# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported): September 12, 2022**

# Adagio Therapeutics, 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**<br>**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** | **ADGI** | **The Nasdaq Stock Market LLC** |

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

Emerging growth company ☒

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

**Item 8.01. Other Events.**

On September 12, 2022, the Company announced the upcoming name and ticker symbol change via a press release. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference in this Item 8.01.

On September 12, 2022, the Company issued a press release entitled "Invivyd Announces Multiple Next Generation COVID-19 Antibody Candidates and Selects Combination for Clinical Advancement Based on Positive in vitro Data Against Omicron Variants." A copy of the press release is filed herewith as Exhibit 99.2 and is incorporated by reference in this Item 8.01.

On September 12, 2022, the Company posted a corporate presentation on its website at www.Invivyd.com. A copy of the presentation is filed herewith as Exhibit 99.3 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 September 12, 2022 |
| 99.2 | Press Release, dated September 12, 2022 |
| 99.3 | Corporate Presentation, dated September 12, 2022 |
| 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.

**ADAGIO THERAPEUTICS, INC.**

Date: September 12, 2022

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

**Exhibit 99.1**

**Adagio Therapeutics Announces Corporate Name Change to Invivyd**

- New name reflects Company focus on leveraging its integrated discovery platform to generate anti-viral antibodies that transcend the limits of naturally occurring immunity
- The Invivyd corporate mission is to provide antibody solutions that provide superior protection against viral diseases, starting with COVID-19
- Company's shares to trade under new ticker symbol "IVVD" starting on September 13

**WALTHAM, MASS; September 12, 2022 –** Adagio Therapeutics, (Nasdaq: ADGI), a clinical-stage biopharmaceutical company on a mission to protect humanity from serious viral respiratory diseases, announced today that the Company has changed its name to Invivyd. This new name reflects the Company's strategy for leveraging its integrated discovery platform to develop and commercialize antibodies that transcend the limits of the human immune system to better prevent and treat infectious respiratory viral diseases, beginning with COVID-19. In conjunction with the name change, the Company will begin trading under the new ticker symbol "IVVD" on the Nasdaq Global Market at market open on September 13, 2022.

"I'm excited for our new name as it reflects our commitment to advancing antibody solutions to overcome limitations in both the immune system and existing COVID-19 treatments," said David Hering, Invivyd's chief executive officer. "Our team understands how viruses are constantly evolving to exploit the limitations of the human immune system. Invivyd leverages a platform we believe is nimble enough to target a virus that will continue to change, and durable enough to increase the probability of providing a longer period of protection than other antibody solutions. Our goal is to change the paradigm for combatting viral infection by delivering rapid and lasting antibody immunity to protect the general public and ensure vulnerable populations are never left behind."

Invivyd (pronounced "in-viv-id") has best-in-class antibody discovery and development capabilities working at the intersection of evolutionary virology, predictive modeling, and antibody engineering. The company's discovery platform is designed with the aim of providing better solutions to protect the vulnerable with antibodies engineered to be superior to naturally occurring human antibodies.

"Now, three years into the human experience with SARS-CoV-2, it is more clear than ever that we need more durable, more effective prevention and treatment than can be achieved through the human immune response," said Laura Walker, Ph.D., co-founder and chief scientific officer of Invivyd. "Invivyd has a powerful, best-in-class integrated discovery platform aimed at identifying and developing high quality molecules as viral evolution demands. I am thrilled with the opportunity to deploy our considerable expertise and resources toward providing ongoing protection to people in need."

Beyond COVID-19 the company has multiple antibody candidates in discovery stage for prevention of seasonal influenza.

Marc Elia, chairman of the Invivyd Board of Directors commented, “Viral respiratory diseases, including COVID-19, present unique challenges and impose an unacceptable burden on humankind. We are delighted to launch an enhanced corporate identity following a period of change that positions Invivyd to create a meaningful impact for the company’s stakeholders using its best-in-class integrated discovery platform and internal capabilities.”

Along with the new name, the Company has adopted a new logo and refreshed its corporate website to reflect the company’s strategy moving forward. Visit www.invivyd.com to learn more.

**About Invivyd**
(Nasdaq: IVVD)

Invivyd, formerly Adagio Therapeutics (Nasdaq: ADGI), is a biopharmaceutical company on a mission to protect humanity from serious viral respiratory diseases. The company is developing antibodies to transcend the limits of naturally occurring immunity and provide superior protection from viral diseases, beginning with COVID-19. 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 products for use in both prevention and treatment of disease. Invivyd’s most advanced pipeline candidate is adintrevimab, an investigational monoclonal antibody which has demonstrated clinically meaningful results in global Phase 3 clinical trials against multiple variants of concern for the prevention and treatment of COVID-19. Adintrevimab is not approved for use in any country. The safety and efficacy of adintrevimab have not been established. The company also has multiple discovery stage candidates for the prevention of seasonal influenza. Visit www.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 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 adintrevimab 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 adintrevimab to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S. and globally; 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 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 adintrevimab 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 adintrevimab 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 June 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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**Contacts**

**Media Contact:**

Tony Berry, Evoke Canale
774-317-0422
anthony.berry@evokegroup.com

**Investor Contact:**

Chris Brinzey, ICR Westwicke
339-970-2843
chris.brinzey@westwicke.com

# Invivyd Announces Multiple Next Generation COVID-19 Antibody Candidates and Selects Combination for Clinical Advancement Based on Positive *in vitro* Data Against Omicron Variants

- *Integrated discovery platform is producing a stream of candidate antibodies demonstrating broad in vitro neutralization against past variants of concern (e.g., D614G, beta, delta) and Omicron sublineages BA.1, BA.2, BA.4, BA.5 and BA.2.75, as well as SARS-CoV-1*
- *Antibodies target highly conserved epitopes under low immune pressure*
- *NVD200, a novel combination of two monoclonal antibodies, expected to advance into clinical trials in Q1 2023*

**WALTHAM, MASS; September 12, 2022 –** Invivyd, (Nasdaq: IVVD beginning September 13), formerly Adagio Therapeutics (Nasdaq: ADGI), a clinical-stage biopharmaceutical company on a mission to protect humanity from serious viral respiratory diseases, announced today that the Company has generated multiple next-generation candidate antibodies for the prevention and treatment of COVID-19, including two molecules designated for near-term clinical development in combination as NVD200. NVD200 is expected to enter the clinic in the first quarter of 2023.

The integrated Invivyd discovery platform generated dozens of potent and broadly neutralizing anti-SARS-CoV-2 monoclonal antibody candidates over the past two quarters. Now included in Invivyd's pipeline are multiple novel discovery-stage molecules that were produced using the company's deep expertise at the intersection of evolutionary virology, predictive modeling, and antibody engineering. These molecules are all designed to be high-functioning and long-lasting with a high barrier to viral escape. The company's antibody candidates are tuned to optimize across potency, breadth of neutralization, barrier to escape, and half-life. Such antibodies may be deployed prior to exposure to SARS-CoV-2 to prevent disease or, once sick, to treat disease.

"COVID-19 continues to impose a significant and unacceptable burden on humanity, which is why I am pleased that our integrated discovery platform has been so productive at identifying novel candidates with potential to transcend the limitations of the human immune response," said David Hering, CEO of Invivyd. "Our approach is designed to find unique molecules that target the validated SARS-CoV-2 spike protein at sites under limited immune pressure, which we expect to translate into a high barrier to viral escape. We are rapidly advancing NVD200, our novel combination candidate, toward the clinic with a Phase 1 clinical trial expected to start in the first quarter of next year. At the same time, we are diligently monitoring emerging variants to inform our development plans for the multiple additional discovery candidates in our pipeline, as well as innovating to provide a steady stream of new candidates to address the continuously evolving viral threat."

NVD200 is a combination of two monoclonal antibodies which demonstrated potent *in vitro* neutralizing activity against prior and current SARS-CoV-2 variants of concern, including Omicron BA.1, BA.2, BA.4, BA.5, and BA.2.75 sublineages, as well as the more antigenically divergent SARS-CoV-1. This antibody combination has been selected for neutralization potency, breadth of coverage, and non-dominant epitope recognition. The antibodies in the combination target non-overlapping epitopes that are rarely

targeted by endogenous neutralizing antibodies, which limits immune pressure on these sites and increases the probability of sustained utility in an evolving viral landscape. One of the antibodies in the combination is a re-engineered version of adintrevimab, the company's most advanced product candidate, which met all primary endpoints with statistical significance in a pre-Omicron setting in global Phase 3 clinical trials for the prevention and treatment of COVID-19.

"The multiple novel antibodies we have engineered further expand on our discovery work with adintrevimab and subsequent clinically meaningful results," said Laura Walker, Ph.D., co-founder and chief scientific officer of Invivyd. "Over the past two years, remarkable advances have been made in our understanding of the plasticity of the SARS-CoV-2 receptor binding domain, the co-evolution of the virus and the human antibody response, and the importance of neutralization in protection, allowing us to select and engineer lead molecules that we believe will have sustained utility. We have also created a continuous discovery process to stay ahead of viral variation, so any gaps in coverage may be rapidly filled."

Invivyd's platform includes continuous variant monitoring and extensive exploration of the vast universe of potential antibodies outside of the common human immune repertoire. The company has already identified hundreds of neutralizing monoclonal antibodies and selected them based on stringent selection criteria including potency, breadth of coverage across SARS-CoV-2 variants and other sarbecoviruses, immunorecessive epitope targeting, and specified developability criteria.

**About Invivyd**

(Nasdaq: IVVD)

Invivyd, formerly Adagio Therapeutics (Nasdaq: ADGI), is a biopharmaceutical company on a mission to protect humanity from serious viral respiratory diseases. The company is developing antibodies to transcend the limits of naturally occurring immunity and provide superior protection from viral diseases, beginning with COVID-19. 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 products for use in both prevention and treatment of disease. NVD200, Invivyd's first antibody combination product for COVID-19, is expected to enter the clinic in Q1 2023. Invivyd's most advanced pipeline candidate is adintrevimab, an investigational monoclonal antibody which has demonstrated clinically meaningful results in global Phase 3 clinical trials against multiple variants of concern for the prevention and treatment of COVID-19. Adintrevimab is not approved for use in any country. The safety and efficacy of adintrevimab have not been established. The company also has multiple discovery stage candidates for the prevention of seasonal influenza. Visit www.invivyd.com to learn more.

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**Media Contact:**

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chris.brinzey@westwicke.com

Exhibit 99.3

INVIVYD

# Investor Presentation
# September 2022

Transcending the limitations of the immune system

# Forward Looking Statements

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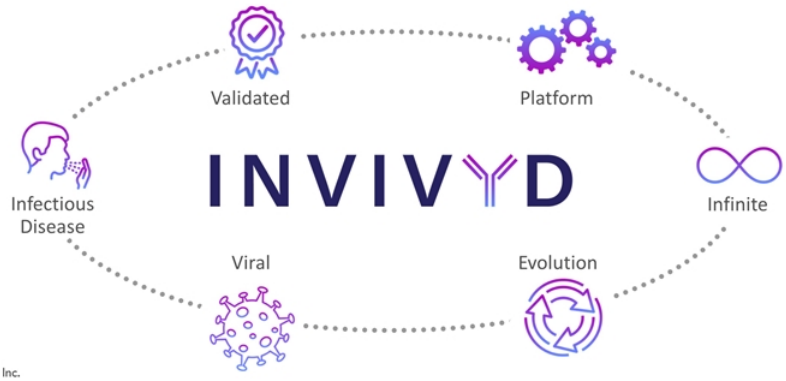
Forward-looking statements include statements concerning, among other things, the future of the COVID-19 landscape including the expectation of continued evolution and emergence of new variants and subvariants; our ongoing research and clinical development plans; the timing, progress and results of our 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 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; 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 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 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.

This presentation contains industry, statistical and market data from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. This information involves many assumptions and limitations, and you are cautioned not to give undue weight to these estimates. We have not independently verified the accuracy or completeness of the data contained in these industry publications and other publicly available information. We do not undertake to update such data after the date of this presentation.

# A Fresh Start

## What's in the name?

- New Company and Board leadership, aligned with shareholders
- Substantial drug development and industry expertise brought to bear
- Company rapidly deploying best-in-class technology with an evolved strategy
- New name, renewed energy, major promise



# Invivyd: Transcending the Limitations of the Immune System

## Engineered antibodies designed to protect humans from serious viral diseases, starting with COVID-19

### Engineered antibodies

- To transcend the limits of naturally occurring immunity and provide superior protection from viral diseases

### Discovery platform

- Integrates evolutionary virology, predictive modeling, and antibody engineering to generate high-quality, long-lasting antibodies with high barrier to viral escape

### Initial focus on COVID-19 treatment and prevention

- Growing number of antibodies aiming to provide broader, more dynamic coverage and overcome the challenge of viral evolution

### Iterative platform strategy

- Near-term COVID-19 focus, with plans to expand into influenza and other respiratory viruses

### Multiple potential catalysts in next 18 months

- Initiation and data readouts expected from clinical trials of NVD200 for prevention and treatment of COVID-19

# The Problem

## The immune system lacks sufficient response to many respiratory viruses, including SARS-CoV-2

**There is an antibody titer gap between normal human immune response and the antibodies we need for safety, wellness and normal functioning**

- COVID-19 inflicts an unacceptable burden on humankind even with vaccines and therapeutics
  - The human immune response to vaccination and infection has kept us alive but at continued risk
  - Mucosal immunity induced by infection and vaccination is weak and short-lived
  - Oral antivirals have limitations (e.g., presymptomatic infection, adherence, viral rebound)
  - Available mAbs are largely based on common human immune repertoires, making them susceptible to loss of activity through mutational escape
- To be safe and well, we require higher quality, more durable protection than our immune systems can produce in response to vaccination or infection

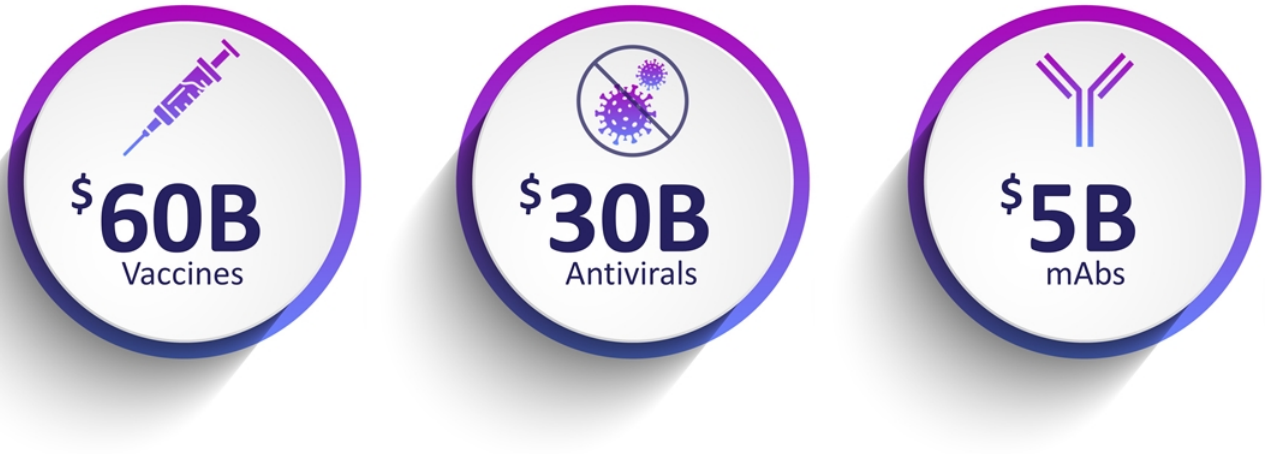
# The Invivyd Solution

## An integrated discovery platform aiming to continuously yield high-quality antibodies designed for breadth, potency, and higher barrier to viral escape

**Potential to address a broad array of viral infectious diseases**

- Unique capability to combat viral evolution through discovery platform
- Explore expanses of the antibody universe beyond the common repertoire to:
  - Find candidates that target sites not under immune pressure to mutate
  - Predict viral evolution and anticipate future variants
  - Engineer to optimize across potency, breadth, half-life
- Antibodies designed for prevention and treatment
- Generate continuous stream of candidates to flex and adapt as the virus mutates

# COVID-19 Prevention and Treatment Represents a $95 Billion Market in 2022




Source:
Data compiled from 2020-2022 revenues from company earnings calls; 2023-2025 forecasted revenues from Global Data report "COVID-19 Sector Forecast: H1 2022, Global Analyst Consensus Sales Forecast," June 2022

# Significant Need for Differentiated Approaches to Prevention and Treatment

## Large Prevention Market

- 54 million people in U.S. aged 65+[1]
- 20 million immunocompromised in U.S. with 11 million moderate to severe[2]
- 115 million adults in U.S. with comorbidities[3]
- Potential PrEP* population of ~25 million across U.S., EU and Canada[4]
- Potential as vaccine alternative with more durable protection

## Treatments for Serious Disease Needed

- More than 6.4 million deaths globally to date[5]
  - 1 million+ in U.S.[5]
- **Even with vaccination, 1 million+ deaths in 2022 alone[6]**
- 4,500+ hospitalizations daily in U.S. (as of September 2022)[7]
- COVID-19 deaths have contributed to U.S. life expectancy drop of 6.6 years in last two years for some ethnic minorities[8]

*Pre-Exposure Prophylaxis

Sources:

1. www.census.gov
2. Health Advances epidemiological estimate
3. www.census.gov and https://wwwnc.cdc.gov/eid/article/26/8/20-0679_article
4. Health Advances Epidemiological Analysis completed Jan. 2022
5. https://covid19.who.int/
6. https://covid19.healthdata.org/global?view=cumulative-deaths&tab=trend
7. https://covid.cdc.gov/covid-data-tracker/#datatracker-home

INVIVYD

# mAbs Providing Extended Protection Offer a Compelling Alternative for the Vulnerable or Unvaccinated

**ONLY 68%** of **U.S. adults** fully vaccinated for coronavirus as of Sept. 2022[1]; protection waning constantly

**20%** of all U.S. adults strongly opposed vaccination[4]; **OF THOSE**

**20%** said they would be interested in a mAb[5]

**ONLY 55%** of people **aged 50+** with a past COVID-19 vaccine said they're very likely to get a fall booster[2]

**40%** 

of parents **do not** intend to vaccinate their children <12 years old[6]

**~10%** of physicians would **exclusively use mAb** approach for their moderate/severe immunocompromised patients[3]

**ONLY 2.8%**

of children **under age 5** have been vaccinated[7]

Sources:

1. https://usafacts.org/visualizations/covid-vaccine-tracker-states
2. https://ihpi.umich.edu/sites/default/files/2022-08/NPHA-poll-extra_covid-boosters-annotated-questionnaire_08082022-v3.pdf
3. Internal market research
4. Internal market research
5. Internal market research
6. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-july-2022/
7. https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-vaccination-rates-among-children-under-5-have-peaked-and-are-decreasing-just-weeks-into-their-eligibility/

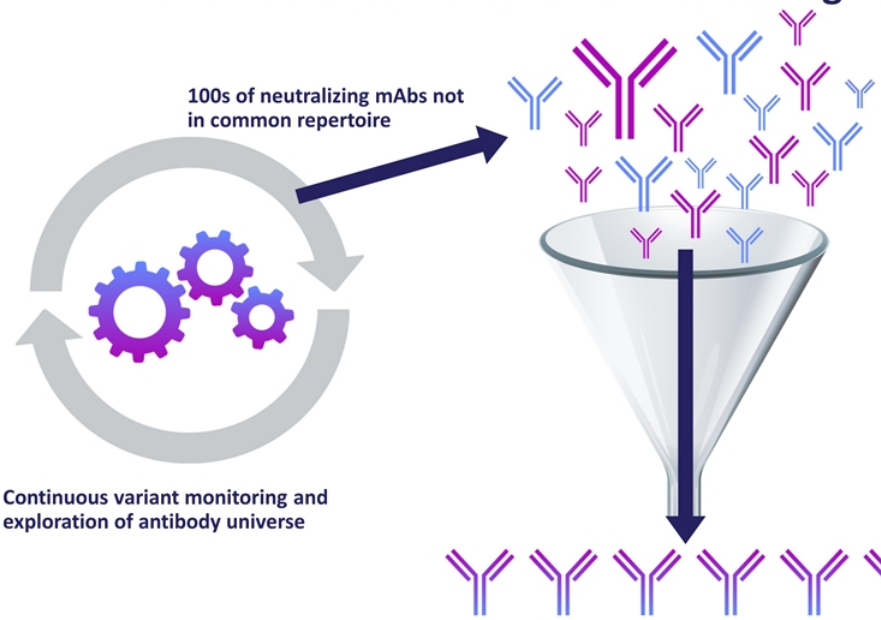
# Discovery Platform Overview

## Strategy designed to overcome the challenges of viral evolution

**Continuous monitoring, analysis, engineering and optimizing to identify a stream of novel antibodies designed to address an evolving viral threat**

- Deeply mine human antibody repertoires induced following diverse SARS-CoV-2 exposures
- Pinpoint dominant sites on the viral spike protein targeted by human immune repertoire and map mutational escape routes; predict future variants via deep analysis of immune pressures
- Identify potent, pan-variants of concern (VOC) mAb candidates that target rare epitopes, privileged by lack of human immune pressure
- Select mAbs with activity against other SARS-like viruses, further increasing the barrier to escape
- Optimize for breadth, potency, epitope, half-life, and manufacturability

# Ongoing Discovery Creates Continuous Flow of Pipeline Candidates with the Goal of Addressing Virus Evolution




**Stringent Selection Criteria**

- ✓ High potency neutralization
- ✓ Breadth of coverage
- ✓ No polyreactivity
- ✓ Low viscosity
- ✓ Rare epitopes
- ✓ No sequence liabilities

**Steadily Growing Pool of High Potential Development Candidates to Tap as Virus Evolution Dictates**

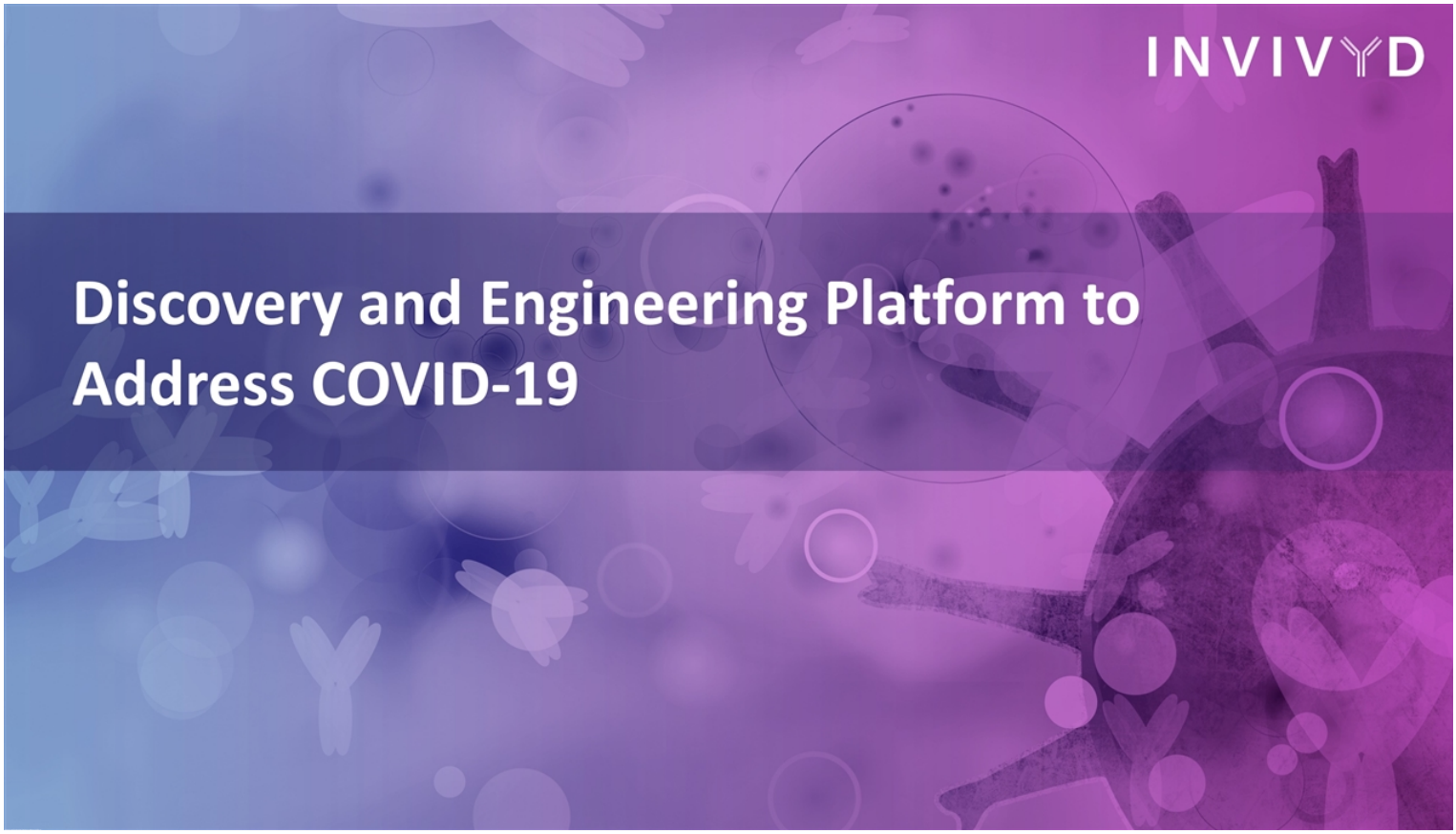
# Robust Pipeline of Engineered Antibodies for Treatment and Prevention of Viral Diseases

| PROGRAM | PLATFORM | INDICATION(S) | DEVELOPMENT STATUS | | | | | STATUS |
|---|---|---|---|---|---|---|---|---|
| | | | DISCOVERY | IND-ENABLING | PHASE 1 | PHASE 2 | PHASE 3 | |
| **Coronaviruses** | | | | | | | | |
| NVD200 | mAb combination | Prevention | | | | | | Phase 1 initiation Q1 2023 |
| NVD200 | mAb combination | Treatment | | | | | | |
| COVID Combo Candidate #2 | mAb combination | Prevention | | | | | | Active monitoring of variants |
| COVID Combo Candidate #2 | mAb combination | Treatment | | | | | | |
| Multiple additional discovery assets | mAb | Prevention/ Treatment | | | | | | Active monitoring of variants |
| Adintrevimab | mAb | Prevention | | | | | | EUA submission ready depending on variant |
| Adintrevimab | mAb | Treatment | | | | | | |
| **Non-COVID** | | | | | | | | |
| 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.

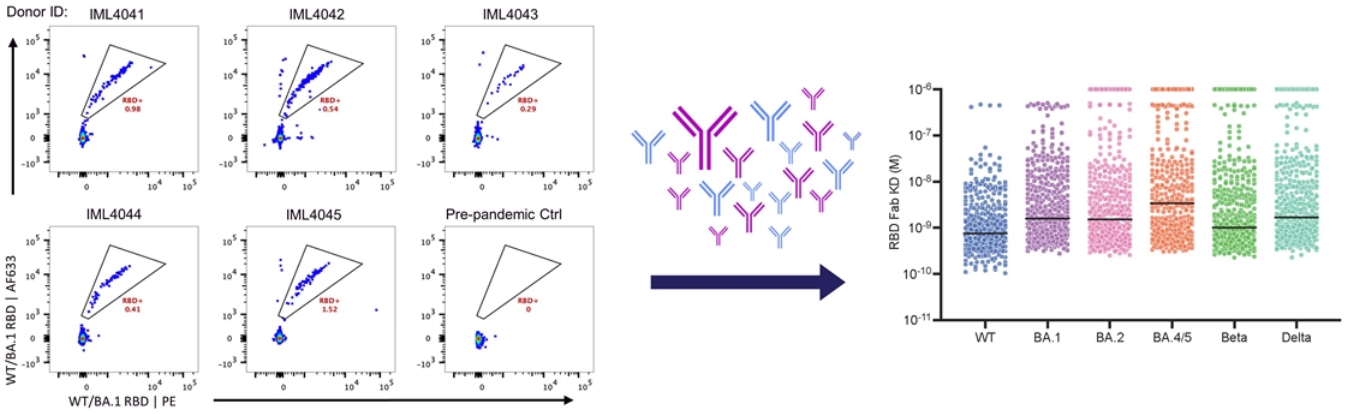
# Invivyd Aims to Establish Best In Class Performance Across Five Key Disciplines

- **Prediction** of viral evolution and rational selection of privileged epitopes
- Candidate antibody **discovery and engineering**
- Efficient clinical **development** for multiple use cases and populations
- Flexible and highly efficient **manufacturing**
- **Commercial** design for a mature, large drug category, not solely a pandemic emergency


INVIVYD
Discovery and Engineering Platform to Address COVID-19

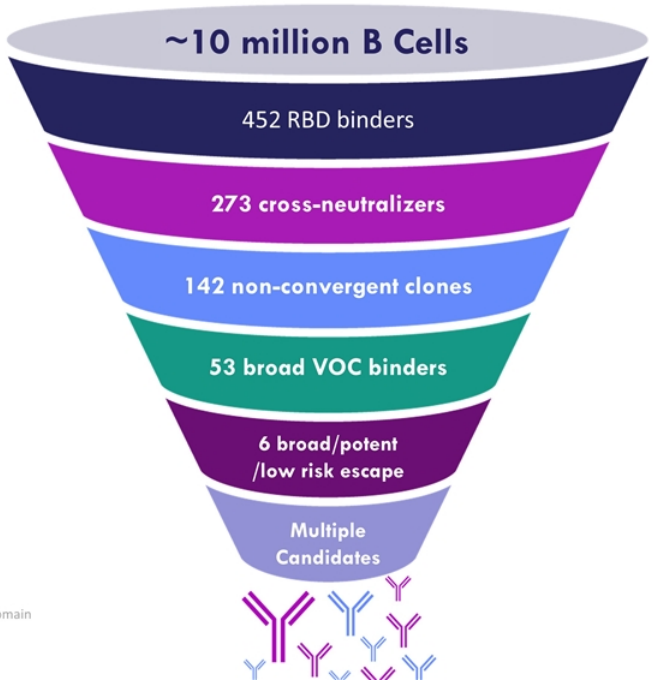
# The Beginning: Deep B Cell Mining Identifies Preliminary Binders

## Continuous monitoring and mining of diverse immune repertoires generates optimal starting points for engineering antibody candidates




RBD, receptor binding domain

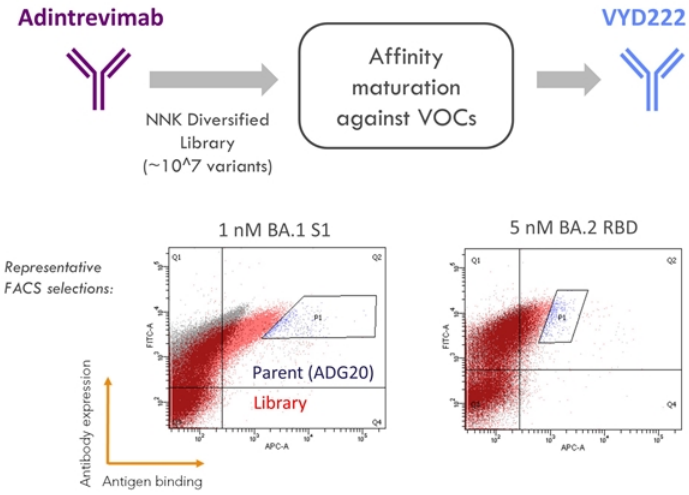
# Invivyd Explores Vast Antibody Diversity to Identify Optimal, Complementary Candidates for Engineering



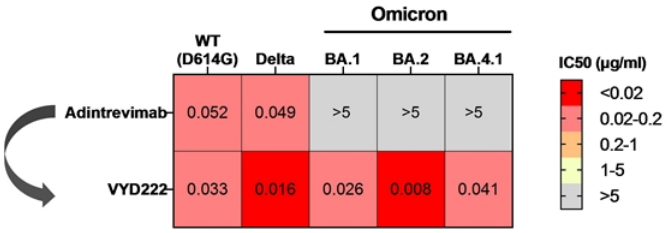

Highly productive Omicron lineage campaign yielded multiple candidates for engineering optimization

RBD, receptor binding domain
VOC, variant of concern

# Unique Engineering Capability Allows for Fine Tuning and Optimization: the Recovery of Adintrevimab




RBD, receptor binding domain
VOC, variant of concern



# Two Candidates Selected from Multiple Promising mAbs Identified

## Data Shows Broad Neutralizing Activity Against Pre-Omicron VOCs and Omicron (+sub-lineages)

**Authentic virus**

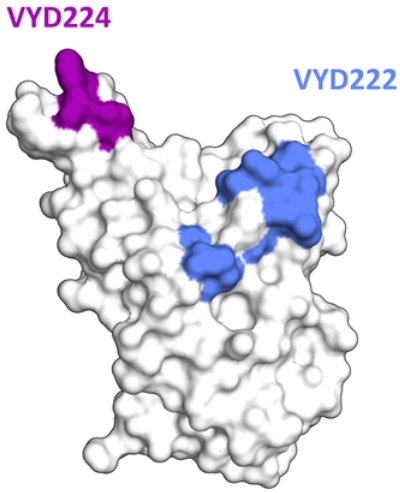
| | WT (D614G) | Delta | Omicron BA.1 | Omicron BA.2 | Omicron BA.4 |
|---|---|---|---|---|---|
| VYD222 | 0.033 | 0.016 | 0.026 | 0.008 | 0.041 |
| VYD224 | 0.010 | 0.006 | 0.010 | 0.016 | 0.126 |
| NVD200 | 0.017 | 0.014 | 0.013 | 0.013 | 0.050 |
| Bebtelovimab | 0.021 | 0.027 | 0.004 | 0.010 | 0.026 |
| Adintrevimab | 0.052 | 0.049 | >5 | >5 | >5 |

Neut. $IC_{50}$ (µg/ml): <0.02; 0.02-0.2; 0.2-1; 1-5; >5

**Pseudovirus**

| | WT | BA.2.75 | BA.5 |
|---|---|---|---|
| VYD222 | 0.030 | 0.100 | 0.030 |
| VYD224 | 0.030 | 0.010 | 0.080 |
| Adintrevimab | 0.040 | >5 | >5 |

Neut. $IC_{50}$ (µg/ml): <0.02; 0.02-0.2; 0.2-1; 1-5; >5




VOC, variant of concern

# Our Scale Generates Rational Combinations: NVD200 for Prevention & Treatment of COVID-19

- Combination of VYD222 and VYD224
- Neutralizing activity against VOCs, and SARS 1
- Designed for:
  - High potency
  - Lack of polyreactivity
  - Long half life
  - Developability
  - Patient and system ease of use
- Potential to resist escape
  - Target non-overlapping epitopes of Spike RBD
  - Conserved across coronaviruses

RBD, receptor binding domain
VOC, variant of concern

# Continuous and Repeatable Process Designed to Address Viral Evolution


INVIVYD
Next Steps and Milestones


INVIVYD
Expansion and Execution

# Future Expansion

## Diseases where we see limitations of the human immune system

**Positioned to address significant market need in seasonal influenza**

- Potential annual impact of seasonal influenza[1]
  - 41 million cases
  - 710,000 hospitalizations
  - 52,000 deaths
- Vaccine efficacy ranges from 10-60%[2] and wanes within ~3 months after vaccination[3]

**Invivyd engineered antibodies have potential to provide broader, more lasting protection than natural immunity**

- Generated neutralizing antibodies covering 100+ years of viral evolution including animal spillovers, etc.
- Approach looks to cover all circulating H1 and H3 strains

Sources
1. https://www.cdc.gov/flu/about/burden/index.html
2. https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm
3. https://www.science.org/doi/10.1126/science.aaz8432

# Management Team with Track Record of Success

**Dave Hering**
CEO & Director

**Laura Walker, Ph.D.**
Co-founder & Chief Scientific Officer

**Jill Andersen**
Chief Legal Officer & Corporate Secretary

**Becky Dabora, Ph.D.**
Chief Technology & Manufacturing Officer

**Jane Pritchett Henderson**
Chief Financial & Business Officer

**Ellie Hershberger, Pharm.D.**
Chief Development Officer

**Eric Kimble**
Chief Commercial Officer

# Our Vision

**Engineered antibodies designed to protect humans from serious viral diseases, starting with COVID-19**

### Engineered antibodies

- To transcend the limits of naturally occurring immunity and provide superior protection from viral diseases

### Discovery platform

- Integrates evolutionary virology, predictive modeling, and antibody engineering with the aim of generating high-quality, long-lasting antibodies with high barrier to viral escape

### Initial focus on COVID-19 treatment and prevention

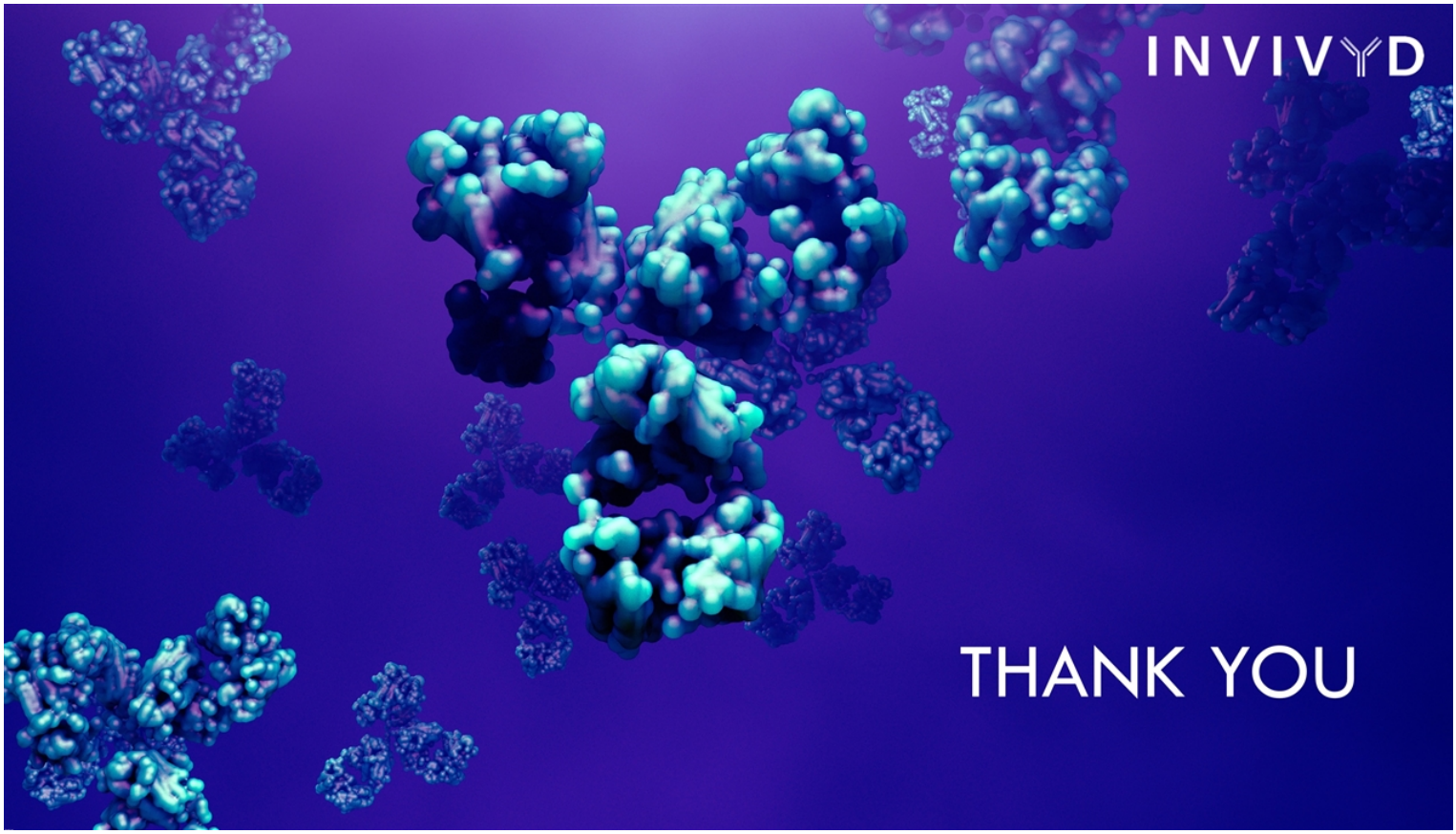
- Growing number of antibodies with the potential to provide broader, more dynamic coverage and overcome the challenge of viral evolution

### Iterative platform strategy

- Near-term COVID-19 focus, expanding into influenza and other respiratory viruses

### Multiple potential catalysts in next 18 months

- Initiation and data readouts expected from clinical trials of NVD200 for prevention and treatment of COVID-19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THANK YOU

# Corporate Strategy

## Achieve Mission in COVID-19 and Expand Beyond

**Use Invivyd's best-in-class discovery platform to develop engineered antibodies to provide a strong and lasting immune response against many viruses that cause upper respiratory infections.**

- **Develop and commercialize** engineered antibodies to provide protection more durable than natural immunity against viral infectious diseases, beginning with our lead asset(s) for COVID-19.
- **Establish Invivyd as long term COVID class leader** with next generation COVID-19 combo program for prevention (BLA enabled) and position company for sustained, durable product coverage
- **Pursue near term wins** in COVID-19 in current public health emergency window
- **Expand pipeline** where there is an unmet need and weak and short-lived immunity is seen such as with seasonal influenza