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): January 9, 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 January 9, 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 January 9, 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: January 9, 2023

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

Exhibit 99.1

INVIVYD

J.P. Morgan 41st Annual Healthcare Conference

January 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, 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; 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.

OVERVIEW OF INVIVYD

INVIVYD

OUR FOCUS

- Antibodies designed to protect humanity from serious viral diseases
- Initial focus on COVID-19 with antibodies designed towards addressing variants of concern

DISCOVERY PLATFORM

- Rapid antibody isolation, engineering, and predictive modeling of viral evolution
- Identification and engineering of antibodies across multiple dimensions such as potency, durability, half-life, potential to resist escape, and manufacturability

LEAD PROGRAM

- NVD200 for COVID-19; a combination monoclonal antibody product
- Phase 1 trial start planned for Q1 2023

APPLICATION IN VIRAL DISEASES

- Growing number of antibodies aiming to overcome the challenges of viral evolution, starting in COVID-19
- Plans to expand into other respiratory viruses with ongoing preclinical activity 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

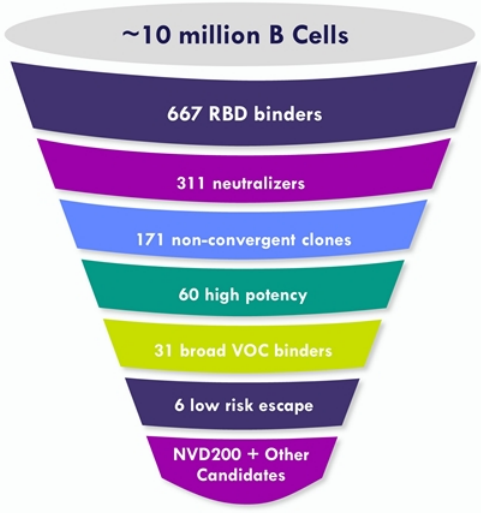
Mine human antibody repertoires induced following contemporary SARS-CoV-2 exposures

+

Pinpoint dominant spike protein sites targeted by human antibody repertoires and map common mutational escape routes to predict future variants

=

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



NVD200: A COMBINATION APPROACH OF TWO ANTIBODIES TARGETING DISTINCT EPITOPES

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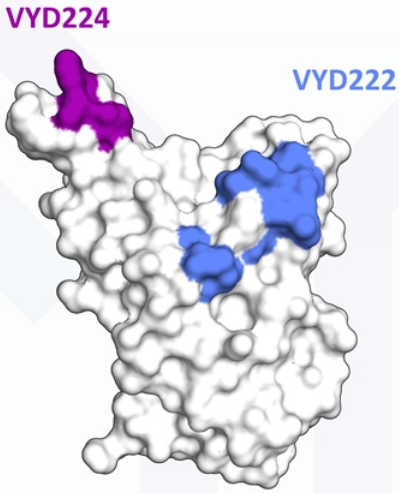
NVD200 = VYD224 + VYD222 (Re-engineered ADG20)

- Designed for:
  - High potency
  - Lack of polyreactivity
  - Long half-life
  - Developability
  - Patient and health system ease of use
  - Potential to resist escape
    - Target non-overlapping epitopes of spike RBD
    - Rare epitopes under less immune pressure
    - Conserved across human ACE2-using sarbecoviruses
- NVD200 shows in vitro neutralizing activity against: Pre-Omicron VOCs, Omicron variants BA.1, BA.2, BA.4, BA4.6 BA.5, BA.2.75, and SARS-CoV-2.
- Phase 1 trial start planned Q1 2023



RBD, receptor binding domain
VOC, variant of concern

ROBUST PIPELINE OF ANTIBODIES FOR TREATMENT AND PREVENTION OF VIRAL DISEASES

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PROGRAMS	PLATFORM	INDICATION(S)	DEVELOPMENT STATUS					STATUS
			DISCOVERY	IND-ENABLING	PHASE 1	PHASE 2	PHASE 3	
CORONAVIRUSES								
NVD200	mAb Combination	Prevention or Treatment						Phase 1 trial start planned for Q1 2023
COVID Candidate #2	mAb	Prevention or Treatment						Active monitoring of variants
COVID Candidate #3	mAb	Prevention or Treatment						Active monitoring of variants
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.

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

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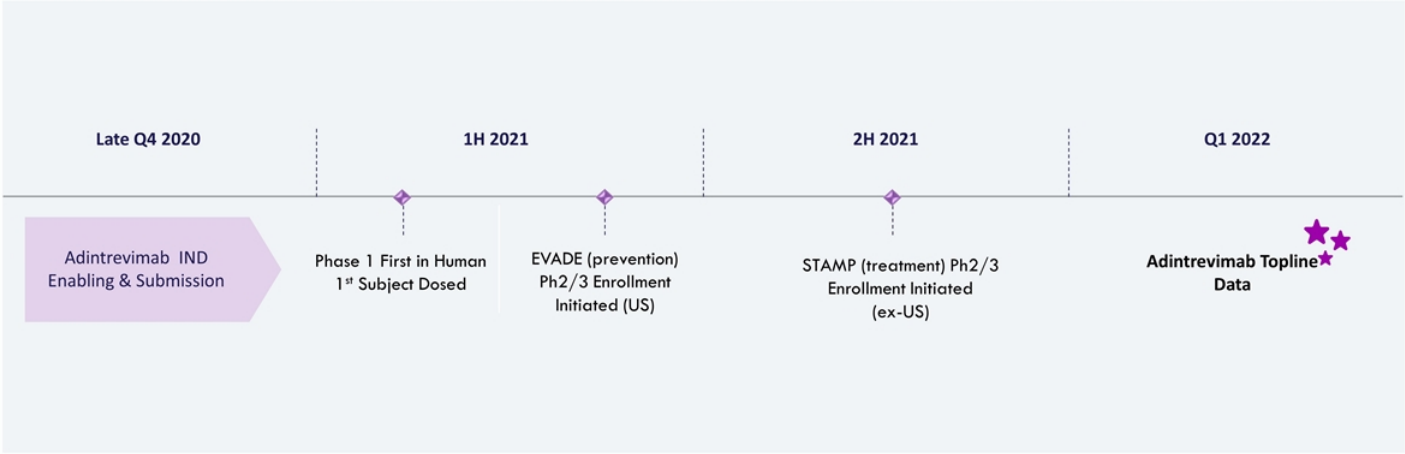

Adintrevimab is an investigational product candidate that is not approved for use in any country. The safety and efficacy of adintrevimab have not been established.

FDA-EMA JOINT WORKING SESSION ON NOVEL STRATEGIES FOR COVID-19 ANTIBODY DEVELOPMENT IN THE FACE OF RAPIDLY EVOLVING VARIANTS – DECEMBER 2022[1,2]

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Multi-sponsor industry presentation provided scientific rationale for the use of surrogate clinical markers to support the development of next-generation RBD mAb products:

- Neutralization is an accepted correlate of protection for next generation SARS-CoV-2 vaccine development
- Meta-analyses of clinical data support that neutralization potency is correlated with efficacy in prevention
- Serum titers achieved with passive administration of mAbs and active immunization with vaccines result in similar levels of protection
  - Neutralization is the driver of efficacy against symptomatic COVID-19
- Next generation mAbs could be discovered and manufactured using technologies and processes used to produce previously authorized mAbs
- Previous anti-SARS-CoV-2 mAbs have demonstrated a consistent, well tolerated safety profile
- Standardized neutralization assays and PK models could help establish protective titer thresholds

BIOTECH

STAT+

Drugmakers ask regulators to change standards on new Covid antibody drugs for most vulnerable

By Jason Mast Dec. 15, 2022

Reprints

Testing for antibody levels.
ALEXANDER ZEMLIANICHENKO/AP

Biotech executives and a handful of academics pleaded with U.S. and European regulators on Thursday to adopt new standards for approving antibody drugs against Covid, particularly for immunocompromised and other vulnerable patients.

1. https://www.ema.europa.eu/en/events/joint-ema-fda-workshop-efficacy-monoclonal-antibodies-context-rapidly-evolving-sars-cov-2-variants
2. https://www.ema.europa.eu/en/documents/agenda/agenda-joint-ema-fda-workshop-efficacy-monoclonal-antibodies-context-rapidly-evolving-sars-cov-2_en.pdf

COMPANY WELL CAPITALIZED TO DEVELOP LEAD CANDIDATE & ADDITIONAL PIPELINE ASSETS

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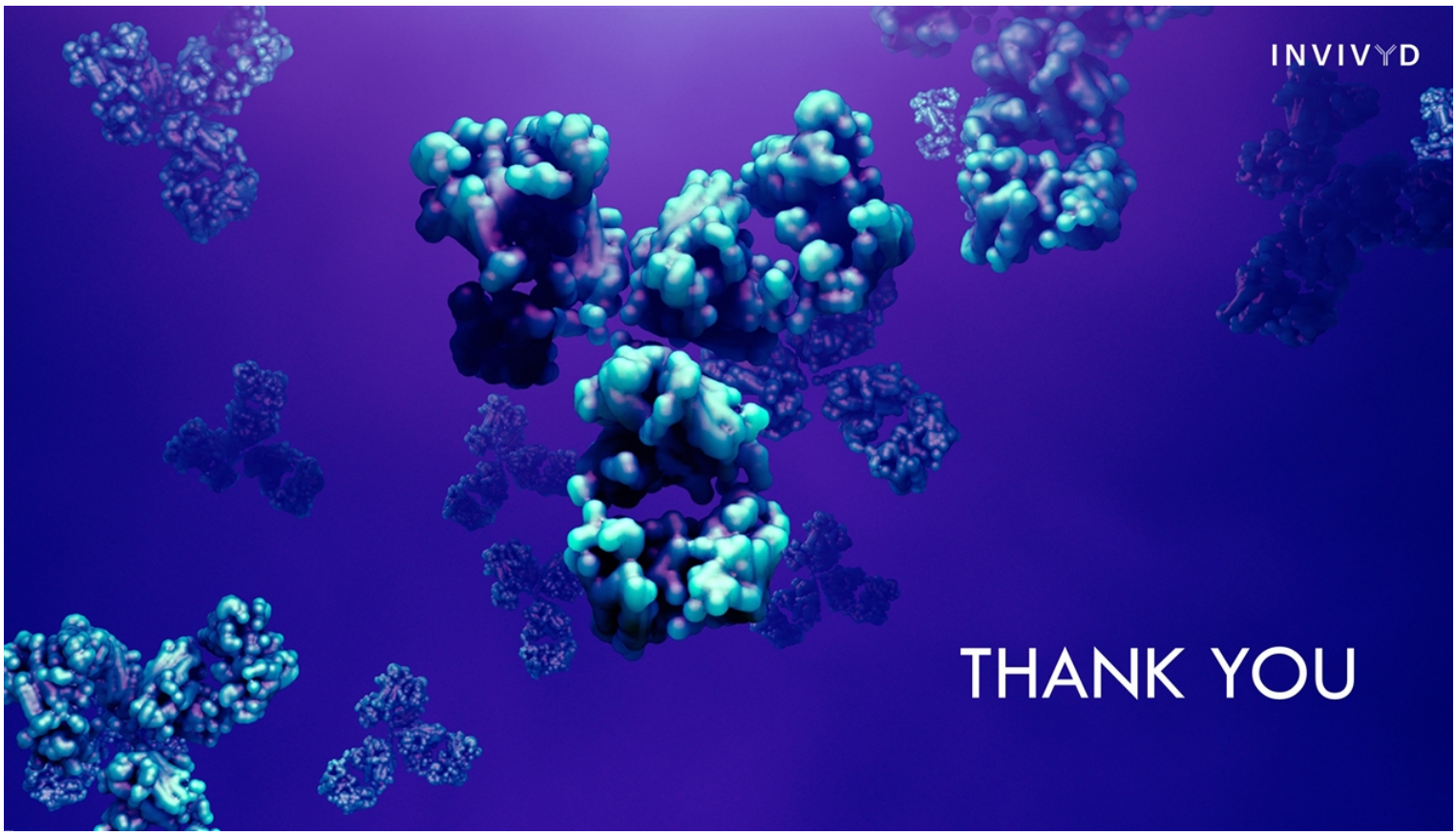
Cash Position:
Cash, cash equivalents and marketable securities were $419 million as of September 30, 2022

Planned cash runway into Q2 2024

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

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