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): June 29, 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 June 29, 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 June 29, 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: June 29, 2023

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

Corporate Overview

June 2023

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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, our belief that our existing cash resources will be sufficient to support operating runway into the second half of 2024; the future of the COVID-19 landscape; our ongoing research and clinical development plans, including with respect to VYD222; the timing, progress and results of our preclinical studies and clinical trials of our product candidates, including our VYD222 program; our expectation that our platform will rapidly and perpetually deliver a stream of monoclonal antibodies ("mAbs") to keep pace with viral evolution and protect the vulnerable from COVID-19; our expectation to engage in continuous monitoring of viral evolution coupled with rapid antibody discovery and engineering to address the evolving SARS-CoV-2 threat; 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 mAbs and our product candidates; the anticipated broad activity and prolonged utility of VYD222, including its design properties; our expectations regarding the scope of any approved indication for our product candidates; our belief that there is a strong scientific rationale for using surrogates of clinical efficacy in clinical trials, potentially accelerating development of VYD222 and future candidates; the possibility for mAb candidates to follow a rapid development pathway using immunobridging via a surrogate endpoint enabled by previously generated clinical trial data from a prototype mAb; our plans to use an immunobridging approach to a VYD222 pivotal clinical trial that would leverage previously generated adintrevimab clinical trial data, through the use of a surrogate marker (serum neutralizing titers) in the primary endpoint; our plans to initiate a VYD222 pivotal clinical trial to rapidly generate data for a potential EUA submission; our vision for a future 'plug and play' approach for viral-directed mAbs, pending alignment with global regulators; the potential for an emergency use authorization ("EUA") or other regulatory approval of any of our product candidates; 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; 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: our ability to gain complete alignment with the applicable regulatory authorities on the clinical trial design and development pathway for VYD222, including the use of an immunobridging approach, and the timing thereof; whether adintrevimab is able to serve as a prototype mAb and we are able to leverage previously generated adintrevimab data in connection with the development of VYD222; the timing and progress of our discovery, preclinical and clinical development activities, including the company's ability to initiate a VYD222 pivotal clinical trial and rapidly generate data for a potential EUA submission; our ability to generate and utilize tools to discover and develop a pipeline of antibodies to treat current and potential future SARS-CoV-2 variants; the impacts of the COVID-19 pandemic on our business and those of our collaborators, our clinical trials and our financial position; 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; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process, including the outcome of our discussions with regulators about our clinical trials and platform-based approach to development; whether we are able to successfully monitor, analyze, engineer and optimize new product candidates and create a stream of mAbs to keep pace with viral evolution and protect the vulnerable from COVID-19; whether VYD222 or any other product candidate or combination of candidates is able to demonstrate and sustain neutralizing activity against predominant SARS-CoV-2 variant(s); 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 (the "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. Such risks may be amplified by the impacts of the COVID-19 pandemic. 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.

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THERE IS AN URGENT NEED FOR NEW THERAPEUTICS THAT PROTECT IMMUNOCOMPROMISED PEOPLE FROM COVID-19

INVIVYD

"Now, many people who are not well-protected by vaccines are in a dangerous and isolating situation—especially because the arsenal of effective COVID-19 treatments is shrinking for everyone as the virus evolves.[1]"

"The withdrawal of Evusheld is a disaster for our immunocompromised patients and illustrates the hard fight ahead against this virus.[2]"

Sources: 1. https://time.com/6251474/immunocompromised-covid-19-evusheld-fda/; 2. https://www.axios.com/2023/02/07/immunocompromised-covid-risk-left-behind-again

MILLIONS OF IMMUNOCOMPROMISED PEOPLE ARE IN URGENT NEED OF NEW THERAPEUTICS THAT PROVIDE PASSIVE IMMUNITY TO COVID-19

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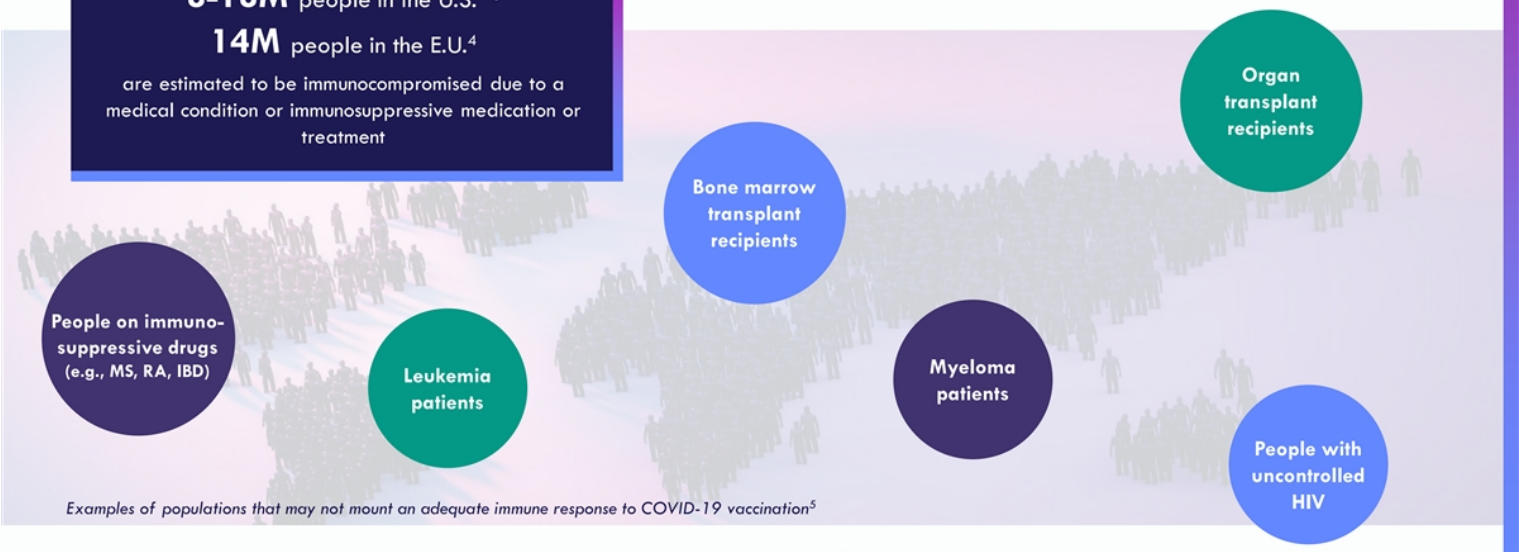
8-18M people in the U.S.[1-3]

14M people in the E.U.[4]

are estimated to be immunocompromised due to a medical condition or immunosuppressive medication or treatment



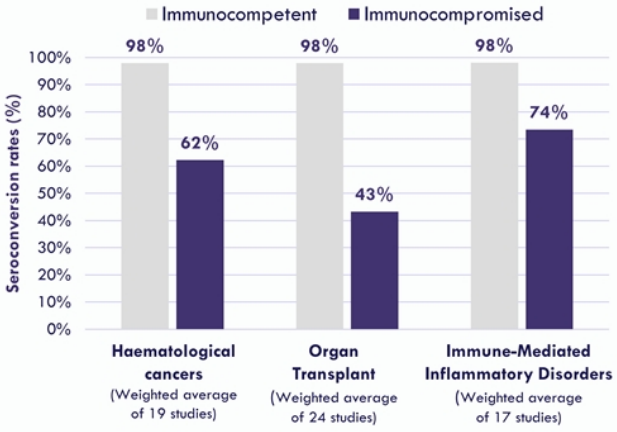
Examples of populations that may not mount an adequate immune response to COVID-19 vaccination[5]

Sources: 1. Harpaz JAMA 2016; 2. Patel Emerg Infect Dis 2020; 3. U.S. Census Bureau Data; 4. European Cancer Patient Coalition: https://ecpc.org/joint-statement-on-the-protection-of-immunocompromised-patients/; 5. Lee BMJ 2022; https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html; MS, multiple sclerosis; RA, rheumatoid arthritis; IBD: inflammatory bowel disease

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

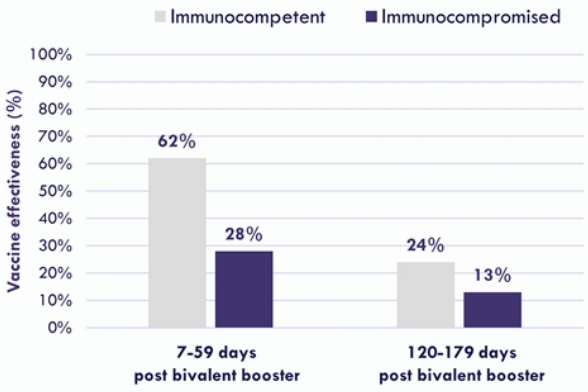
Immunocompromised people are less likely to have detectable SARS-CoV-2 antibodies following vaccination than immunocompetent people

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]



Source: 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, VACCINE EFFECTIVENESS (VE) HAS WANED IN THE FACE OF VIRAL EVOLUTION

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45.7% VE against symptomatic Omicron B.1.1.529 at ≥10 wks after two doses of the BNT162b2 vaccine followed by a BNT162b2 booster

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

Monovalent (BNT162b2)	2-4 wks after 2nd dose	≥25 wks after 2nd dose	2-4 wks after booster	**≥10 wks** after booster
Delta B.1.617.2	90.9%	62.7%	95.1%	89.9%
Omicron B.1.1.529	65.5%	8.8%	67.2%	45.7%

4-29% VE against infection with more recent Omicron variants up to 26 weeks from mRNA bivalent booster

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 monoclonal antibody (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

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

WE BELIEVE PREVENTION OF COVID-19 IN VULNERABLE POPULATIONS IS A LONG-TERM, POTENTIALLY LARGE OPPORTUNITY

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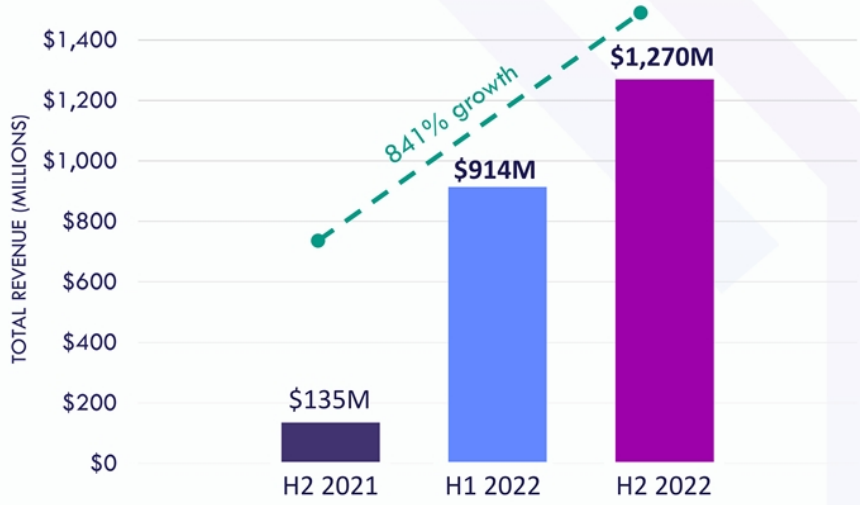
$2.2B in total revenue of Evusheld® in 2022, a mAb previously authorized to protect vulnerable populations from COVID-19



Sources: Results publicly reported by AstraZeneca.

MONOCLONAL ANTIBODIES PLAY A CRITICIAL ROLE IN THE COVID-19 MEDICINE CABINET

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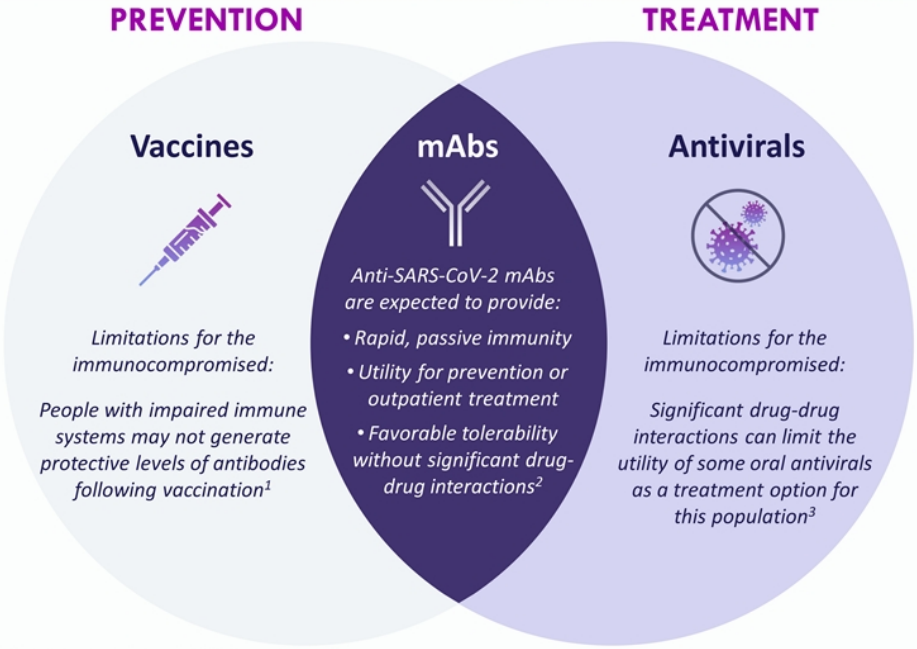

Sources: 1. Lee BMJ 2022; 2. McCreary JAMA Netw Open 2023; 3. Marzolini Clin Pharmacol Ther 2022

INVIVYD IS ON A MISSION TO RAPIDLY AND PERPETUALLY DELIVER MONOCLONAL ANTIBODIES THAT HELP PROTECT THE VULNERABLE FROM COVID-19

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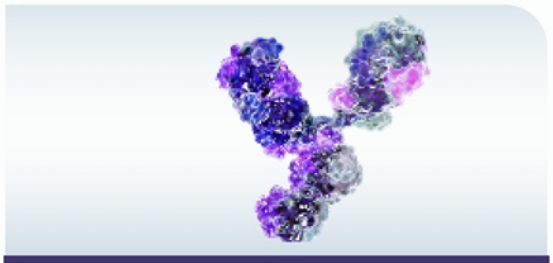
Previous mAbs for the prevention of COVID-19 in vulnerable populations, such as immunocompromised people, have lost activity against SARS-CoV-2 variants of concern and have been deauthorized in the U.S.



Combining expertise in virology, antibody engineering and predictive modeling, Invivyd has a platform designed to rapidly deliver a stream of mAb candidates to keep pace with viral evolution

Invivyd demonstrated development speed with ADG20: IND to pivotal data in 16 months

Adintrevimab (ADG20) is an investigational product candidate that is not approved for use in any country. The safety and efficacy of adintrevimab have not been established.

INVIVYD HAS A PLATFORM DESIGNED TO RAPIDLY DELIVER A STREAM OF MONOCLONAL ANTIBODIES TO KEEP PACE WITH VIRAL EVOLUTION

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Continuous monitoring of viral evolution coupled with rapid antibody discovery and engineering to address the evolving SARS-CoV-2 threat

MINE

Mine human antibody repertoires induced following contemporary SARS-CoV-2 exposures

MONITOR

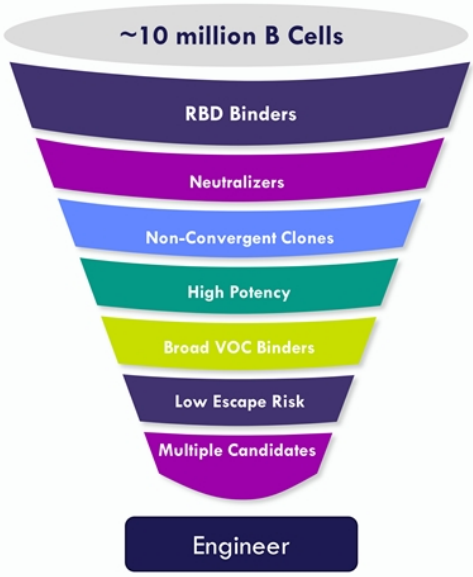
Monitor variants continuously, pinpoint dominant spike protein sites targeted by human antibody repertoires, and map common mutational escape routes with the aim to predict future variants

IDENTIFY

Identify potent mAb candidates that target rare epitopes not under strong immune pressure

OPTIMIZE

Engineer to optimize candidate properties



RBD, receptor binding domain
VOC, variant of concern

VYD222: ENGINEERED FOR BROAD ACTIVITY AND PROLONGED UTILITY

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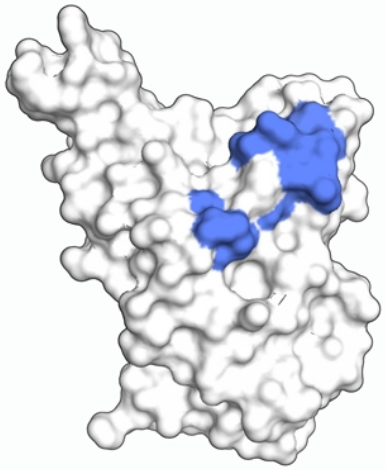
VYD222 is engineered from adintrevimab (ADG20), a product candidate that Invivyd took from IND to pivotal data in 16 months

Designed for:

- High potency
- Lack of polyreactivity
- Long half-life
- Developability
- Potential to resist escape
  - Target non-overlapping epitopes of spike RBD
  - Rare epitopes under less immune pressure
  - Conserved across human ACE2-using sarbecoviruses



VYD222

VYD222 mAb candidate has demonstrated *in vitro* neutralizing activity against variants of concern, including Omicron sub-lineages up to and through XBB.1.5

RBD, receptor binding domain

INVIVYD IS PURSUING THE RAPID ADVANCEMENT OF VYD222 FOR THE PREVENTION OF SYMPTOMATIC COVID-19 IN IMMUNOCOMPROMISED PEOPLE

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Anticipated development path for VYD222

- ☑ Early March 2023: Elected VYD222 for clinical advancement, with plans to leverage adintrevimab data to accelerate the development of VYD222
- ☑ End of March 2023: Dosed first participants in VYD222 Phase 1 clinical trial
- ☑ June 22, 2023: Reported positive initial data from ongoing VYD222 Phase 1 healthy volunteer clinical trial
  - VYD222 was generally well-tolerated at all dose levels, with no serious adverse events having been reported
  - As predicted by pre-clinical *in vitro* testing, early serum samples from the first, lowest dose cohort showed strong neutralization activity against Omicron XBB.1.5, one of the dominant SARS-CoV-2 variants circulating globally
- ☑ June 26, 2023: Announced general alignment with FDA on pathway to potential EUA for VYD222
  - Unique, rapid development pathway for mAbs using immunobridging via serum neutralizing titers could be enabled by previously generated clinical trial data from prototype mAb, when certain criteria are met
  - Invivyd plans to use an immunobridging approach to a VYD222 pivotal clinical trial that would leverage previously generated adintrevimab clinical trial data, by using a surrogate marker (serum neutralizing titers) in the primary endpoint
- ☐ Initiate VYD222 pivotal clinical trial using a surrogate endpoint to rapidly generate data for a potential EUA submission
- ☐ Submit VYD222 EUA request

EUA, Emergency Use Authorization

STRONG RATIONALE FOR USING SURROGATES OF CLINICAL EFFICACY IN CLINICAL TRIALS, POTENTIALLY ACCELERATING DEVELOPMENT OF VYD222 AND FUTURE CANDIDATES

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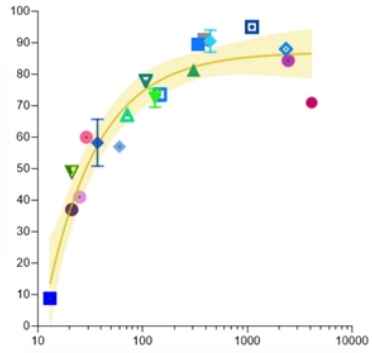
Serum neutralizing titers (either mAb or vaccine-induced) correlate with protection against symptomatic SARS-CoV-2 infection across multiple variants

Reported protection against symptomatic COVID-19 (%)

(Data from Phase 2/3 trials and real-world vaccine effectiveness studies)



- AZD1222/WT (2nd dose + 14-28d)
- AZD1222/Alpha (2nd dose + 14-28d)
- AZD1222/Gamma (2nd dose + 14-28d)
- AZD1222/Delta (2nd dose + 14-28d)
- AZD1222/Omicron (2nd dose + 28d)
- BNT162b2/WT (2nd dose + 7-17d)
- BNT162b2/Alpha (2nd dose + 7-17d
- BNT162b2/Beta (2nd dose + 7-17d)
- BNT162b2/Gamma (2nd dose + 7-17d)
- BNT162b2/Delta (2nd dose + 7-17d)
- BNT162b2/Delta (2nd dose + 6M)
- BNT162b2/Delta (3rd dose + 28d)
- BNT162b2/Omi BA.1 (2nd dose + 6M)
- BNT162b2/WT (1st dose + 28d)

Vaccines

- adintrevimab/Omi BA.1/BA1.1 (d28)
- adintrevimab/Omi BA.1/BA1.1 (d60)
- adintrevimab/Omi BA.1/BA1.1 (d90)
- adintrevimab/Delta (d90)
- adintrevimab/Delta (d180)

Invivyd's proprietary mAb candidate and associated clinical trial data

Previously published clinical data provide insight into the relationship between serum neutralizing titers and protection against symptomatic COVID-19

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

EVOLVING REGULATORY PARADIGM PROVIDES SUPPORT FOR INVIVYD'S VISION AND STRATEGY

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THE PAST

- A single SARS-CoV-2 directed mAb candidate: adintrevimab (ADG20)
- ADG20 pivotal trials with clinical event endpoints

TODAY

- Multiple SARS-CoV-2 directed mAbs in discovery or development
- ADG20 trial data provide support for the potential use of surrogate markers (e.g., serum neutralizing titers) to predict protection against symptomatic COVID-19, which may accelerate VYD222 clinical development and submission for EUA

VISION FOR THE FUTURE

- A portfolio of mAbs on the market to address SARS-CoV-2 and other viral threats, with a robust pipeline of mAbs in development
- A 'plug and play' approach (similar to approach used for flu and SARS-CoV-2 vaccines) that leverages a validated CMC platform plus *in vitro* neutralization data and PK/PD modeling to rapidly deliver mAbs that keep pace with viral evolution, pending alignment with global regulators

EUA, Emergency Use Authorization

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

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PROGRAMS	PLATFORM	INDICATION(S)	DEVELOPMENT STATUS					STATUS
			DISCOVERY/ PRECLINICAL	IND-ENABLING	PHASE 1	PHASE 2	PHASE 3	
CORONAVIRUSES								
VYD222	mAb	Prevention						Initial Ph 1 data reported in Q2 2023
VYD224	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.

INVIVYD IS POSITIONED TO POTENTIALLY FULFILL A LARGE UNMET NEED

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Providing vulnerable populations, such as immunocompromised people, with protection from COVID-19 is a long-term, large opportunity

Invivyd is executing on its strategy to rapidly advance VYD222, with the recent announcement of positive initial Phase 1 VYD222 data and general alignment with FDA on a pathway to a potential VYD222 EUA for prevention of symptomatic COVID-19

Well capitalized with $333.4 million in cash, cash equivalents and marketable securities as of March 31, 2023 expected to support operating runway into second half of 2024

MANAGEMENT TEAM WITH TRACK RECORD OF SUCCESS

INVIVYD

Dave Hering
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

Robert Allen, Ph.D.
Chief Scientific Officer

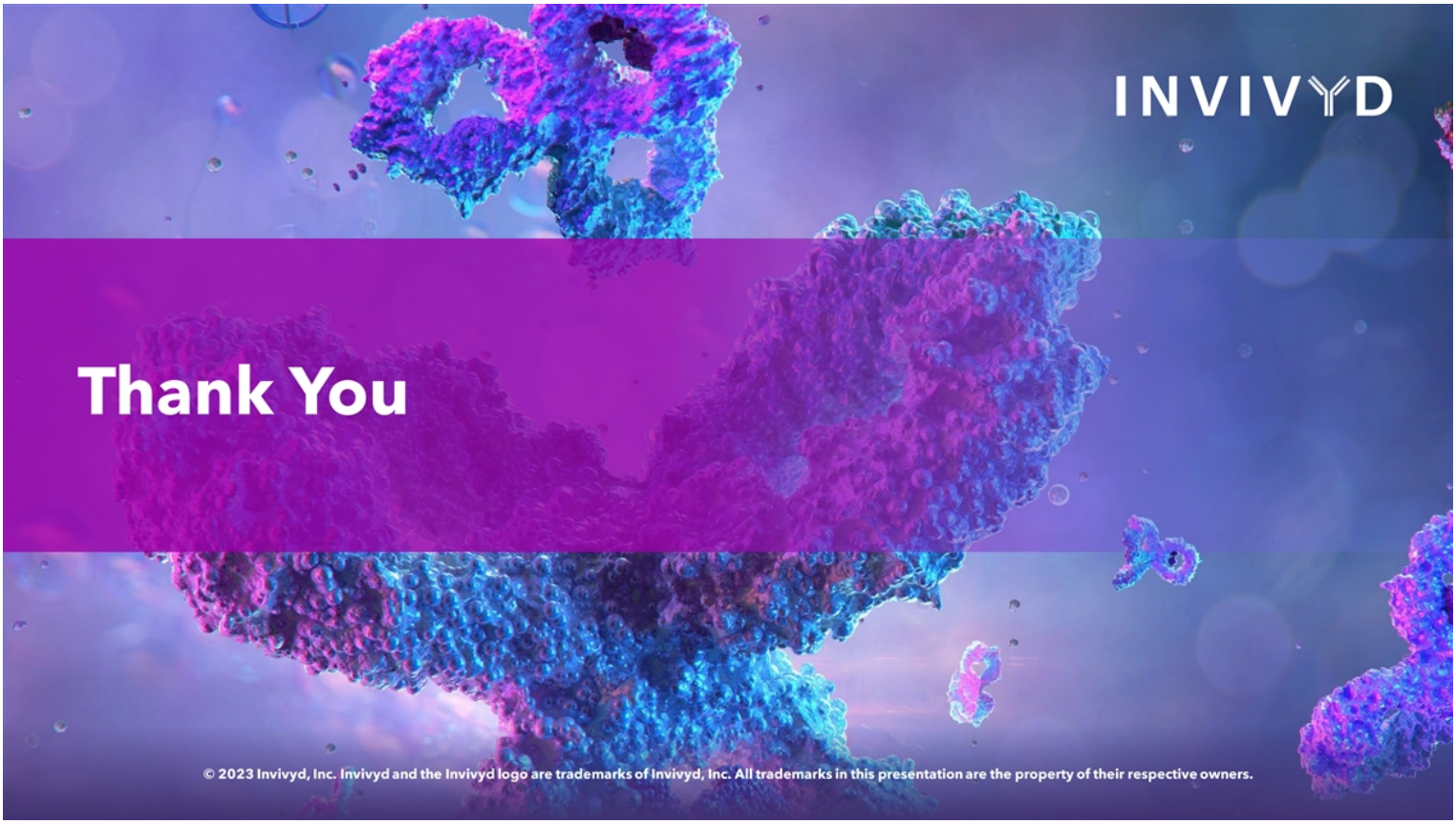
SmartPharm THERAPEUTICS sorrento

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

Celgene NOVARTIS

Jeremy Gowler
Chief Operating & Commercial Officer

SANDOZ A Novartis Division EMERGENT



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