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): March 6, 2023

Invivyd, Inc.
(Exact Name of Registrant as Specified in 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 March 6, 2023, Invivyd, Inc. (the "Company") issued a press release announcing the election of VYD222 to advance into the clinic as a novel monoclonal antibody (mAb) therapeutic option for COVID-19. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference in this Item 8.01.

Also on March 6, 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 99.2 and is incorporated by reference in this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated March 6, 2023
99.2	Corporate Presentation, dated March 6, 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: March 6, 2023

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

Exhibit 99.1

INVIVYD OPTIMIZES DEVELOPMENT EFFICIENCY WITH ELECTION OF VYD222 FOR NEAR-TERM CLINICAL ADVANCEMENT TO ADDRESS URGENT UNMET NEED FOR COVID-19 MONOCLONAL ANTIBODIES

Company seeks to utilize emerging global COVID-19 regulatory frameworks to accelerate development of VYD222 and its pipeline of other candidates

VYD222 mAb candidate has demonstrated in vitro neutralizing activity against dominant variants of concern, including XBB.1.5

Invivyd maintains guidance for initiating a clinical trial in the first quarter of 2023

WALTHAM, Mass., March 6, 2023 – Invivyd, Inc. (Nasdaq: IVVD), a clinical stage biopharmaceutical company on a mission to protect the vulnerable from serious viral infectious diseases, today announces the election of VYD222 to advance into the clinic as a novel monoclonal antibody (mAb) therapeutic option for COVID-19. The company aims to leverage evolving COVID-19 regulatory paradigms and maximize efficiency to deliver this much-needed product for immunocompromised individuals and other vulnerable populations.

As of January 2023, there are no monoclonal antibodies authorized or approved in the U.S. for the prevention or treatment of COVID-19. Monoclonal antibodies are well suited to meet the need of immunocompromised individuals because they provide a prompt onset of protection, have a well-characterized safety profile, and do not rely on the individual's immune response.

"The lack of commercially available mAbs in the U.S. is an unacceptable situation for the estimated 8 million people with impaired immune systems who don't respond to vaccination and means a return to the isolation many of us experienced early in the pandemic," stated Pete Schmidt, M.D., M.Sc., Chief Medical Officer of Invivyd. "This urgent need was recently acknowledged by the FDA and EMA at a joint workshop in December where a variety of options such as the use of surrogate endpoints and immunologic bridging studies were discussed."

VYD222 is one of the mAb components of NVD200, a combination product that Invivyd previously selected for clinical advancement prior to evolution in the current global COVID-19 regulatory paradigm. The company is prioritizing the clinical development of VYD222 instead of NVD200 with the aim of providing patients with a mAb as quickly and efficiently as possible. VYD222 was engineered from adintrevimab, Invivyd's investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 3 clinical trials for both the prevention and treatment of COVID-19. The adintrevimab clinical data package has the potential to support accelerated development of VYD222. The company continues to plan for a Phase 1 clinical trial start in Q1 2023. Once aligned with regulatory authorities, pivotal studies are planned to swiftly follow.

David Hering, CEO of Invivyd, added, "The rapid evolution of SARS-CoV-2 requires a product strategy that is equally nimble, capital efficient, and which can leverage the evolving regulatory landscape to optimize development pathways. Our approach to discovery and development is designed to perpetually deliver new product candidates that keep pace with viral evolution. Through ongoing surveillance and antibody engineering, our innovation engine has generated multiple additional antibodies currently being evaluated for IND enablement to provide multiple distinct options to address future viral variation."

About Invivyd
(Nasdaq: IVVD)

Invivyd, Inc., is a biopharmaceutical company on a mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with SARS-CoV-2. Invivyd's technology works at the intersection of evolutionary virology, predictive modeling, and antibody engineering, and is designed to identify high-quality, long-lasting antibodies with a high barrier to viral escape. The company is generating a robust pipeline of product candidates for use in both prevention and treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications. Visit invivyd.com to learn more.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "could," "expects," "intends," "potential," "projects," and "future" or similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, the ability for Invivyd, other companies or combination of companies and industry representatives to influence regulators to change or adopt new development pathways or timelines; the ability of Invivyd to accelerate development timelines for the unmet need for treatment of COVID-19; the interest or acceptance by regulatory authorities of regulatory and clinical strategies to support potentially expedited development of novel monoclonal antibody therapies; the potential for success and or expedited discovery, development, or commercialization of antibody therapies for COVID-19; the continued unmet need for prevention and treatment of COVID-19, particularly for immunocompromised and other vulnerable populations; the viability and acceptability of new regulatory strategy, policy or approach to drug development and the potential of the same to maintain pace with changing COVID-19 variants; 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 and the timing thereof; our plans to advance VYD222 or other early stage candidates as a potential prophylaxis and treatment option for COVID-19, including disease caused by most variants, as either a single or combination agent; the potential for VYD222 or other product candidates to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; the potential for the clinical data package resulting from clinical trials of adintrevimab to support accelerated VYD222 monotherapy development; our plans to advance VYD222 into the clinic; our expectations that we will be able to achieve regulatory alignment and advance pivotal studies with VYD222; our plans, technology and resources to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and seasonal influenza, in the U.S. and globally; 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 ability to gain alignment with the applicable regulatory authorities on the clinical development pathway for VYD222 and the timing thereof; the ability for Invivyd and/or other companies, scientists, clinicians or industry representatives to impact the strategy, policy or approach to drug development drafted or applied by regulatory authorities, including the FDA and EMA; the impact of any such change on the speed or success of development and commercialization of antibodies for the prevention and/or treatment of COVID-19; the ability of the company to generate and utilize tools to discover and develop antibodies to treat current and potential future 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 pipeline candidates or combination of 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; whether VYD222 or any other pipeline candidate or combination of candidates is able to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; whether we are able to successfully submit an emergency use authorization in the future, and the outcome of any such emergency use authorization submission; whether research and development efforts will improve efficacy of adintrevimab against predominant variants or identify additional monoclonal antibodies or combination of antibodies for the prevention and treatment of COVID-19 and other infectious diseases; whether research and development efforts will identify and result in safe and effective therapeutic or preventative options for other infectious diseases in the U.S. or globally 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 press release are described under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, each filed with the Securities and Exchange Commission (the "SEC"), and in our other filings with the SEC, and in Invivyd'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 press release are made as of this date, and Invivyd undertakes no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

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

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Exhibit 99.2
INVIVYD
TD Cowen 43rd Annual Health Care Conference
March 6, 2023

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," "could," "intend," "target," "project," "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 quarter 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; the timing, progress and results of our preclinical studies and clinical trials of our product candidates; the initiation, modification and completion of studies or trials and related preparatory work; the period during which the results of our clinical trials and other studies and research activities will become available, and our research and development programs; our ability to identify novel antibodies designed to address the evolving SARS-CoV-2 threat; our ability to obtain and maintain regulatory approvals for our product candidates; our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if approved for commercial use; our expectations regarding the scope of any approved indication for our product candidates; our ability to successfully commercialize our product candidates, including for a new drug category; our ability to leverage our platform to identify and develop future product candidates in additional areas of need; our ability to identify patients with the diseases treated by our product candidates and to enroll these patients in our clinical trials; our manufacturing capabilities and strategy; our ability to successfully execute on the components of our vision to create the "perpetual machine"; the anticipation of ongoing discussions with health authorities; the potential for an emergency use authorization in the U.S. or other regulatory approval; our preclinical activity, plans, technology and resources to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza, in the U.S. and globally; our belief in the potential to discover and develop pipeline candidates as potent and durable antibodies or combination of antibodies for COVID-19; 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 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 our product candidates or combination of 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; whether we are able to successfully monitor, analyze, engineer and optimize new product candidates; whether we are able to create a flow of product candidates that address virus evolution; whether our product candidates or combination of candidates are able to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; whether we are able to successfully submit an emergency use authorization in the future, and the outcome of any such emergency use authorization submission; whether research and development efforts will improve efficacy of our product candidates against predominant variants or identify additional monoclonal antibodies or combination of antibodies for the prevention and treatment of COVID-19 and other infectious diseases; whether research and development efforts will identify and result in safe and effective therapeutic or preventative options for other infectious diseases in the U.S. or globally 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 and our most recent Quarterly Report on Form 10-Q, each 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.

OUR VISION & PURPOSE

Providing Hope for Vulnerable People Against Viral Diseases

Our purpose is to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with SARS-CoV-2

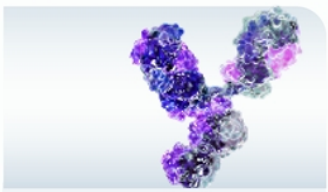
COVID IS THIRD LEADING CAUSE OF DEATH IN THE U.S.[1]

INVIVYD

Vaccination and increased levels of population immunity have reduced SARS-CoV-2 associated diseases and mortality; however, significant unmet medical need remains

Immunocompromised people are vulnerable to infection

- CDC estimates ~2.7% of U.S. population may be immunocompromised, approximately 8 million people[2,3]



No vaccine alternatives for prevention

- There are no monoclonal antibodies authorized or approved for COVID-19 prevention or treatment in U.S. against circulating variants[4,5]

People at higher risk of hospitalization and death

- ~56 million people in U.S. aged 65+[6]
- 116 million adults in U.S. with comorbidities[7]

Undervaccinated population

- As of January 31, 2023, ~60% of population in the U.S. aged 65+ have not received the updated bivalent booster[8]

Near term focus with initial candidate VYD222

Longer term R&D focus with additional pipeline candidates

1. https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-leading-cause-of-death-ranking/
2. Harpaz R, et al. Prevalence of Immunosuppression Among US Adults, 2013. *JAMA*. 2016;316(23):2547-2548.
3. https://www.census.gov/library/stories/2021/08/united-states-adult-population-grew-faster-than-nations-total-population-from-2010-to-2020.html
4. https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-bebtelovimab-not-currently-authorized-any-us-region#:~:text=FDA%20Announces%20Bebtelovimab%20is%20Not%20Currently%20Authorized%20in%20Any%20US%20Region,-Share&text=%5B11%2F30%2F2022%5D,to%20neutralize%20Omicron%20subvariants%20BQ.
5. https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-evusheld-not-currently-authorized-emergency-use-us#:~:text=Based%20on%20this%20revision%2C%20Evusheld,SARS%2DCoV%2D2%20variants.
6. www.census.gov 1/31/2023
7. www.census.gov 1/31/23 and https://wwwnc.cdc.gov/eid/article/26/8/20-0679_article
8. https://www.cnn.com/2022/12/16/health/bivalent-boosters-vaccine-effectiveness-studies/index.html

VYD222 is an investigational product candidate not approved for use in any country. The safety and efficacy of VYD222 have not been established.

INVIVYD: A PLATFORM APPROACH TO INNOVATION

INVIVYD

OUR FOCUS	DISCOVERY PLATFORM	PIPELINE	APPLICATION IN VIRAL DISEASES

• Antibodies designed to protect humanity from serious viral diseases
• Continuous innovation to address COVID-19 variants of concern
	• Rapid repeated antibody isolation, engineering, and predictive modeling of viral evolution
	• Candidate optimization for potency, half-life, potential to resist escape, and ease of manufacture
		• VYD222: a monoclonal antibody for prevention or treatment of COVID-19
		  ◦ Engineered from adintrevimab (ADG20), which has robust safety data package
		  ◦ Phase 1 clinical trial start planned for Q1 2023
		• VYD224, Candidate 3, Candidate 4: additional monoclonal antibodies for prevention or treatment of COVID-19
			• Growing number of antibodies aiming to overcome SARS-CoV-2 viral evolution
			• Plans to expand into other respiratory viruses with ongoing discovery campaigns in influenza

INVIVYD IN ACTION: APPROACH TO SELECTION OF NEXT GENERATION COVID-19 PRODUCT CANDIDATES

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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

PREDICT

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

IDENTIFY

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

OPTIMIZE

Engineer to optimize candidate properties

SHOWCASE OF VYD222: ENGINEERED FOR BROAD ACTIVITY AND PROLONGED UTILITY

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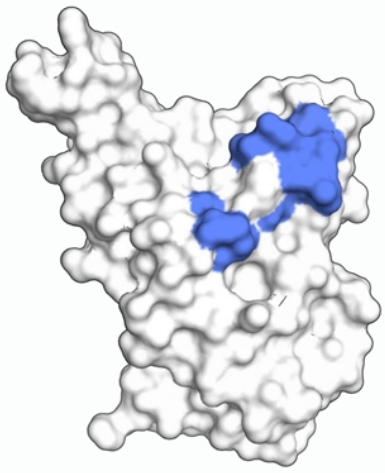
VYD222 (Engineered from adintrevimab)

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

RBD, receptor binding domain
VOC, variant of concern

VYD222 DEMONSTRATED BROAD IN VITRO NEUTRALIZING ACTIVITY AGAINST VARIANTS OF CONCERN AND SUB-LINEAGES

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VARIANT	SUBLINEAGE	VYD222	EVUSHELD®*	BEBTELOVIMAB®
WT(D614G)	WT(D614G)	✓	✓	✓
Delta	B.1.617.2	✓	✓	✓
Omicron	BA.1	✓	-	✓
	BA.4/5	✓	✓	✓
	BA.4.6	✓	X	✓
	BF.7	✓	-	-
	BQ.1.1	✓	X	X
	BA.2.75	✓	-	✓
	XBB.1	✓	X	X
	XBB.1.5	✓	X	X

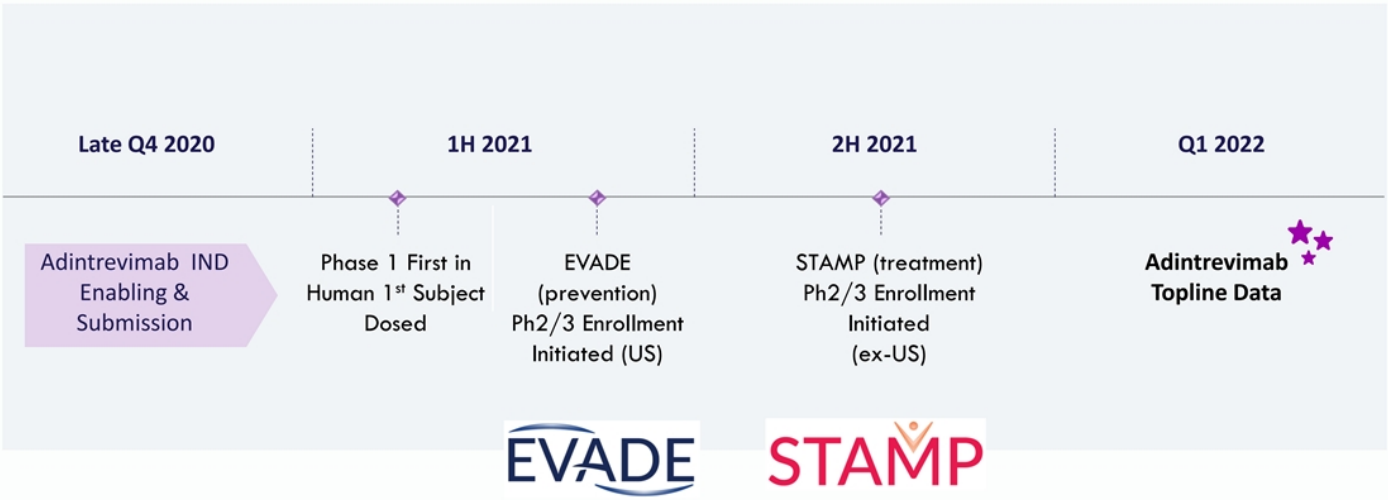
Neutralization data from published studies or measured by Invivyd using public sequences. Data current as of March 3, 2023. VYD222 data generated by Labcorp-Monogram Biosciences using the pseudovirus PhenoSense® SARS-CoV-2 Neutralizing Antibody Assay.

As of January 2023, there are no authorized or approved COVID-19 mAbs on the market in the U.S.

✓ Neutralizing in standardized *in vitro* assays
X Not neutralizing in standardized *in vitro* assays
\- Data Not Available
Current Circulating Variants

DEMONSTRATED DEVELOPMENT SUCCESS AND SPEED WITH ADINTREVIMAB: FROM IND TO TOPLINE DATA IN 16 MONTHS

INVIVYD



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

REGULATORS CONSIDERING STRATEGIES TO ACCELERTATE MONOCLONAL ANTIBODY DEVELOPMENT TIMELINES

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- Regulators are seeking strategies to streamline development of monoclonal antibodies and vaccines
- The necessity of streamlined development for new mAb products is supported by the science
- Understanding of SARS-CoV-2 biology has grown exponentially
- Accumulating data enables scientists to predict mAb effectiveness based on *in vitro* data which can then be confirmed in patients
  - This is especially true for products closely related to those previously studied

Possible Implication: Advance medicines to patients faster

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

ADVISORY COMMITTEE MEETING

Vaccines and Related Biological Products Advisory Committee January 26, 2023 Meeting Announcement

JANUARY 26, 2023

World Health Organization

WHO/BS/2023.2442
ENGLISH ONLY

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.

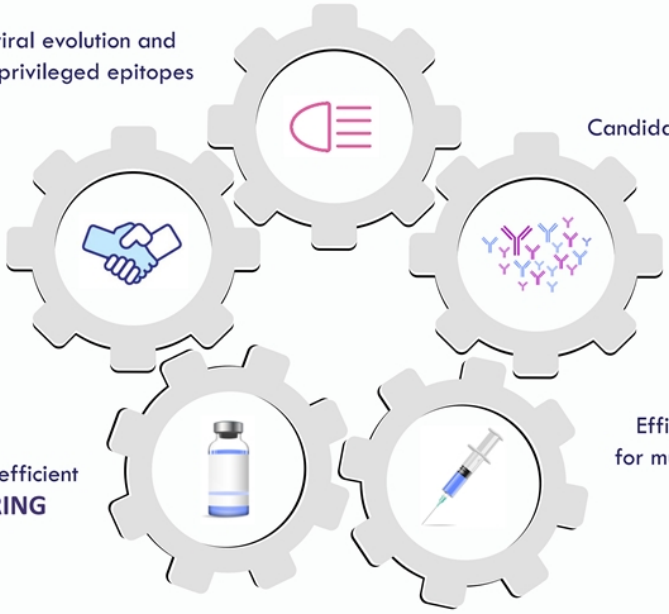
BUILDING ON OUR VISION TO CREATE THE "PERPETUAL MACHINE"

INVIVYD

PREDICTION of viral evolution and rational selection of privileged epitopes

Candidate antibody **DISCOVERY** and **ENGINEERING**

COMMERCIAL design for a large drug category, not solely a pandemic emergency

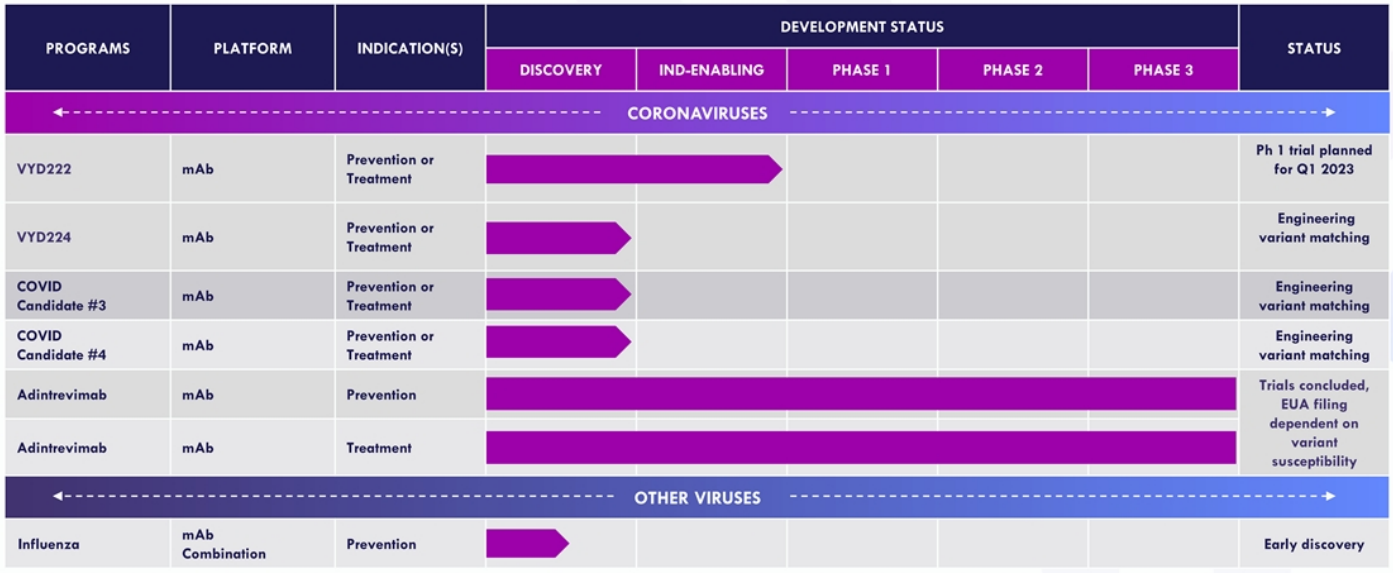


Efficient clinical **DEVELOPMENT** for multiple use cases and populations

Flexible and highly efficient **MANUFACTURING**

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

INVIVYD



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

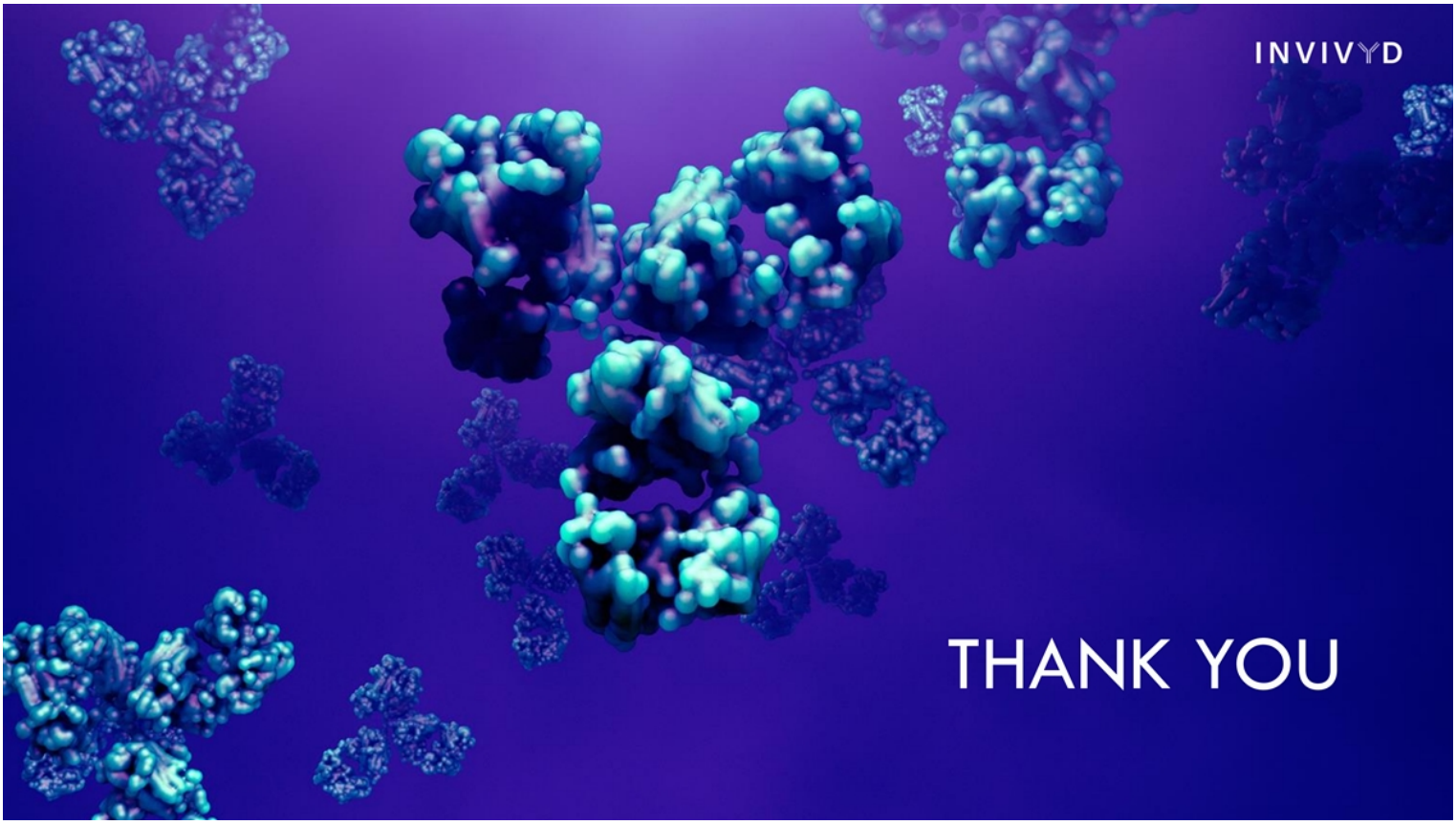
INVIVYD

Cash Position:
Cash, cash equivalents and marketable securities were $419 million as of September 30, 2022

Planned cash runway into Q2 2024

Total fully diluted shares of common stock outstanding* as of September 30, 2022:
130.4 million

*Includes vested and unvested outstanding options as of September 30, 2022; excludes treasury stock


INVIVYD
THANK YOU