



# INVESTOR PRESENTATION

October 2024



# Forward-Looking Statements

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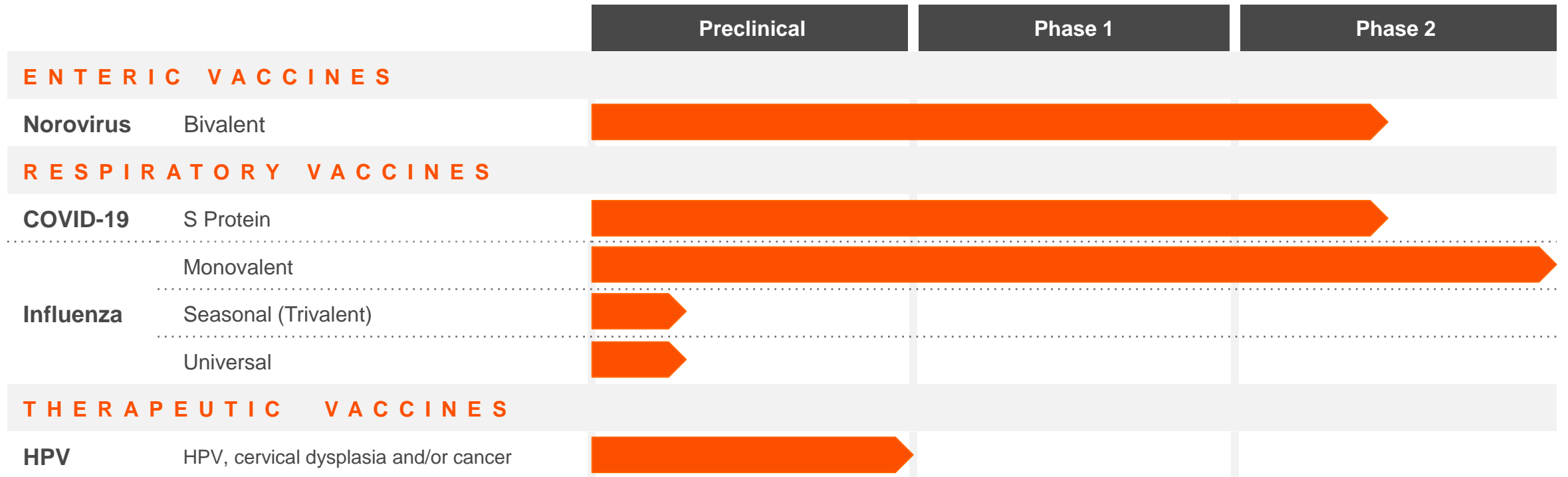
This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Vaxart's strategy, prospects, plans and objectives, results from preclinical and clinical trials, commercialization agreements and licenses, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "should," "believe," "could," "potential," "will," "expected," "plan" and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to Vaxart's ability to develop (including enrolling a sufficient number of participants and manufacturing sufficient quantities of its product candidates) and commercialize its COVID-19 vaccine candidate and preclinical or clinical results and trial data (including plans with respect to the COVID-19 vaccine product candidates); expectations regarding the timing and nature of future announcements including, those related to clinical trials and results of preclinical studies; Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for coronaviruses; the potential applicability of results seen in our preclinical trials to those that may be seen in human studies or clinical trials; the expected role of mucosal immunity in blocking transmission of COVID-19; and Vaxart's expectations with respect to the effectiveness of its products or product candidates, including Vaxart's potential role in mitigating the impact of COVID-19 globally. Vaxart may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Vaxart makes, including uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials or preclinical studies, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial and preclinical study data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; decisions by regulatory authorities impacting labeling, manufacturing processes, and safety that could affect the availability or commercial potential of any product candidate, including the possibility that Vaxart's product candidates may not be approved by the FDA or non-U.S. regulatory authorities; that, even if approved by the FDA or non-U.S. regulatory authorities, Vaxart's product candidates may not achieve broad market acceptance; that a Vaxart collaborator may not attain development and commercial milestones; that Vaxart or its partners may experience manufacturing issues and delays due to events within, or outside of, Vaxart's or its partners' control, including the recent outbreak of COVID-19; difficulties in production, particularly in scaling up initial production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations; that Vaxart may not be able to obtain, maintain and enforce necessary patent and other intellectual property protection; that Vaxart's capital resources may be inadequate; Vaxart's ability to obtain sufficient capital to fund its operations on terms acceptable to Vaxart, if at all; the impact of government healthcare proposals and policies; competitive factors; and other risks described in the "Risk Factors" sections of Vaxart's Quarterly and Annual Reports filed with the SEC. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

# EXECUTIVE SUMMARY



- Oral tablet vaccine platform designed to provide improved convenience as well as generate substantial systemic and mucosal immunity
- Clinical proof-of-concept demonstrated in two challenge studies against both respiratory and GI viruses
- Three pipeline programs in norovirus, influenza and COVID-19
- Phase 2 challenge data in norovirus suggest compelling real-world profile for our bivalent vaccine candidate
- Demonstrated protective activity in a Phase 2 study for influenza, protection similar to market leading injectable
- BARDA Project NextGen award up to \$456.1M (\$96.5M currently available) to prepare and execute an approximately 10,000 participant Phase 2b trial for COVID-19 evaluating our vaccine candidate head-to-head against an FDA approved mRNA vaccine comparator

# Vaxart Has Multiple Promising Clinical-Stage Programs



# Vaxart's Oral Vaccine Candidates Have the Potential to Address Many of the Shortcomings of Injectable Vaccines

## Cross-reactivity & Broad Immune Responses

- Broad immune responses in preclinical & clinical COVID-19 and influenza studies
- Cross-reactivity in COVID-19 and norovirus clinical trials

## Long Duration of Protection and Immune Responses

- Long-lasting protection demonstrated in influenza human vaccine study
- Long-lasting antibody responses in clinical norovirus and COVID-19 trials

## Reduction in Transmission

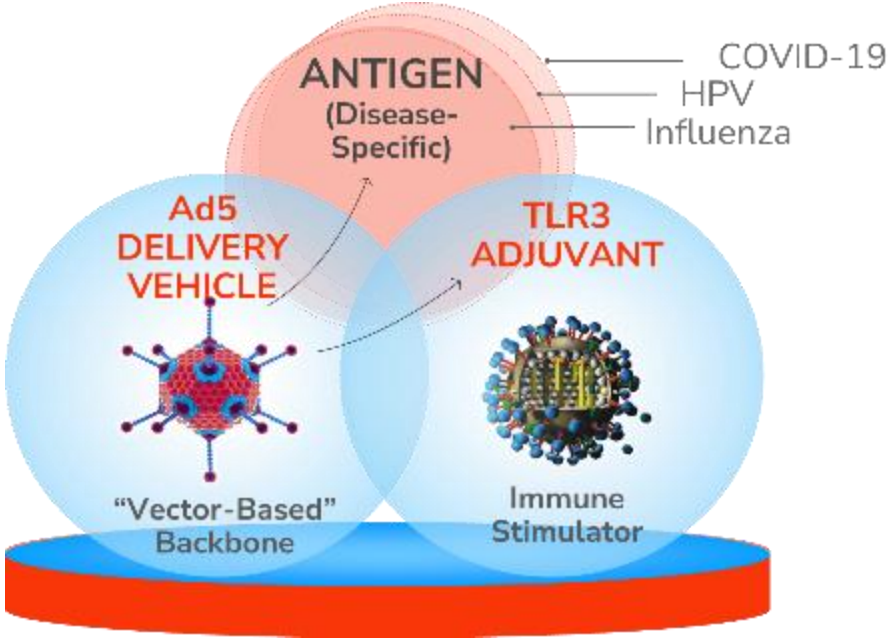
- Reduction in viral transmission in preclinical COVID-19 study
- Reduction in shedding in influenza and norovirus clinical trials

## Benign Safety and Tolerability to Date

- Benign safety and tolerability profile observed across 19 clinical trials against 7 different viruses, evaluating 800+ participants

# Vaxart's Proprietary VAAST® Platform is Unique

## Proprietary Oral Vaccine Platform: VAAST



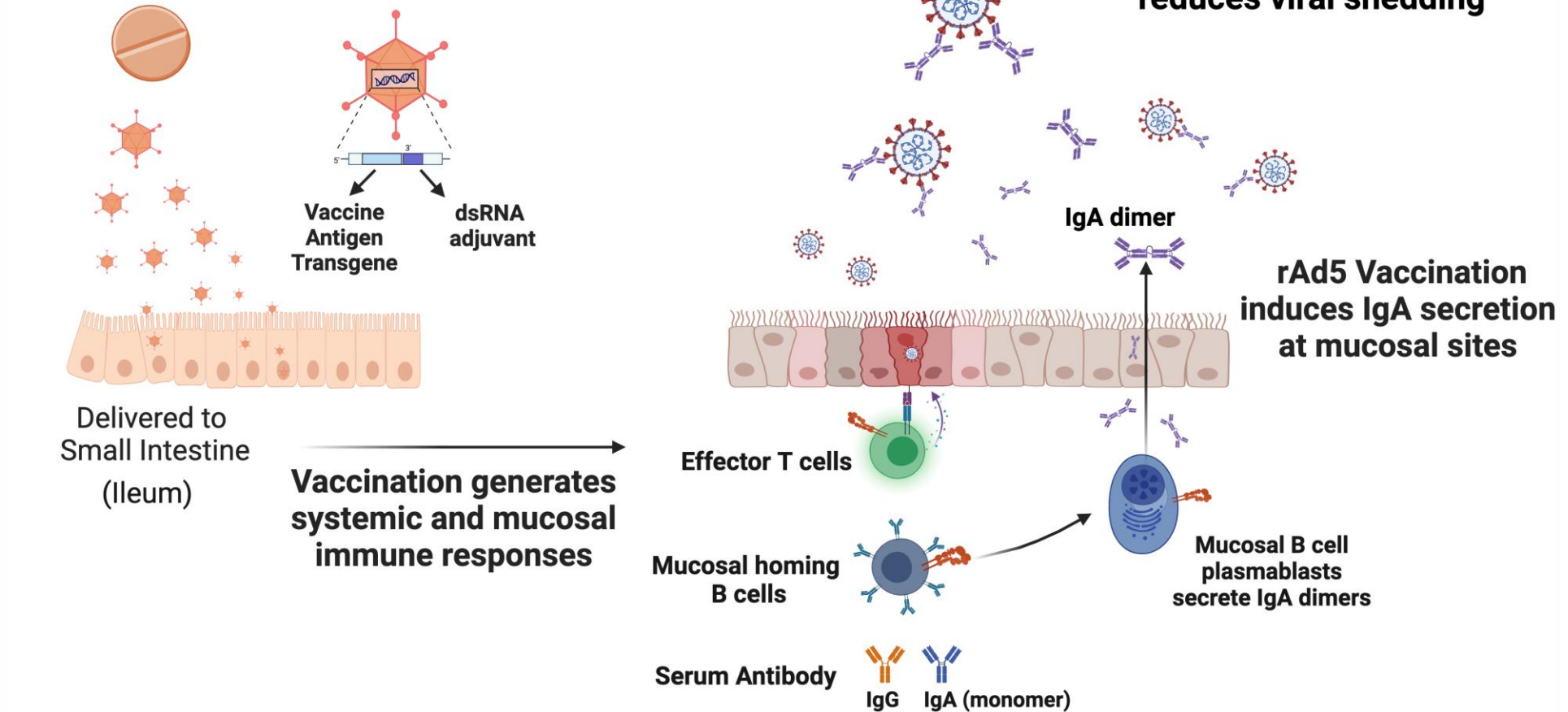
Room-temperature (25°C) stable enteric-coated tablets





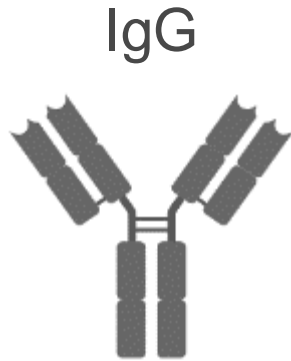
# VAAST Platform Utilizes Mucosal Immunity to Generate IgA in Addition to IgG to Potentially Block Infection and Transmission

## Oral rAd5 Vaccine Tablet



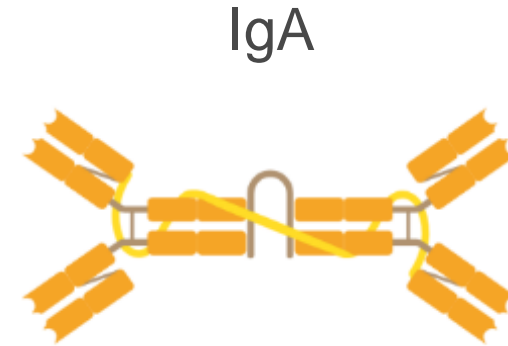
# Vaxart Has Shown IgA Mucosal Responses Have Greater Cross-Reactivity Compared to IgG Systemic Responses

## ANTIBODY CROSS-REACTIVITY: IgG VS. IgA



### Characteristics:

- Major antibody isotype induced systemically
- Major isotype produced by mRNA vaccines
- Binding affinity is significantly reduced when challenged with variants
- Has shown poor cross-reactivity with respect to known variants<sup>1,2</sup>



### Characteristics:

- Predominantly present in the mucosal tissues
- Efficiently produced through VAAST platform
- Minimal decrease in binding affinity when challenged with variants
- Shown to have greater cross-reactivity against both SARS-CoV-2<sup>1</sup> and Influenza<sup>2</sup> variants

**Cross-reactive nature of our platform - mucosal IgA responses may lead to high variant coverage**



# Norovirus Program Has Generated Compelling Data for a Multi-Billion Dollar Opportunity, No Vaccine Approved

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1

**Norovirus**

2

**Influenza**

3

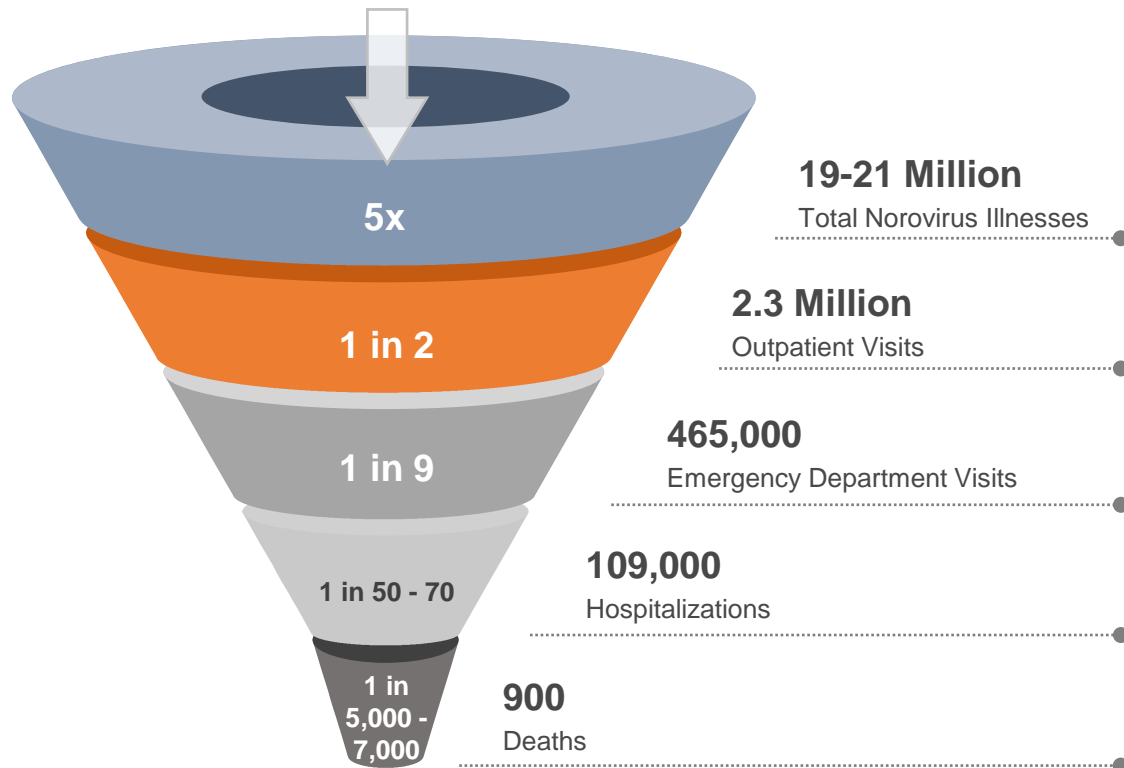
**COVID-19**

## Highlights:

- \$10bn+ annual U.S. economic burden
- Norovirus human phase 2 challenge study results indicate potential of our vaccine candidate to reduce rates of norovirus infection, illness, and shedding
- Phase 1 data
  - Durable immune responses to 200 days
  - Responses in elderly similar to younger adults
  - No interference observed for bivalent vaccine

# Norovirus has a \$10 Billion+ Annual Economic Burden in the U.S.

## Norovirus Annual Burden in the U.S.



### Economic Burden

**\$10.6 billion**

U.S. economic burden annually<sup>1</sup>

**\$60.3 billion**

Global economic burden annually<sup>2</sup>

### Risk Groups

#### Elderly

Adults  $\geq 65$  years old are at high-risk for severe symptoms and clinical outcomes including longer disease duration and death<sup>3</sup>

#### Children

Children  $< 5$  years old have the highest incidence of norovirus; significant economic burden attributed to parental lost productivity to care for sick children<sup>1,4</sup>

#### Common Outbreak Settings<sup>5</sup>

- Healthcare facilities including long-term care facilities and hospitals (most commonly reported setting in the U.S. and other industrialized countries)
- Schools and childcare centers
- Restaurants and catered events (leading cause of outbreaks from contaminated food)
- Cruise ships

Source: CDC website (<https://www.cdc.gov/norovirus/data-research/>)

<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8171800/>

<sup>4</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6814392/>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4846012/>

<sup>5</sup> <https://www.cdc.gov/norovirus/outbreak-basics/index.html>

<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6546097/>

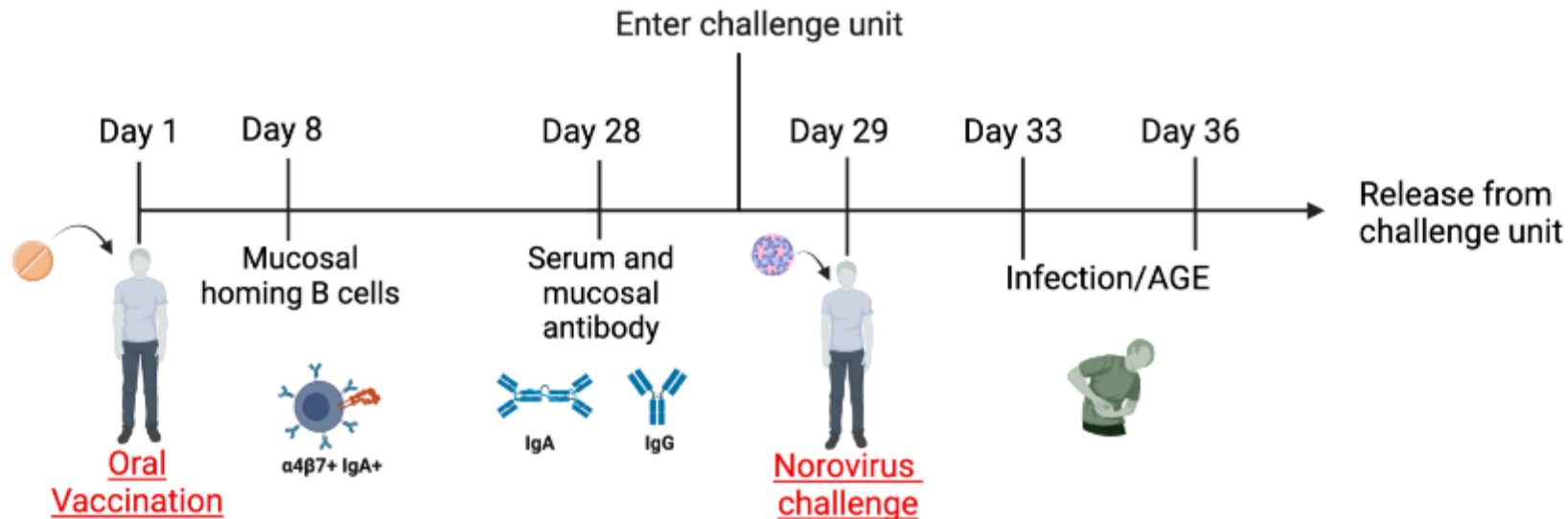
# Norovirus Clinical Program Has Demonstrated Robust Immunogenicity, Promising Efficacy, and Benign Safety/Tolerability Profile

Trial ID	Phase	N	Vaccine	Top line data	Completed
NVV-101	Phase 1 double blinded	60	Placebo GI.1	<ul style="list-style-type: none"> <li>Safety/dose escalation (GI.1)</li> </ul>	✓
NVV-102	Phase 1 open label	60	GI.1	<ul style="list-style-type: none"> <li>Safety/dose ranging and effective interval for boosting immunogenicity (GI.1)</li> </ul>	✓
NVV-103	Phase 1 double blinded	80 23* 12**	Placebo GI.1 monovalent GII.4 monovalent GI.1/GII.4 bivalent	<ul style="list-style-type: none"> <li>Safety/immunogenicity monovalent and bivalent formulations</li> <li>Duration of protection*</li> <li>boost response**</li> </ul>	✓
NVV-104	Phase 1b double blinded	66	Placebo GI.1	<ul style="list-style-type: none"> <li>Safety/dose in elderly adults (GI.1)</li> </ul>	✓
NVV-105	Phase 1 open label	30	GI.1	<ul style="list-style-type: none"> <li>Boost interval (GI.1)</li> </ul>	✓
NVV-201	Phase 2 double blinded	141	Placebo GI.1 Infectious virus (GI.1)	<ul style="list-style-type: none"> <li>Vaccine efficacy against GI.1 challenge (GI.1)</li> </ul>	✓
NVV-202	Phase 2 double blinded	135	Placebo GI.1/GII.4 bivalent	<ul style="list-style-type: none"> <li>Dose ranging study. Safety/immunogenicity of the bivalent formulation</li> </ul>	✓
NVV-108	Phase 1 double blinded	76	Placebo GI.1/GII.4 bivalent	<ul style="list-style-type: none"> <li>Safety/immunogenicity of the bivalent formulation in healthy lactating mothers</li> </ul>	Topline Announced

# NVV-201 Study: Norovirus Challenge Study

- **Phase 2 double-blinded placebo controlled study**

- GI.1 vaccine candidate or placebo, given to healthy participants
- Given norovirus infection 29+ days after vaccination
- Determine infection and rate of acute gastroenteritis (AGE) in placebo and vaccinated participants
- Measure immune parameters; determine which ones are important at predicting protection



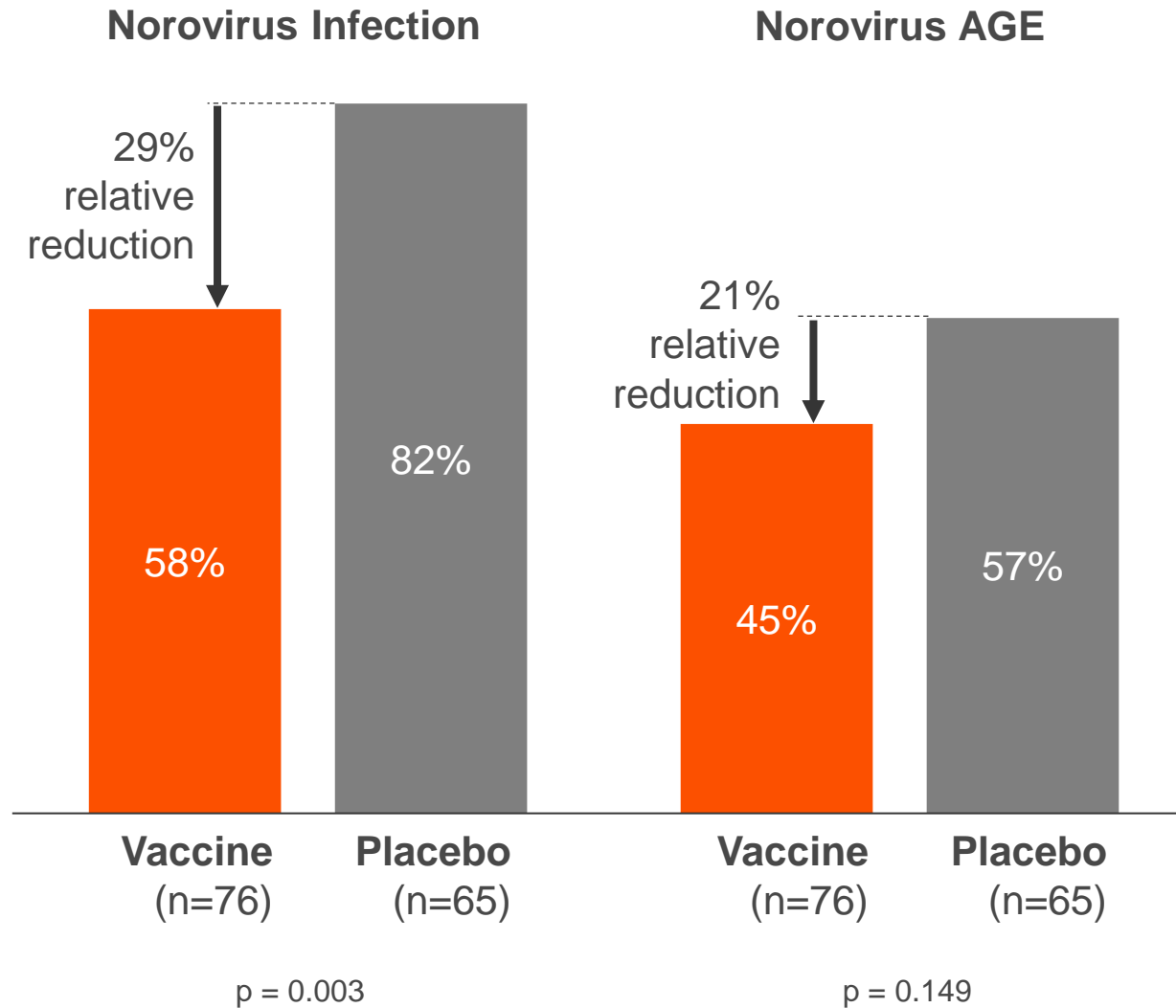
# Norovirus Challenge Study: Topline Safety

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- No vaccine-related Serious Adverse Events (SAEs)
- No vaccine-related solicited Grade-3 Adverse Events (AEs)
- Benign safety and tolerability data profile consistent with safety of the platform in previous studies

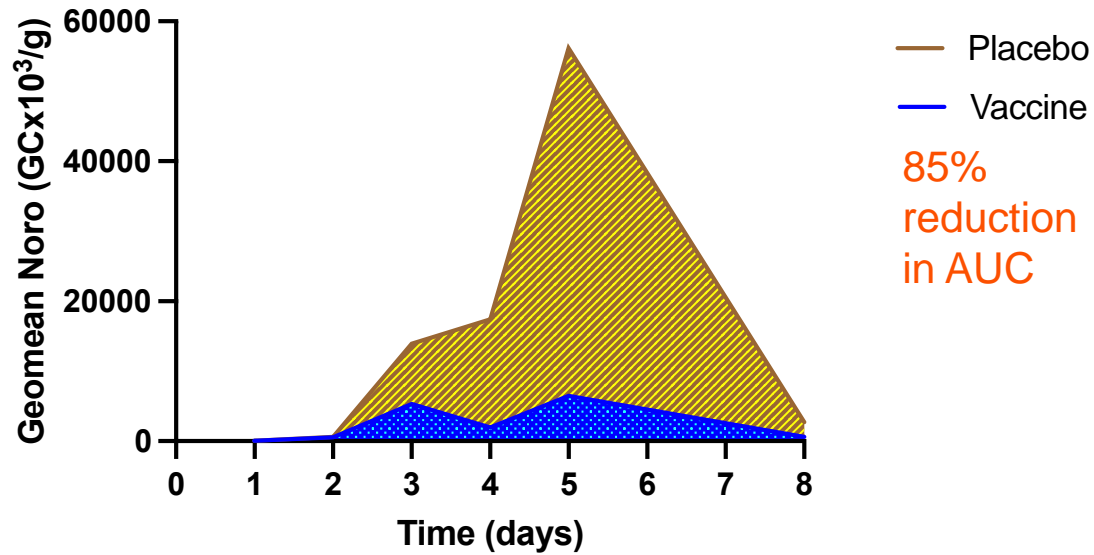
# Norovirus Challenge Study: Protection Against Infection and Illness

Full analysis (N=141)

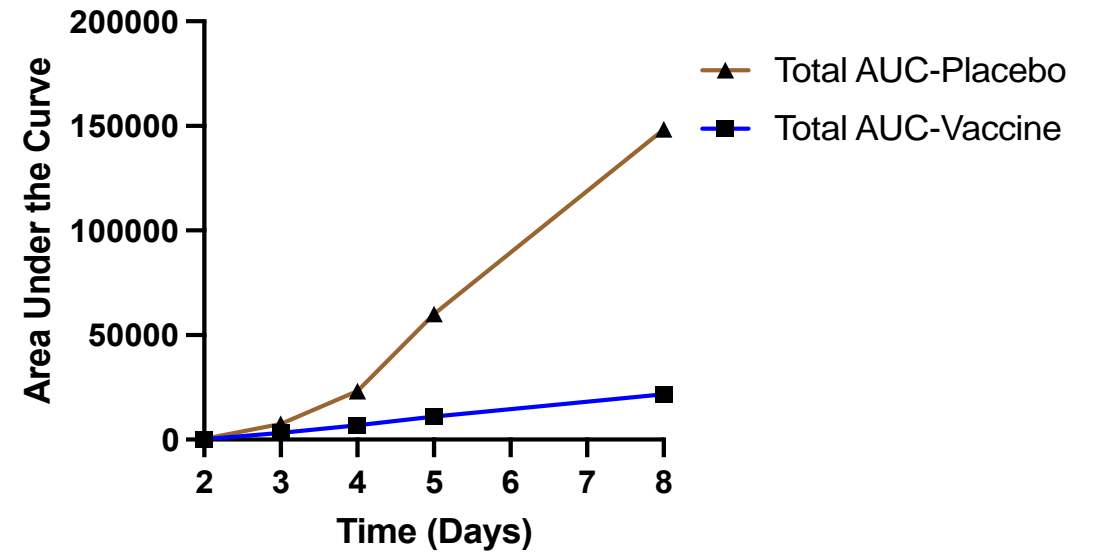


# Norovirus Challenge Study: 85% Reduction in Viral Shedding

### Viral Shedding Full Analysis Set - Stool Samples



### Running AUC Full Analysis Set - Stool Samples



LOD is 256 copies per reaction or 1.52x10<sup>5</sup> copies per mL



# Vaxart's Norovirus Data Appears Favorable Despite More Aggressive Challenge

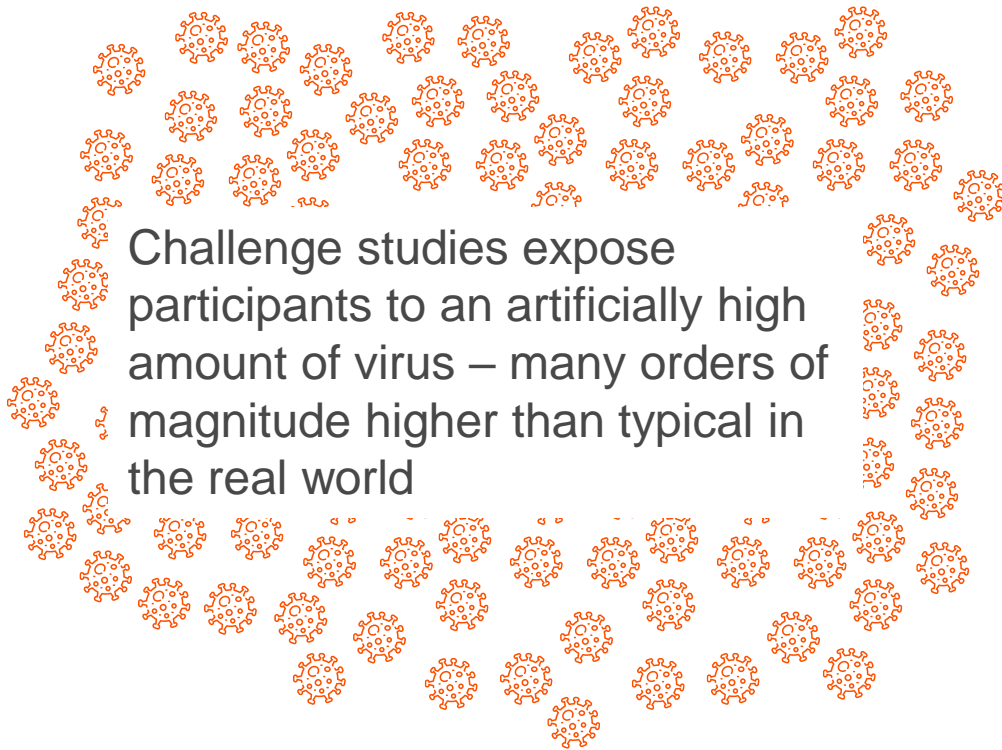
	Vaxart Oral Tablet GI.1 Challenge	Injectable Vaccine <sup>1</sup> GI.4 Challenge
<b>Application</b>	Oral tablet	Intramuscular injection
<b>Doses</b>	1	2
<b>Placebo Attack Rates</b>		
• Norovirus infection	82%	63%
• Noro-AGE	57%	33%
<b>Vaccine Protection</b>		
• Reduction in infection	29%	14%
• Reduction in Noro-AGE	21%	22%
• Reduction in shedding	85%	~30% <sup>2</sup>

*Cross-study comparison. Vaccines not studied head-to-head directly*

<sup>1</sup> Bernstein et. al, JID, 2015

<sup>2</sup> Exact number was not disclosed. ~30% is an estimate based on the graphic in the publication.

# Reasons to Expect More Significant Real-World Protection From Our Norovirus Bivalent Vaccine Candidate

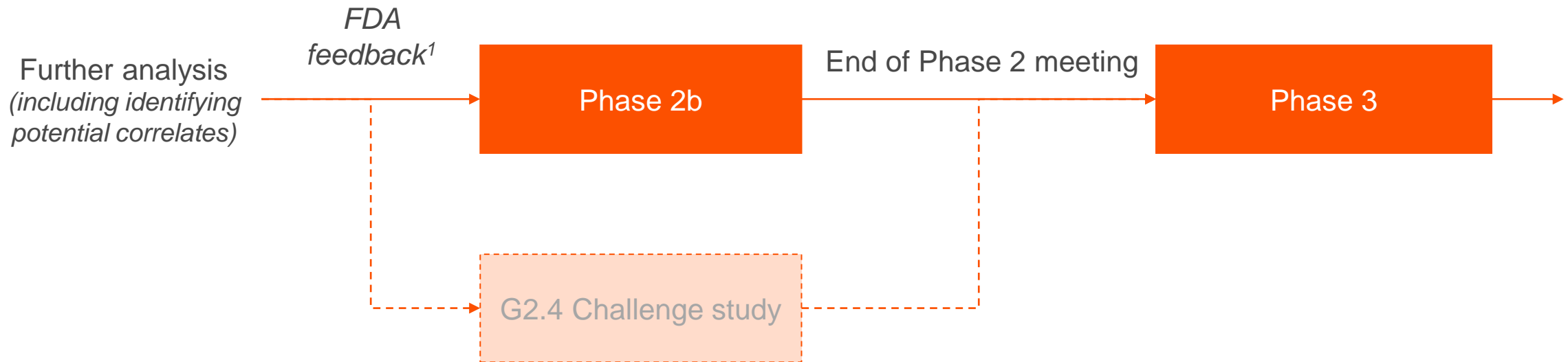


Real-world efficacy is 50-100% more than that seen in several challenge studies

Virus	Vaccine	Challenge study	Field study
Flu	Fluzone	27%	49-66%
Norovirus	HIL-214	22%	34%
Typhoid	Vi-TT; Typbar-TCV	55%	82%
RSV	Multiple	10-60%	43-60%

# Additional FDA Feedback Will Clarify Next Steps For the Norovirus Program

## Adults and Elderly



## Infants and Mothers



October 2024

<sup>1</sup> Determine next steps based on regulatory feedback from the FDA, clinical data on current constructs, and preclinical data generated on new constructs (more potent than current constructs).

# Vaxart's Influenza Program Has Shown Promising Phase 2 Data Compared to an Approved Injectable Vaccine

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1

**Norovirus**

2

**Influenza**

3

**COVID-19**

## Highlights:

- Demonstrated to be at least as protective as an approved injectable vaccine in a phase 2 challenge trial
- Very different mechanism of action: mucosal rather than serum antibodies
- Reduces shedding
- Favorable safety data

# Human Influenza Challenge Design

- A single dose administration of one of the following:
  - Arm 1: VXA-A1.1 oral vaccine + placebo IM injection (n=60+extra)
  - Arm 2: QIV (Fluzone) injection + oral placebo tablet (n=60+extra)
  - Arm 3: Placebo IM injection + oral placebo tablet (n=30+extra)
- Participants with baseline HAI titers <10
- Challenge after day 90 (up to 120 days)
  - A wild-type influenza A/Ca/2009/pH1N1 strain was administered to participants in all treatment groups
- Primary endpoint
  - Number and % of participants protected against infection and illness following influenza (A/CA/2009/pH1N1) challenge. VXA-A1.1 compared to placebo and QIV (Fluzone).

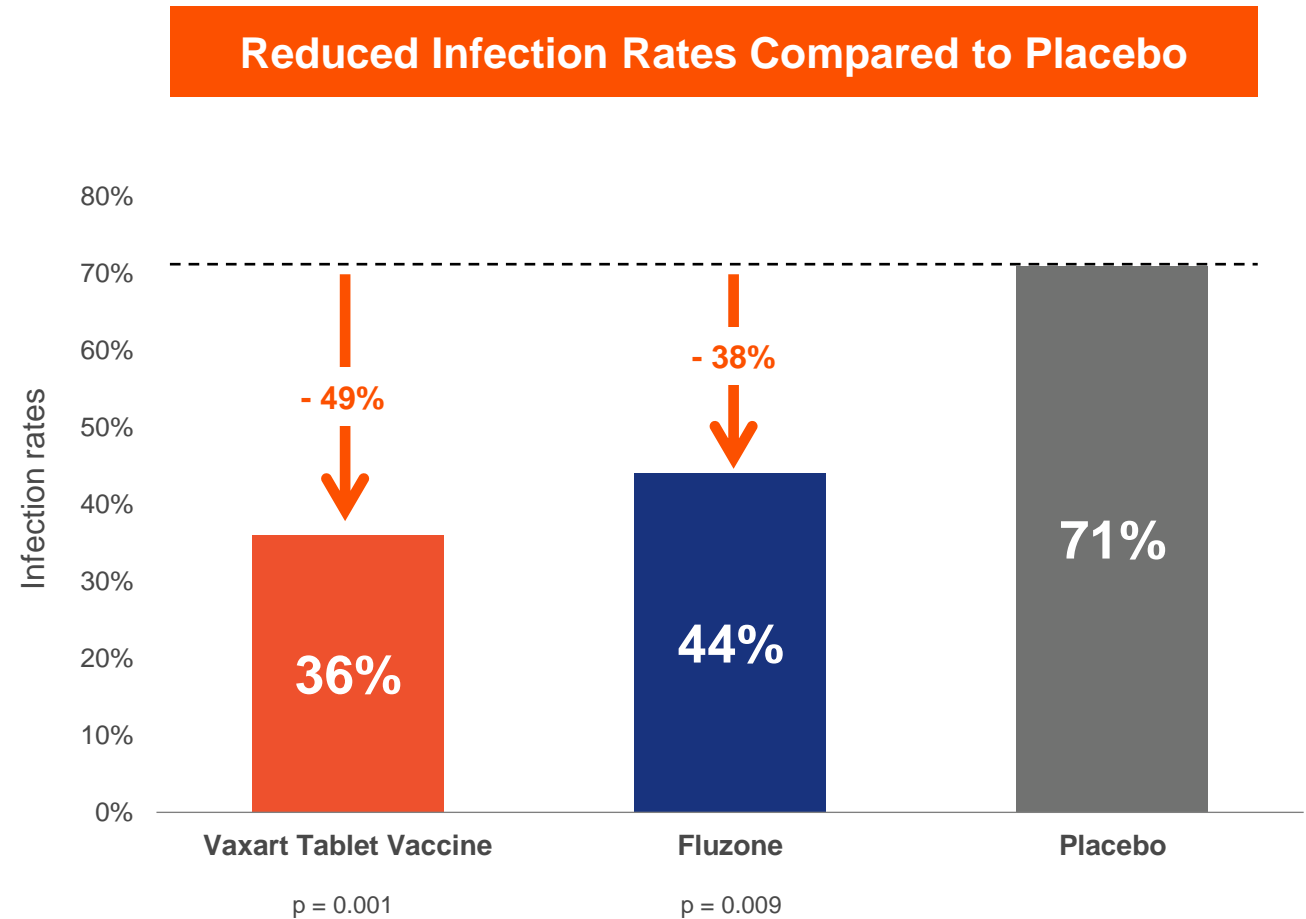


# Vaxart's Oral Influenza Vaccine Candidate Reduced Shedding (Infection Rate)

## VAXART ORAL TABLET vs. FLUZONE

Oral vaccine candidate protected against influenza infection as well as market leading injected vaccine after influenza challenge. 80% chance of improved protection.

- Infection was measured by influenza virus shedding in participants
- Shedding reductions are believed to typically translate to lower transmission



Note: Infection defined as detectable viral shedding on any day after the first 36 hours from challenge.

# Vaxart Has Initiated the Sentinel Cohort for the Phase 2b Trial Evaluating its COVID-19 Vaccine Candidate H2H Against an Approved mRNA Comparator

1

**Norovirus**

2

**Influenza**

3

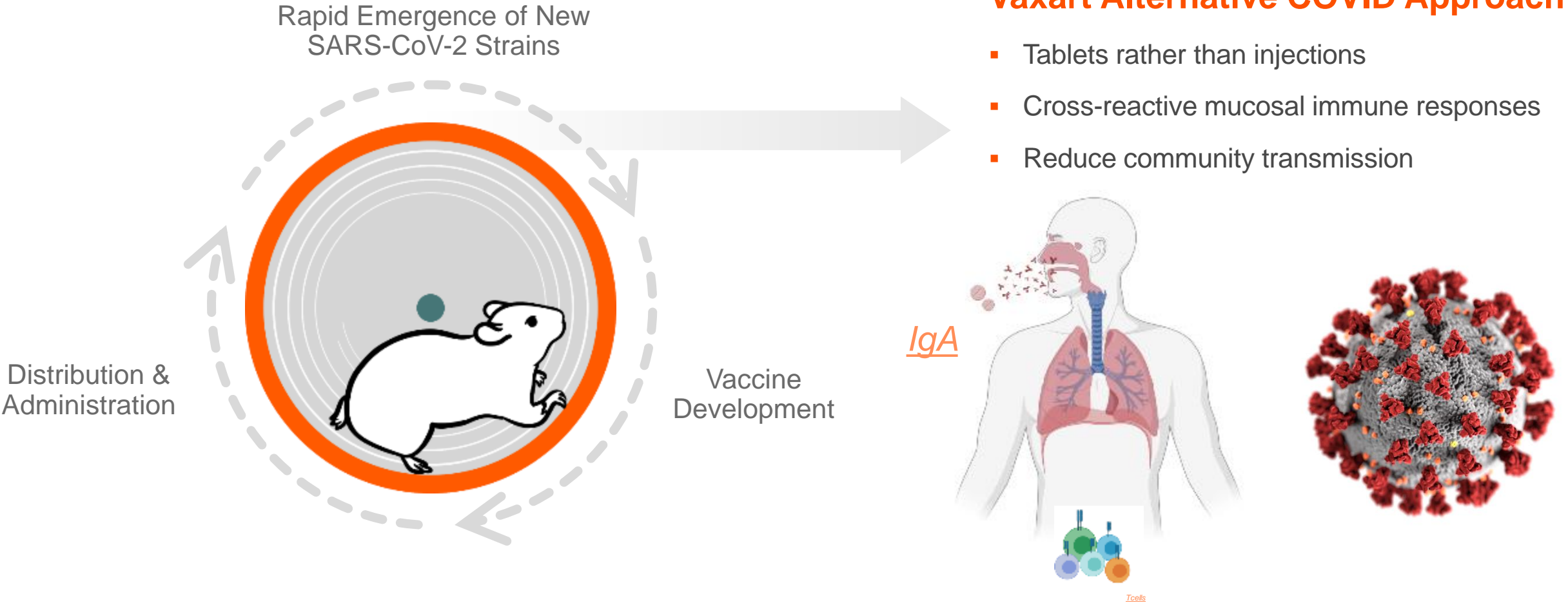
**COVID-19**

## Highlights:

- BARDA funding to prepare and conduct a Phase 2b clinical trial (first part is a sentinel cohort of 400 participants, second part is approximately 10,000 participants)
- Vaccine constructs tested to date trigger robust mucosal responses
  - Cross-reactive
  - Durable responses – to 360 days
  - Reduces transmission
- Potential serum boosting of mRNA vaccines (S construct)
- Benign tolerability data



# Vaxart's Approach to COVID Vaccines Could Provide Multi-strain Coverage in a Rapidly-distributed Tablet



# BARDA<sup>1</sup> is Supporting the Development of Next Generation COVID-19 Vaccines with Project NextGen, a \$5B Initiative

- Project NextGen is focused on developing innovative vaccines and therapeutics providing broader and more durable protection for COVID-19
- Vaxart's COVID-19 vaccine can potentially address most of Project NextGen's desired attributes

## Project NextGen Areas of Focus



### Vaccines that are Easier to Administer and Reduce Spread of the Virus

Mucosal vaccines such as those delivered intranasally, which could have the potential to dramatically reduce infection and transmission, in addition to preventing serious illness and death.



### Better Protection. Longer Lasting Vaccines.

Vaccines that provide broader protection against variants of concern and a longer duration of protection.



### Innovative Solutions for Faster, Cheaper, Rapidly Deployable Technologies

Advancing new technologies that will improve access and enable faster, lower cost, rapid, and flexible production of vaccines and therapeutics.



### Pan-Corona Virus Protection

Pan-Corona virus vaccines which protects against several different coronaviruses.



### Modernized, More Resilient Treatments

New and more durable monoclonal antibodies that are resilient against new variants as they arise.

# Vaxart's BARDA Project NextGen Awards Covers the Preparation and Execution of the P2b Study

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- In Jan 2024, Vaxart received a BARDA Project NextGen award of \$9.27M to prepare for a ~10,000 participant Phase 2b clinical trial evaluating our XBB COVID-19 vaccine candidate
- In Jun 2024, Vaxart received a BARDA Project NextGen award of up to \$452.9M to prepare and execute on the ~10,000 participant Phase 2b trial
- In Sep 2024, Vaxart and BARDA modified the award to increase the funding up to \$456.1M
  - Approximately \$96.5M is currently available which funds
    - Preparing for and conducting the sentinel portion (400 participants) of the Phase 2b trial
    - Manufacturing a vaccine candidate targeting the KP.2 strain
  - Remaining ~\$359.6M will be available when BARDA and Vaxart have mutually determined the trial should proceed to enroll the ~10,000 participants
  - Portion of the award includes overhead coverage and fee

# Initiated the Sentinel Cohort of the COVID-19 P2b Trial in September 2024

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- Double-blind, multi-center, randomized, comparator-controlled study Phase 2b trial comparing our oral tablet COVID-19 vaccine candidate (S protein expressing) to an FDA approved mRNA vaccine head-to-head
- Enroll approximately 10,000 healthy adults 18 years or older
  - Sentinel cohort (initiated in Sept 2024): 400 participants (200 Vaxart XBB vaccine, 200 XBB mRNA)
  - After the Data Safety Monitoring Board (DSMB) and FDA reviews the 30-day safety data on the first 400 participants, proceed to enroll remaining participants
  - Strive to enroll participants in line with U.S. demographics, as well as including at least 25% over the age of 65
- Primary endpoint is relative efficacy of Vaxart's COVID-19 vaccine candidate compared to an FDA approved mRNA comparator for the prevention of symptomatic disease (12 months post vaccination)
- Trial will measure efficacy for symptomatic and asymptomatic disease, systemic and mucosal immune induction, and the incidence of adverse events

# Vaxart Has Generated Promising COVID-19 Clinical Data

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## Trial Data Observed to Date:

### **VXA-CoV2-1 (Expresses S + N): Completed Phase 1**

- Highly immunogenic on eliciting T cells, to both S and N
- T-cell responses to the S appear much higher than those of injectable mRNA vaccines in Phase 1 study<sup>1</sup>
- **Cross-reactive mucosal IgA**
- Durable responses to 360 days
- Benign tolerability

### **VXA-CoV2-1.1-S (Expresses only S): Completed Phase 2a**

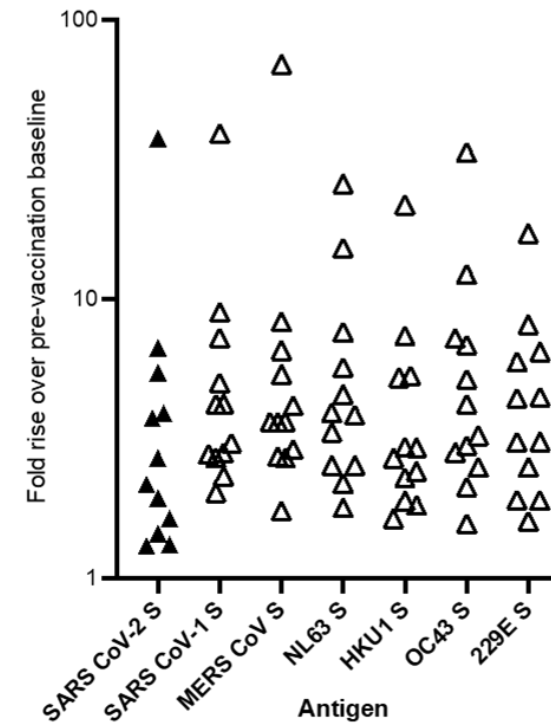
- 72% had an immune response post vaccination
- Better serum responses than S+N
- Ability to boost mRNA vaccines
- **Cross-reactive mucosal IgA**
- Benign tolerability

# In a Phase 1 Trial, Vaxart's COVID-19 Vaccine Candidate VXA-CoV2-1 Has Shown Cross-reactive Nasal IgA Response to all Coronaviruses Tested

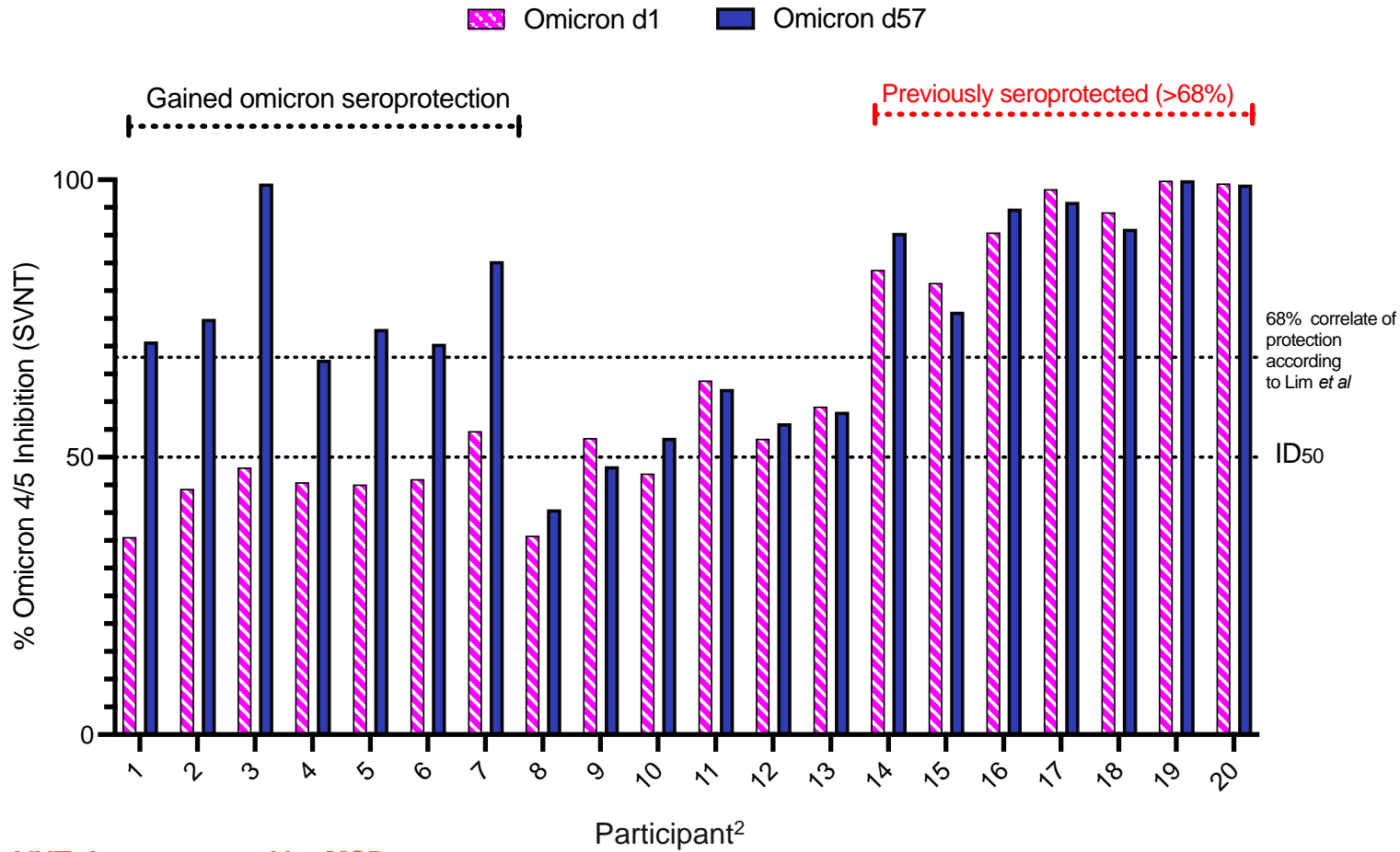
- 46% of participants that had increased IgA antibodies to SARS-CoV-2 S also had increased antibody responses to the S protein of other coronaviruses, including SARS-CoV-1, MERS, and endemic common cold viruses
- Beneficial for maintaining immunization protection against current and future COVID-19 variants (Delta, Omicron, etc.)

## VXA-CoV2-1 (Expresses S + N)

### IgA Cross-Reactivity to Other Coronaviruses



# Vaxart's COVID-19 Oral Vaccine Candidate VXA-CoV2-1.1-S Increased Seroprotection<sup>1</sup> Against Omicron 4/5



SVNT data measured by MSD assay

**Seroprotection improved post oral vaccine**  
**35% pre-vaccination**  
**70% post-vaccination**

<sup>1</sup> Seroprotection as defined in the paper Lim et al. Serum Antibody Response Comparison and Adverse Reaction Analysis in Healthcare Workers Vaccinated with the BNT162b2 or ChAdOx1 COVID-19 Vaccine

<sup>2</sup> Participants given an mRNA priming vaccine before oral immunization





## Corporate Update

# Estimate Current Cash Runway Into 2026, Funding Through Multiple Key Clinical and Regulatory Milestones

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## Norovirus Vaccine

- Additional FDA feedback regarding correlates of protection
- New constructs (if pursuing)<sup>1</sup>: Potential Phase 1 study

## COVID-19 Vaccine

- Enroll sentinel cohort of the COVID-19 P2b trial (400 participants)
- Proceed to initiate the second part of the COVID-19 P2b trial after DSMB and FDA reviews the 30-day safety data on the sentinel cohort
- Primary endpoint is relative efficacy of Vaxart's COVID-19 vaccine candidate compared to an FDA approved mRNA comparator for the prevention of symptomatic disease (12 months post vaccination)

**Influenza Vaccine:** Continuing development of our seasonal influenza vaccine candidate

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[vaxart.com](http://vaxart.com)