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): April 26, 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On April 26, 2023, the Board of Directors of Invivyd, Inc. (the "Company") approved a cash-based incentive program designed to incentivize and retain employees of the Company, pursuant to which substantially all of the Company's executive and non-executive employees would be awarded a cash payment equal to a percentage of each employee's respective annual bonus target in the event that the Company doses the first patient in a pivotal clinical trial of VYD222 by September 30, 2023 (the "Incentive Program"). VYD222 is a monoclonal antibody candidate for prevention of COVID-19 that is currently being evaluated by the Company in a Phase 1 clinical trial. Commencement of any pivotal clinical trial of VYD222 is subject to input from applicable regulatory authorities on the Company's pivotal clinical trial design and to other regulatory and operational requirements. Pursuant to the Incentive Program, (i) David Hering, Chief Executive Officer of the Company, is eligible to receive a cash payment equal to $180,000, and (ii) Jill Andersen, Chief Legal Officer and Corporate Secretary of the Company, is eligible to receive a cash payment equal to $92,000. If the Company does not dose the first patient in a pivotal clinical trial of VYD222 by September 30, 2023, no payments pursuant to the Incentive Program will be made to employees of the Company.

Cautionary Note Regarding Forward-Looking Statements. This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "would be," "in the event that," or similar expressions are intended to identify forward-looking statements, which include statements concerning the Incentive Program and the Company's ongoing research and clinical development plans for VYD222. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on its 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: the timing, progress and results of the Company's Phase 1 clinical trial of VYD222; the Company's ability to gain alignment with applicable regulatory authorities on the Company's clinical trial design and the development pathway for VYD222 and the timing thereof; whether VYD222 is able to demonstrate and sustain neutralizing activity against predominant SARS-CoV-2 variant(s); and whether the Company will dose the first patient in a pivotal clinical trial of VYD222 by September 30, 2023, or at all. 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 Form 8-K are described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission (the "SEC"), and in its other filings with the SEC, and in the Company's 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 Form 8-K are made as of this date, and the Company undertakes no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

Item 8.01. Other Events.

On May 2, 2023, the Company 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 May 2, 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: May 2, 2023

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


Exhibit 99.1
INVIVYD
Corporate Overview
May 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 belief that our existing cash resources will be sufficient to fund our operations into the second half of 2024; the future of the COVID-19 landscape including the expectation of continued evolution and emergence of new variants and subvariants; 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 the clinical trial design, objectives and anticipated data readouts from our VYD222 program; our expectation that our platform will rapidly and perpetually deliver a stream of monoclonal antibodies to keep pace with viral evolution and protect vulnerable populations 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 ability to obtain and maintain regulatory authorizations or approvals for our product candidates; our expectations regarding the size of target patient populations and the potential market opportunity for our product candidates; our expectations regarding the clinical utility and market acceptance of anti-SARS-CoV-2 monoclonal antibodies ("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 ability to successfully commercialize our product candidates; our belief that serum virus neutralizing titers are predictive of protection against symptomatic COVID-19 and have potential to be used as surrogates of clinical efficacy in future trials, potentially accelerating the clinical development path; the anticipation of ongoing discussions with regulators; our goal to establish a new regulatory paradigm to keep pace with viral evolution, and our vision of a future development path for viral-directed mAbs that is similar to the platform-based approach used to periodically modify flu and SARS-CoV-2 vaccines; 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 could be used in prevention or treatment of serious viral threats, 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 alignment with the applicable regulatory authorities on the clinical trial design and development pathway for VYD222 and the timing thereof; the timing and progress of our discovery, preclinical and clinical development activities; 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 pre-clinical studies; 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 regulatory authorities concerning 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 monoclonal antibodies to keep pace with viral evolution; 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.

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

INVIVYD


TIME

HEALTH • COVID-19

Without Evusheld, Immunocompromised People Are on Their Own Against COVID-19

Immunocompromised worry they're getting left behind again

Tina Reed, Sabrina Moreno

Illustration: Natalie Peeples/Axios

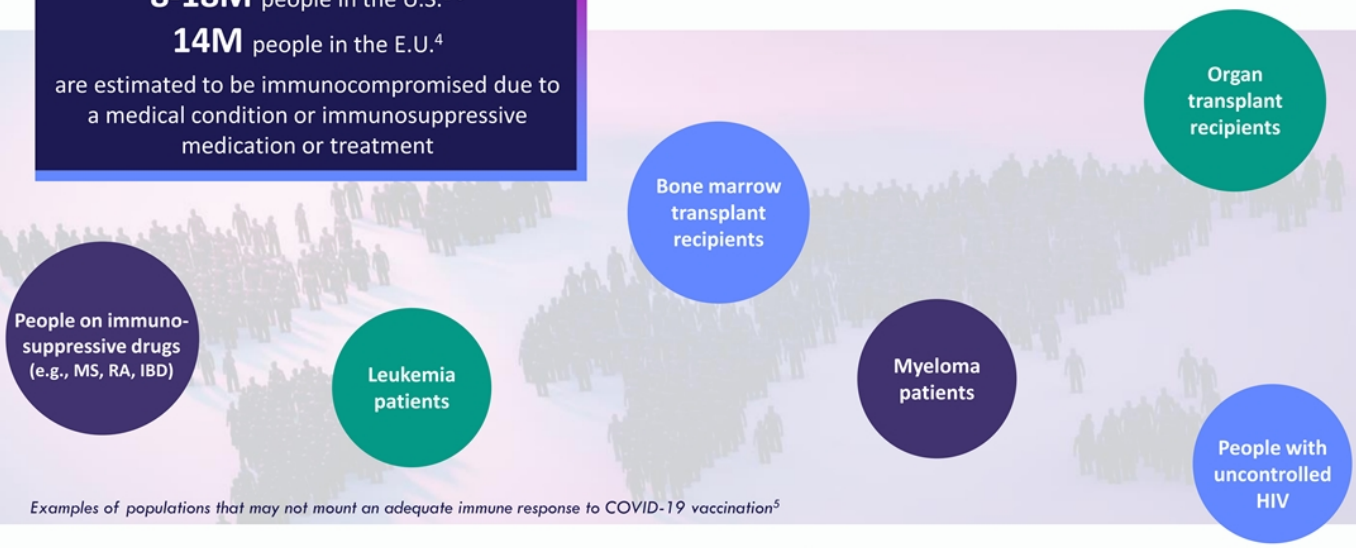
> "Now, many people who are not well-protected by vaccines are in a dangerous and isolating situation—especially because the arsenal of effective COVID-19 treatments is shrinking for everyone as the virus evolves.[1]"

> "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 MAY NOT ADEQUATELY RESPOND TO COVID-19 VACCINES AND MAY BE AT HIGHER RISK FOR SEVERE OUTCOMES INVIVYD

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



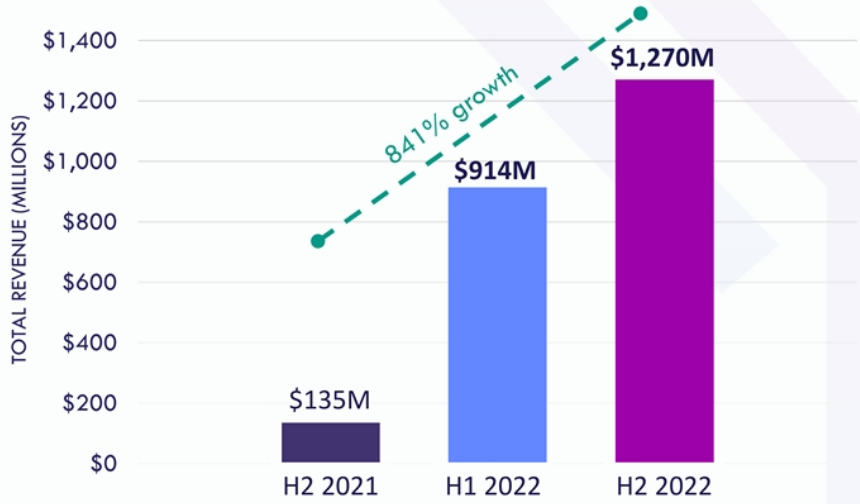
Examples of populations that may not mount an adequate immune response to COVID-19 vaccination[5]

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

PREVENTION OF COVID-19 IN VULNERABLE POPULATIONS IS A LARGE OPPORTUNITY

INVIVYD

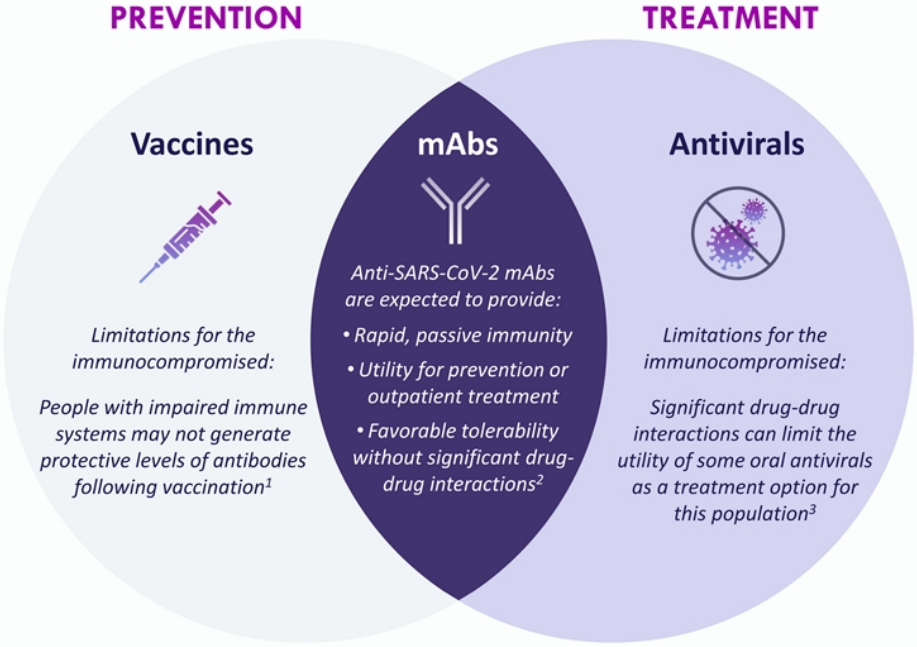
$2.2B in total revenue of Evusheld® in 2022, a monoclonal antibody (mAb) previously authorized to protect vulnerable populations from COVID-19



Sources: Results publicly reported by AstraZeneca.

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

INVIVYD

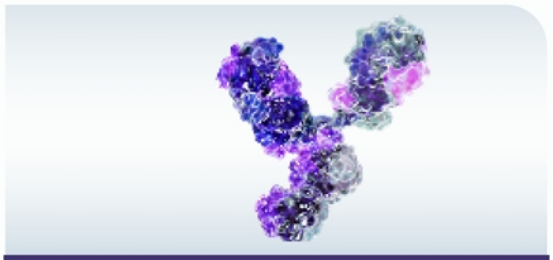


Sources: 1. Lee BMJ 2022; 2. McCreary JAMA Netw Open 2023; 3. Marzolini Clin Pharmacol Ther 2022

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

INVIVYD

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

INVIVYD

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

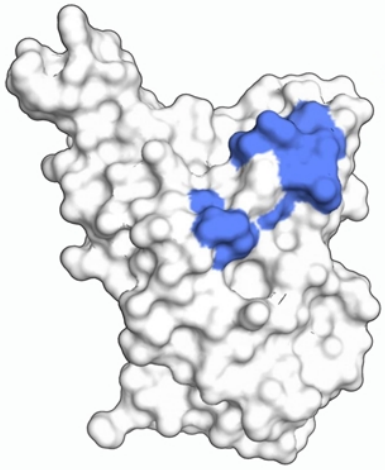
VYD222: ENGINEERED FOR BROAD ACTIVITY AND PROLONGED UTILITY

INVIVYD

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



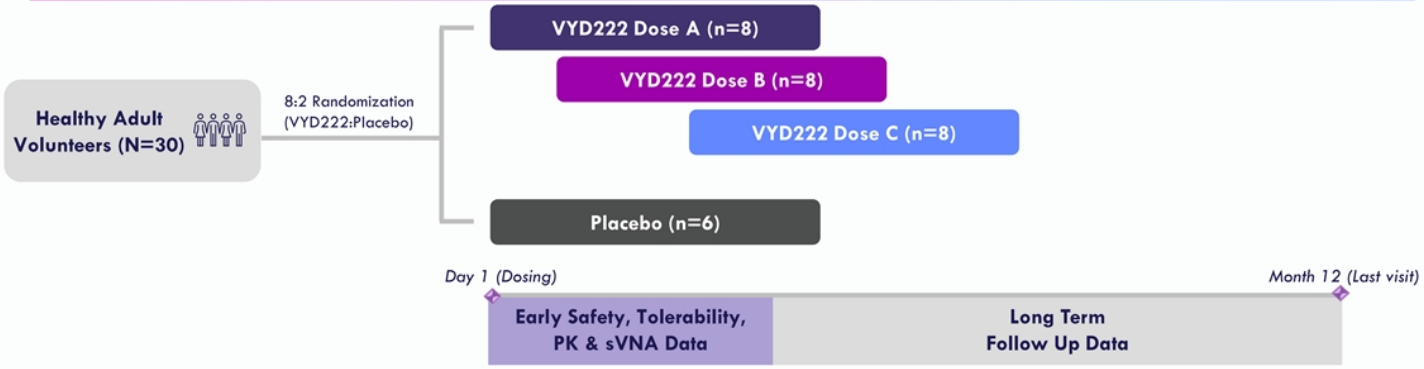
VYD222

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

ONGOING PHASE 1 TRIAL OF VYD222 WITH INITIAL DATA READOUTS PLANNED FOR Q2 2023

INVIVYD



OBJECTIVES:

- Primary: Safety and tolerability through 12 months
- Secondary: Pharmacokinetic (PK) and immunogenicity assessments
- Exploratory: Serum virus neutralizing antibody (sVNA) activity

KEY DESIGN ELEMENTS:

- Dose-ranging trial will evaluate three different doses, each administered as a single IV push. All doses are designed to provide durability in the face of viral evolution and flexibility at the time of regulatory submission.
- Trial is designed to potentially enable rapid advancement into a pivotal Phase 3 trial.

Source: Clinicaltrials.gov (NCT05791318); IV, intravenous

SERUM VIRUS NEUTRALIZING ANTIBODY TITERS MAY PREDICT PROTECTION AGAINST SYMPTOMATIC COVID-19

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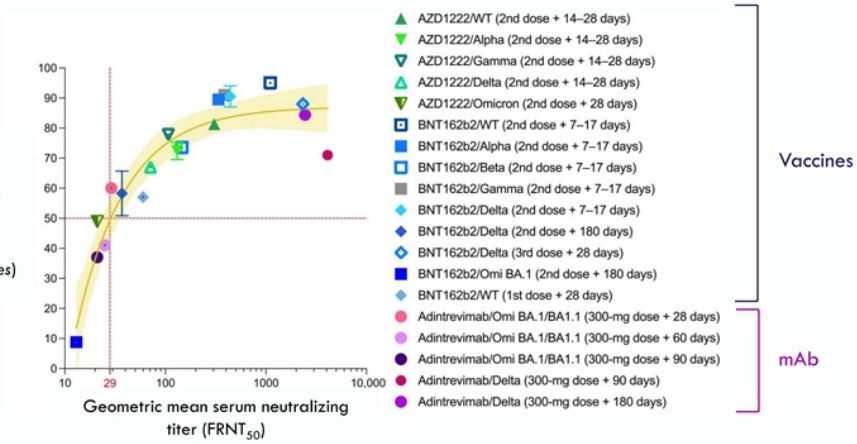
Serum neutralizing titers (either mAb or vaccine-induced) correlate with protection against symptomatic SARS-CoV-2 infection across multiple variants

Reported protection against symptomatic COVID-19 (%)

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



Strong scientific rationale for using surrogates of clinical efficacy in future trials, potentially accelerating clinical development path

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

REGULATORS AND GOVERNMENT AGENCIES ARE SEEKING TO SUPPORT DEVELOPMENT OF MONOCLONAL ANTIBODIES FOR COVID-19

INVIVYD

Regulators & government agencies are considering strategies to accelerate mAb development timelines

Project Next Gen: $5B+ program to accelerate development of new COVID-19 therapeutics, with mAbs noted as one of three priorities

April 2023

"Joint EMA-FDA Workshop: Efficacy of monoclonal antibodies in the context of rapidly evolving SARS-CoV-2 variants"

December 2022

U.S. FOOD & DRUG ADMINISTRATION

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

"WHO Guideline on the nonclinical and clinical evaluation of monoclonal antibodies and related biological products intended for the prevention or treatment of human infectious diseases."

Draft document – August 2022

World Health Organization

Invivyd is focused on rapidly and perpetually developing mAb candidates

Demonstrated development speed with ADG20:
From IND to pivotal data in 16 months

Invivyd aims to work with global regulators to establish a new regulatory paradigm that supports the rapid development of mAbs in the face of viral evolution

INVIVYD AIMS TO WORK WITH GLOBAL REGULATORS TO ESTABLISH A NEW PARADIGM TO KEEP PACE WITH VIRAL EVOLUTION

INVIVYD

Invivyd envisions a future development path for viral-directed mAbs that is similar to the platform-based approach used to periodically modify flu and SARS-CoV-2 vaccines

THE PAST	TODAY	VISION FOR THE FUTURE
• A single SARS-CoV-2 directed mAb candidate: adintrevimab (ADG20) • ADG20 pivotal trials with clinical event endpoints	• Multiple SARS-CoV-2 directed mAbs in discovery or development • ADG20 trial data provide support for the potential use of surrogate markers (e.g., sVNA titers) to predict clinical efficacy, which may accelerate VYD222 clinical development and submission for EUA or accelerated approvals, pending alignment with global regulators	• 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 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

sVNA, serum virus neutralizing activity; 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 readouts expected 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.

COMPANY WELL CAPITALIZED TO DEVELOP LEAD CANDIDATE & ADDITIONAL PIPELINE ASSETS

INVIVYD

Cash Position:
Cash, cash equivalents and marketable securities were $372 million as of December 31, 2022

Planned cash runway into H2 2024

Total fully diluted shares of common stock outstanding* as of December 31, 2022:
132.3 million

* Includes vested and unvested outstanding options as of December 31, 2022

MANAGEMENT TEAM WITH TRACK RECORD OF SUCCESS

INVIVYD

Dave Hering
Chief Executive Officer
& Director

Pfizer NOVARTIS

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

AKOUOS Shire

Robert Allen, Ph.D.
Chief Scientific Officer

SmartPharm THERAPEUTICS sorrento

Jeremy Gowler
Chief Operating &
Commercial Officer

SANDOZ A Novartis Division EMERGENT

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

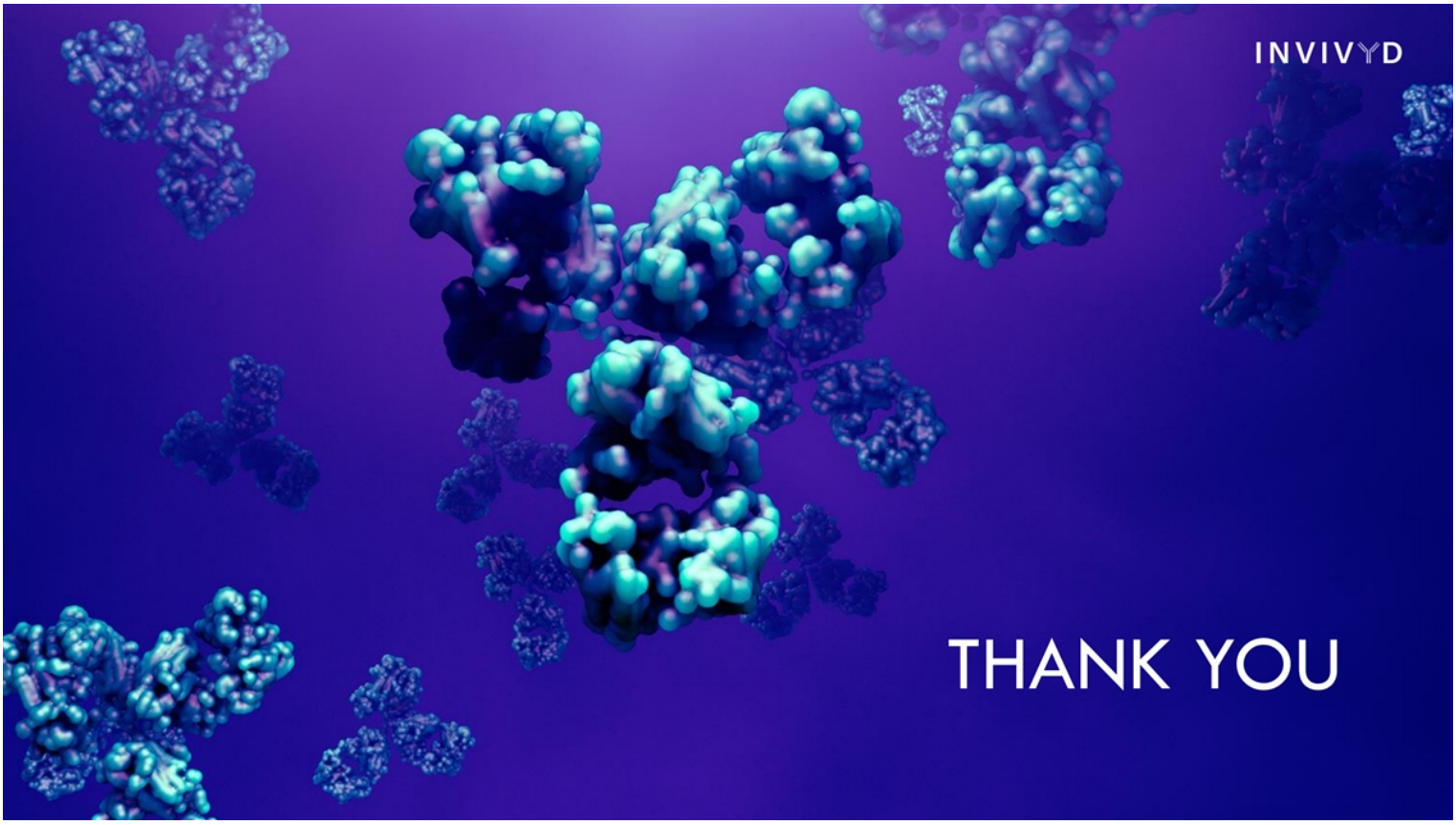
INVICTA MEDICAL ZOSANO PHARMA

Fred Driscoll
Interim Chief Financial Officer

novavax flexion

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

Celgene NOVARTIS


INVIVYD
THANK YOU