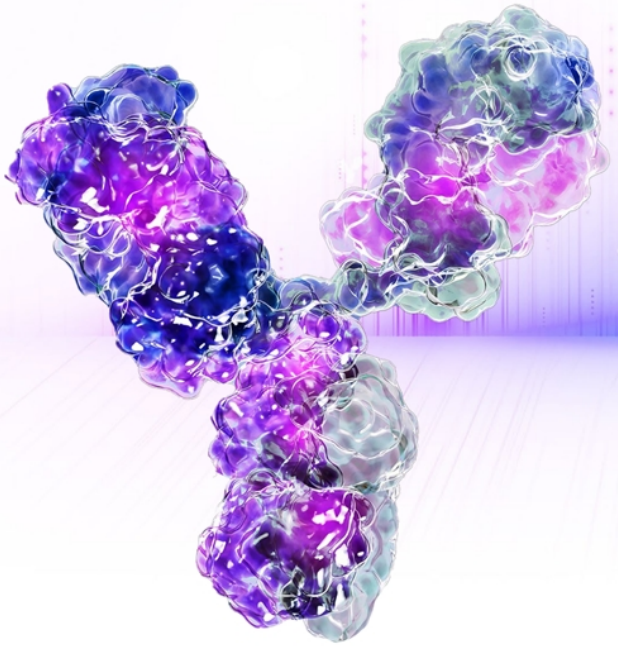
"We know that if a lung transplant patient gets COVID-19, their mortality is very high. Many patients have no way to mount a vaccine response, and those who will be transplanted in the future need something to protect them."
– Transplant Pulmonologist

"[Stem cell transplant patients] are much higher risk from not having an immune system." – Hematologist

"I was using Evusheld® very frequently. It was a real life-saver for many patients. I stopped after it was no longer considered effective." – Neurologist

1. Participants were asked: On a scale from 1 to 10, how much greater risk for contracting severe COVID-19 does a patient with the following conditions have, compared to the general population? Reference: Invivyd-sponsored survey of specialty HCPs in the U.S. (N=141) (Jul 2023)

INVIVYD



Our Platform & VYD222

INVIVYD IS TAKING A PLATFORM-BASED APPROACH DESIGNED TO KEEP PACE WITH VIRAL EVOLUTION

By leveraging state-of-the-art viral surveillance, antibody discovery and engineering, we aim to continuously discover and optimize mAb candidates that can perpetually protect the vulnerable from serious viral threats

VIRAL SURVEILLANCE & PREDICTIVE MODELING

Continuous monitoring of viral evolution and mapping of common mutational escape routes with the aim to predict potential future variants of concern

ANTIBODY DISCOVERY

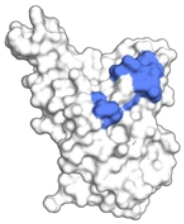
Deep B-cell mining to isolate broadly neutralizing mAbs that target rare viral epitopes that are not under strong immune pressure, increasing the probability of sustained utility

ANTIBODY ENGINEERING

Industry-leading antibody engineering to improve potency, breadth, biophysical properties, and developability of candidates discovered through B-cell mining

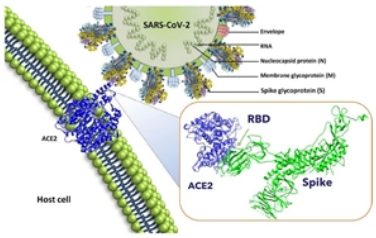
STREAM OF mAb CANDIDATES

VYD222: ENGINEERED FOR BROAD ACTIVITY AND PROLONGED UTILITY



VYD222

Broadly neutralizing, half-life extended mAb candidate in development for the prevention of symptomatic COVID-19 in vulnerable populations, such as immunocompromised people



Binds to the spike protein receptor binding domain (RBD) of SARS-CoV-2, interfering with the virus's ability to infect human cells

EVADE — Ph 2/3 clinical trial of ADG20 for COVID-19 prevention

STAMP — Ph 2/3 clinical trial of ADG20 for COVID-19 treatment

Engineered from adintrevimab (ADG20), a mAb candidate that Invivyd previously studied in 2 clinical trials with clinical endpoints; data from the EVADE trial expected to accelerate VYD222 development

Reference: Saxena SK VirusDis 2020 (SARS-CoV-2 figure)

VYD222 HAS DEMONSTRATED BROAD *IN VITRO* NEUTRALIZING ACTIVITY AGAINST VARIOUS PRE-OMICRON AND OMICRON VARIANTS

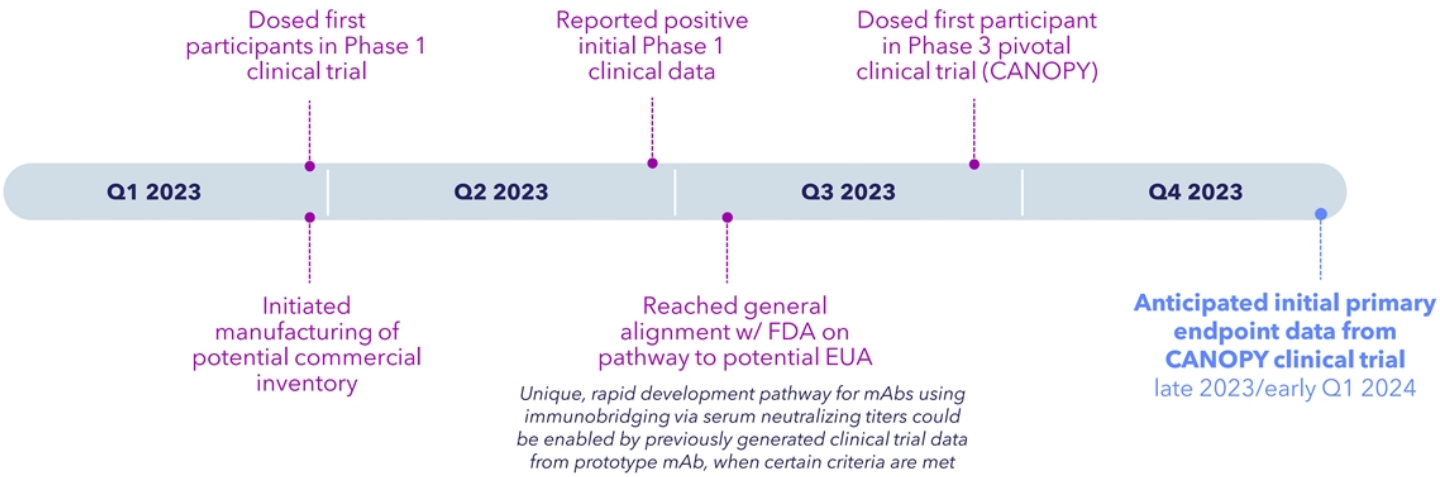
VARIANT	SUBLINEAGE	VYD222[1]
WT(D614G)	WT(D614G)	✓
Delta	B.1.617.2	✓
Omicron	BA.1	✓
	BA.4/5	✓
	BA.4.6	✓
	BF.7	✓
	XBB.1	✓
	XBB.1.5	✓
	XBB.1.16	✓
	XBB.1.5.10	✓

XBB.1.5.10 and EG.5 (one of the dominant variants in the U.S.) have the same mutations in the spike protein[2-3]

✓ Neutralizing in standardized *in vitro* assays

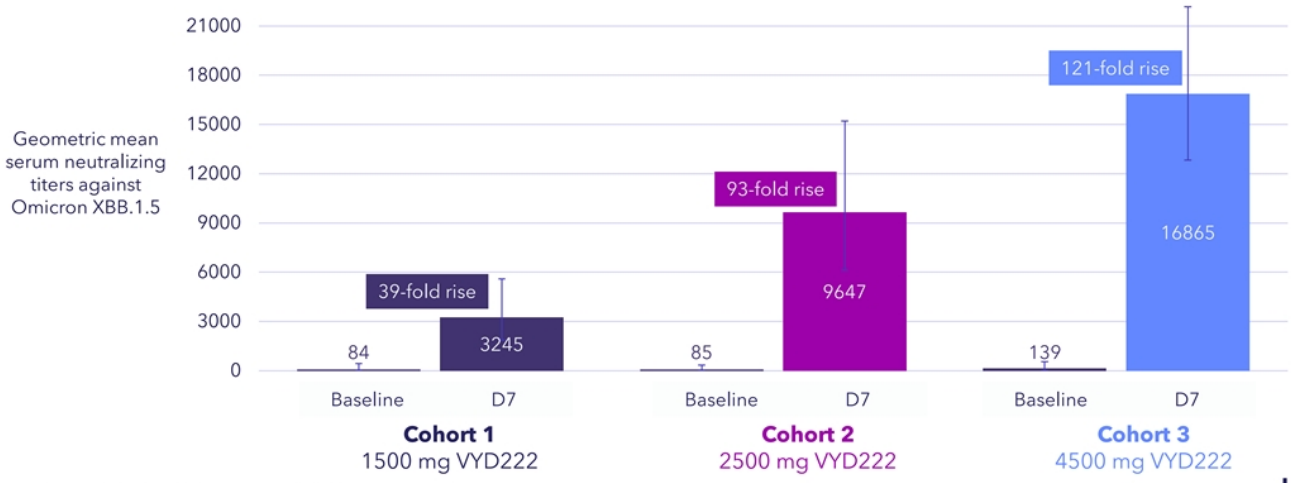
References: 1. VYD222 data generated by Labcorp-Monogram Biosciences using the pseudovirus PhenoSense® SARS-CoV-2 Neutralizing Antibody Assay;
2. https://covid.cdc.gov/covid-data-tracker/#variant-proportions (accessed Sept 6, 2023);
3. covSPECTRUM.org (accessed Sept 7, 2023)

INVIVYD IS RAPIDLY ADVANCING VYD222 FOR THE PREVENTION OF SYMPTOMATIC COVID-19



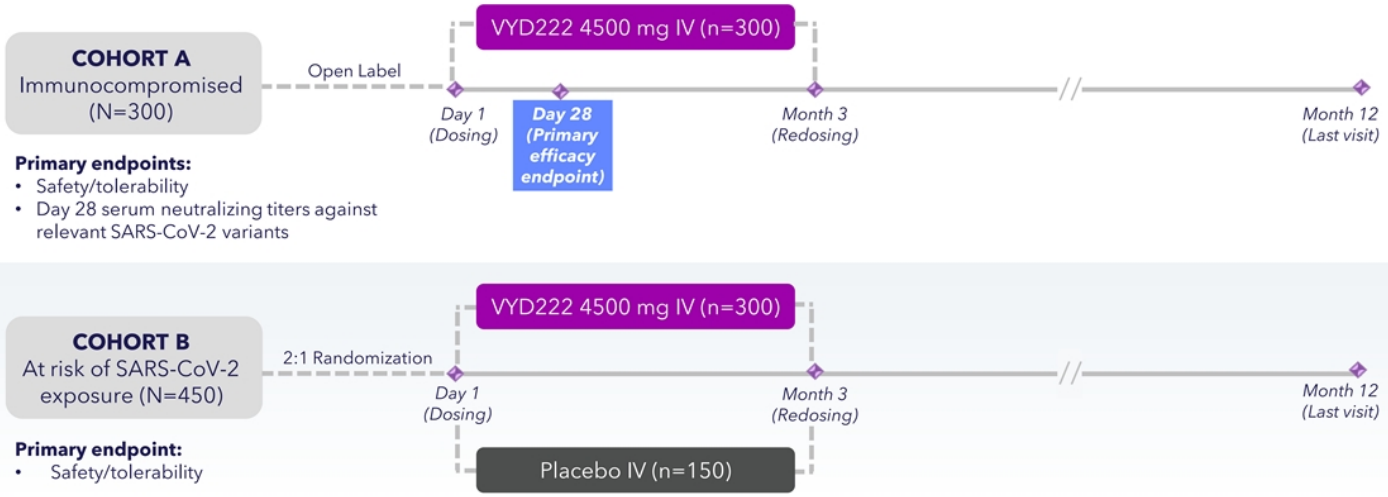
POSITIVE INITIAL VYD222 PHASE 1 CLINICAL TRIAL DATA SHOW STRONG SERUM NEUTRALIZING TITERS & FAVORABLE SAFETY PROFILE

- 30 healthy volunteers enrolled across three different dosing cohorts; in each cohort, participants were randomized 8:2 to VYD222 or placebo
- Initial clinical trial data showed that VYD222 was generally well-tolerated at all three dose levels tested
- As expected, a dose-dependent increase in serum neutralizing titers against Omicron XBB.1.5 was observed



Reference: ClinicalTrials.gov Identifier: NCT05791318

THE CANOPY PHASE 3 CLINICAL TRIAL OF VYD222 IS DESIGNED TO RAPIDLY GENERATE CLINICAL DATA FOR A POTENTIAL EUA

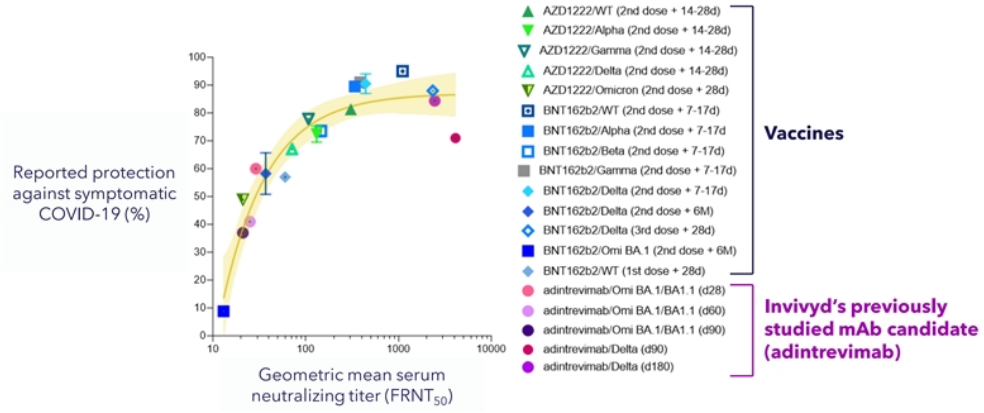


Day 28 titers from Cohort A, plus safety data from both cohorts, expected to enable clinical data package for a potential VYD222 EUA submission for prevention of symptomatic COVID-19

IV, intravenous

DAY 28 SERUM NEUTRALIZING TITERS FROM IMMUNOCOMPROMISED COHORT WILL BE USED IN THE CANOPY PRIMARY EFFICACY ANALYSIS

Serum neutralizing titers (either mAb or vaccine-induced) have been shown to correlate with protection against symptomatic COVID-19



The CANOPY clinical trial primary efficacy analysis will use an immunobridging approach comparing VYD222 data from Cohort A to certain historical data from the company's Phase 2/3 clinical trial of adintrevimab for the prevention of symptomatic COVID-19 (EVADE)

Reference: Schmidt Sci Transl Med 2023; FRNT, focus reduction neutralization test

VYD222 IS ONE OF MANY ANTIBODIES IN INVIVYD'S ROBUST PIPELINE

PROGRAMS	PLATFORM	INDICATION(S)	DISCOVERY/ PRECLINICAL	IND-ENABLING	PHASE 1	PHASE 2	PHASE 3	STATUS
CORONAVIRUSES								
VYD222	mAb	Prevention						Initiated Ph 3 clinical trial in Sept 2023
COVID candidate #2	mAb	Prevention or treatment						Engineering variant matching
COVID candidate #3	mAb	Prevention or treatment						Engineering variant matching
COVID candidate #4	mAb	Prevention or treatment						Engineering variant matching
Adintrevimab	mAb	Prevention						Trials concluded; EUA filing dependent on variant susceptibility
Adintrevimab	mAb	Treatment						
OTHER VIRUSES								
Influenza	mAb combination	Prevention						Early discovery

Investigational therapies are not approved for use by regulatory authorities. The safety and efficacy of pipeline candidates have not been established.

MANAGEMENT TEAM WITH EXPERTISE IN INFECTIOUS DISEASES AND TRACK RECORD OF SUCCESS

Dave Hering, M.B.A.
Chief Executive Officer & Director

Pfizer · NOVARTIS

Peter C. Schmidt, M.D., MSc
Chief Medical Officer

ASSERTIO · ZOSANO PHARMA

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

AKOUOS · Shire

William Duke, M.B.A
Chief Financial Officer

Kaleido BIOSCIENCES · genzyme

Robert Allen, Ph.D.
Chief Scientific Officer

SmartPharm THERAPEUTICS · sorrento

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

Celgene · NOVARTIS

Jeremy Gowler
Chief Operating & Commercial Officer

SANDOZ A Novartis Division · EMERGENT · INVIVYD

INVIVYD IS POISED TO ENTER A TRANSFORMATIONAL PERIOD, WITH A NEAR-TERM OPPORTUNITY TO DELIVER A MUCH NEEDED THERAPEUTIC

Providing vulnerable populations, such as immunocompromised people, with protection from COVID-19 is a compelling, potential long-term value proposition

Invivyd is rapidly executing on its VYD222 clinical development plan, with positive initial Phase 1 clinical data delivered in Q2 2023 and initial primary endpoint data from the CANOPY Phase 3 clinical trial anticipated end of 2023/early Q1 2024

Cash, cash equivalents and marketable securities of $298.4 million as of June 30, 2023 expected to support operating runway into the fourth quarter of 2024, excluding potential contribution of commercial product revenue

INVIVYD

THANK YOU!