

# developing the Pill that Moves the Needle

**Investor Presentation** 

October 2021



### Forward-Looking Statements

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 subjects 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.



# Many Milestones to Drive Near-Term Value





### Transformative, clinically validated, oral vaccine platform

- Potential to transform the vaccine ecosystem
- Completed 15 clinical trials against 7 different viruses, vaccinating 500+ subjects

### **Oral COVID-19 program addresses key logistical and** adoption challenges

- May offer a practical, scalable global response to the pandemic
- Oral convenience, potential superior efficacy due to mucosal immunity, ease of distribution – room temperature. stable
- Potential to mitigate vaccine hesitancy
- First subject in Phase II trial

### Additional large pipeline opportunities

Norovirus, HPV, influenza & RSV

### **Resources to aggressively continue clinical advancement and** commercialization



— Cash: \$199MM (as of June 30, 2021)



# VAAST<sup>TM</sup> Platform Is a Powerful Product Development Engine

### **Completed 15 clinical trials against 7 different viruses, vaccinating 500+ subjects**

		Trials Conducted to Date or in Progress		
		Preclinical	Phase 1	Phase 2
PROPHYLACTIC VAC	CCINES			
COVID-19 (S Protein)				
COVID-19 (S + N Proteins)				
Norovirus <sup>1</sup>	Bivalent			
Seasonal Influenza <sup>2</sup>	Monovalent			
	Quadrivalent			
Influenza	Universal <sup>3</sup>		Janssen Johnson-Johnson	
RSV <sup>4</sup>				
THERAPEUTIC VACO	CINES			
HPV <sup>5</sup>	HPV, cervical dysplasia and/or cancer			

- 1. Bivalent Phase 1 demonstrated IgA ASC response rates of 90 93% for GII.4 and 78 86% for GI.1
- 2. Monovalent H1 flu vaccine completed phase 2 Proof of Concept efficacy study.
- 3. Janssen collaboration with an option to negotiate an exclusive license.

VAXART

4. RSV program to be partnered with new antigen partner. 5. HPV therapeutic pre-IND feedback received.



# A Room Temperature Stable Oral Vaccine Would Have Significant Advantages in Mass COVID-19 Vaccination Campaigns



VS.



VAXART



Would be likely to get the vaccine if offered in pill form

23% of Americans don't plan to get COVID

vaccine

### A pill option could mean as many as 19 million more Americans vaccinated



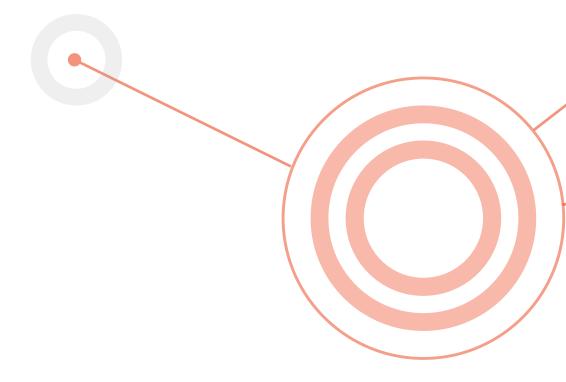




## Tablet Formulation Offers Multiple Advantages vs. Injected Vaccines

### **For Society**

- Can mitigate vaccine hesitance
- Can mass vaccinate in days, not months
- Virtually no environmental footprint: no needles, no syringes, no bandages
- Facilitates social distancing during a pandemic

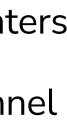


### For Individuals

- No needles, no pain
- No need to set up appointment, drive to/from vaccination site, wait
- Potentially better tolerated

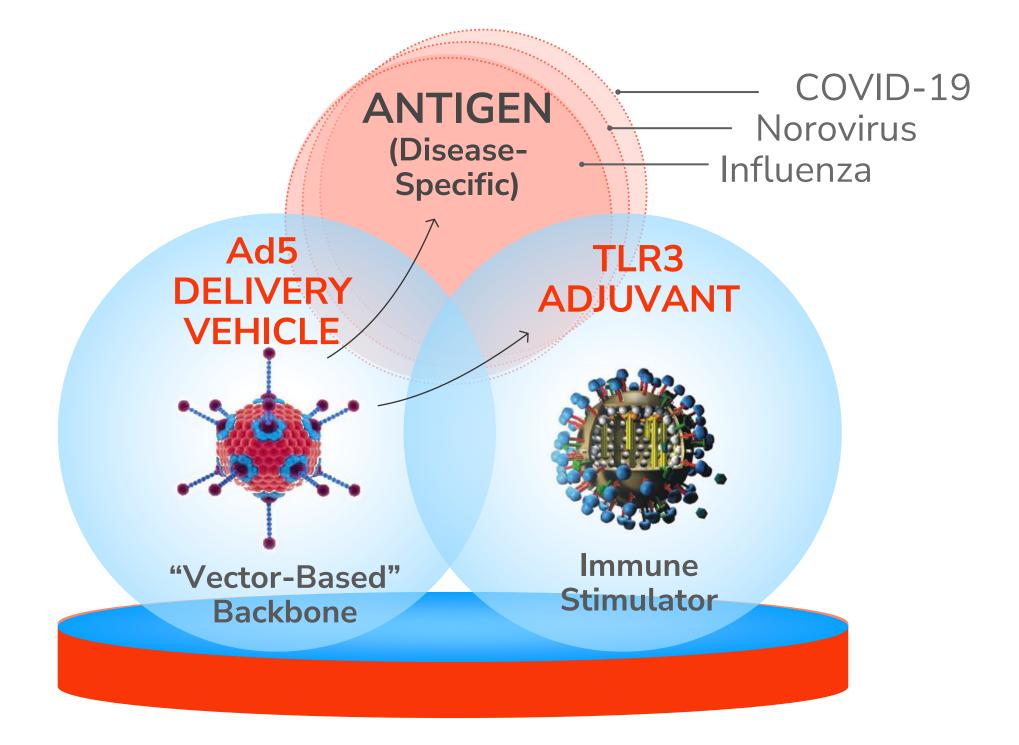
### For Governments

- No need for cold chain
- No need for vaccination centers
- No need for medical personnel to administer



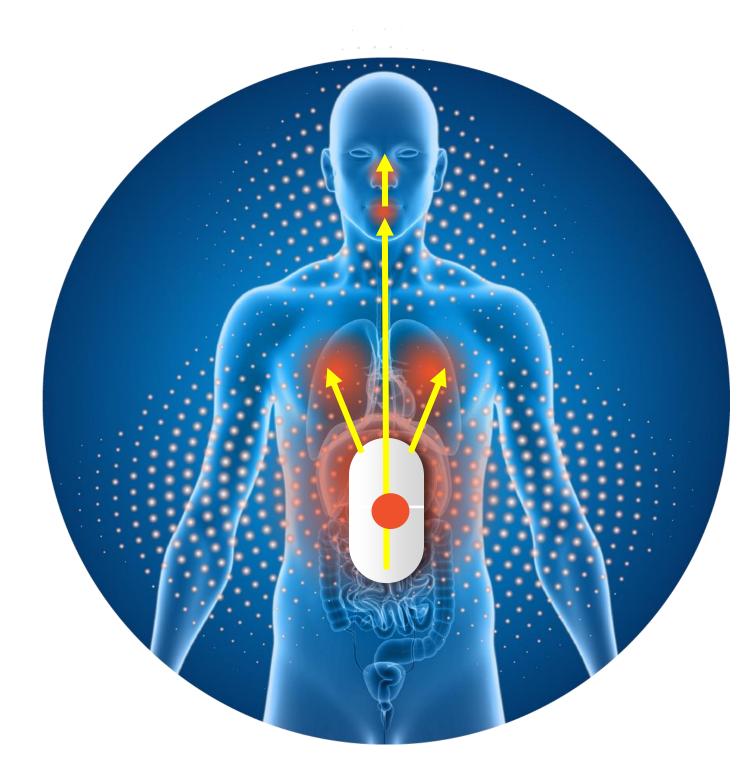


# Vaxart's Proprietary Oral Vaccine Platform Harnesses the Power of Mucosal Immunity and Provides Protection Against a Variety of Viruses



VAAST<sup>™</sup>: <u>Vector-Adjuvant-Antigen</u> <u>Standardized</u> <u>Technology</u>





**Oral vaccine activates** immunity in the right places

### Systemic and mucosal immunity:

- Nose
- Lungs
- ✤ Intestine
- ✤ Mouth

Injectable vaccines only activate systemic immunity





# Demonstrated Clinical Efficacy Against Airborne Viruses

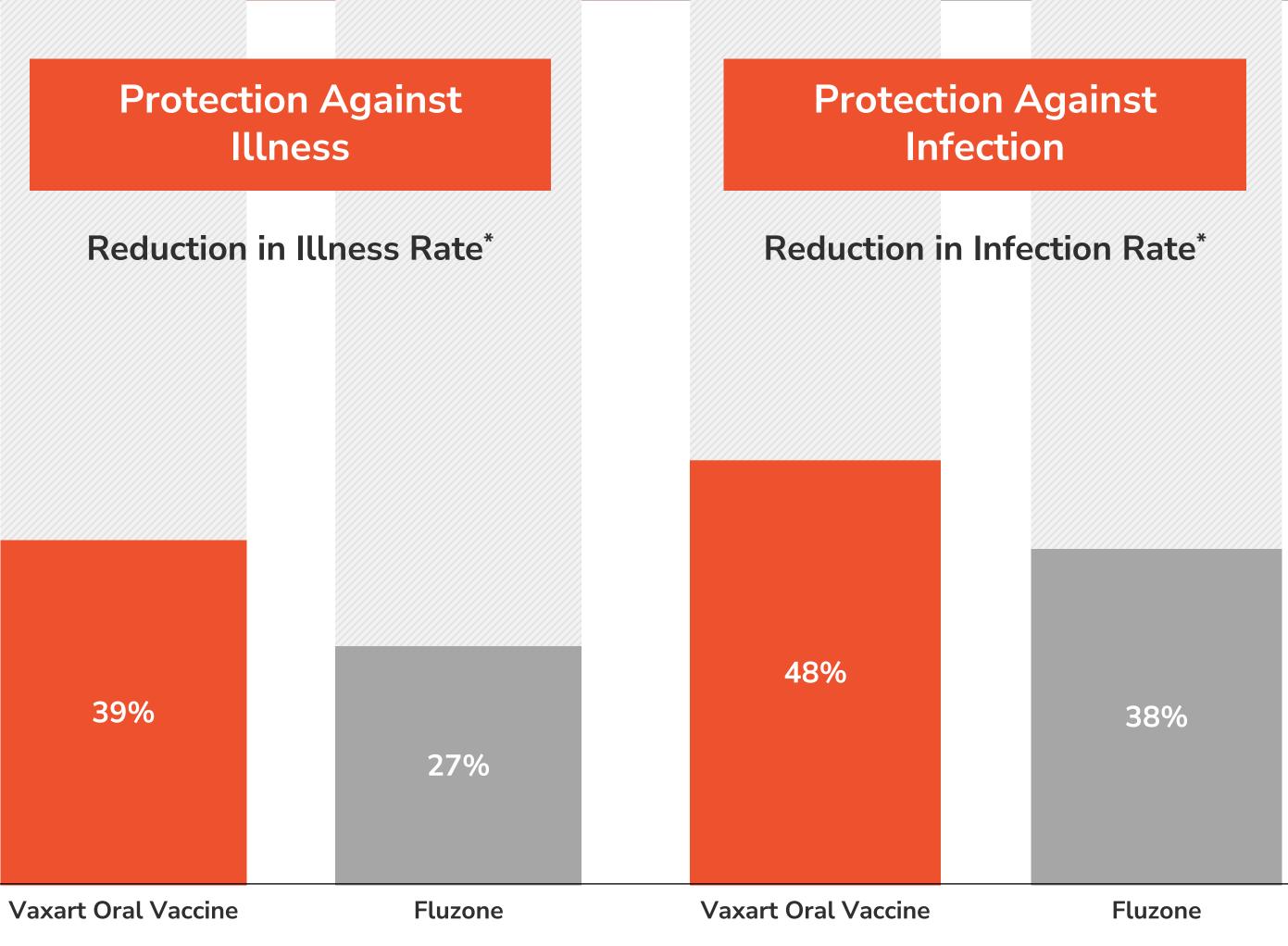
Phase II flu challenge study comparing Vaxart's oral tablet flu vaccine and Sanofi's Fluzone injectable flu vaccine

- Compared to those unvaccinated, illness rates were 39% lower in those taking Vaxart's oral vaccine, and 27% lower in those vaccinated with Fluzone
- **BARDA-funded Phase II** clinical trial



Results published in January 2020

THE LANCET Infectious Diseases



Liebowitz, et al, Lancet ID, 2020

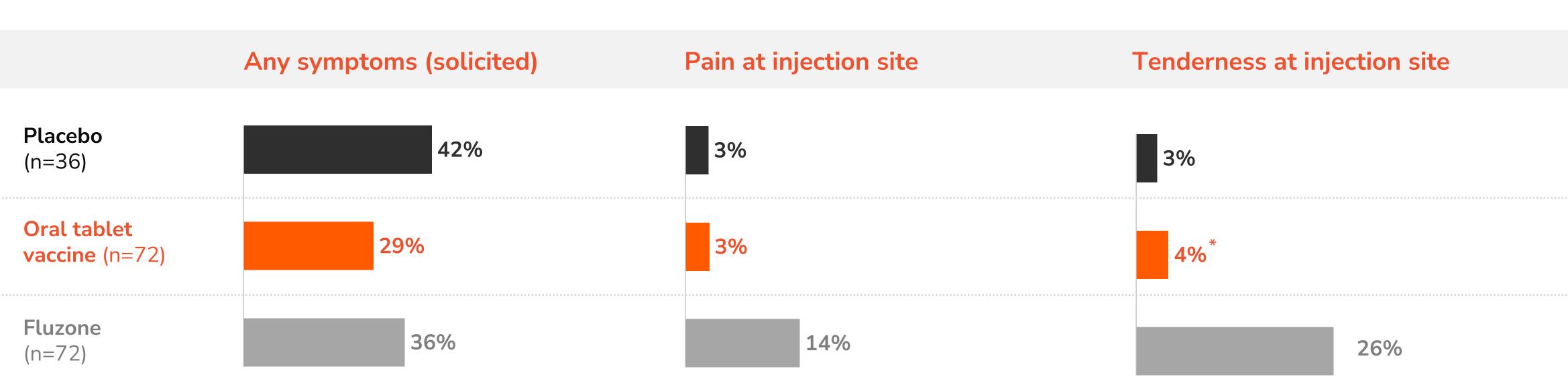


\* Versus placebo



### Favorable Safety and Tolerability Profile, Comparable to Placebo

### Flu challenge study Solicited symptoms after vaccination

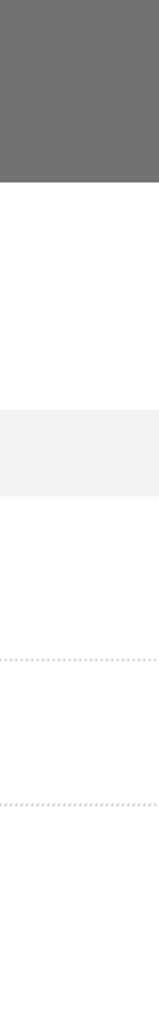


\* Placebo injection given to those receiving the oral vaccine

Source: Liebowitz et al., Lancet Infectious Diseases, Jan 2020

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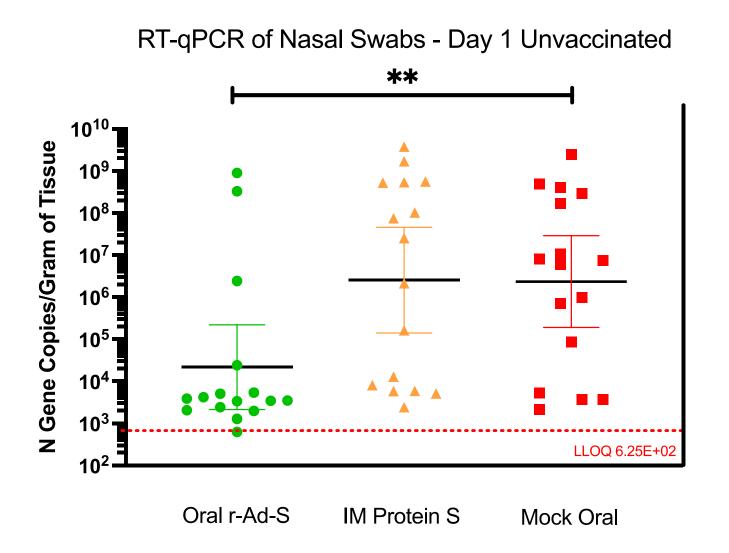
Pain: a key reason why people don't like needles



### Hamster Transmission Study: Oral Vaccination Inhibits Transmission

- •
- transmission to unvaccinated animals from vaccine breakthrough

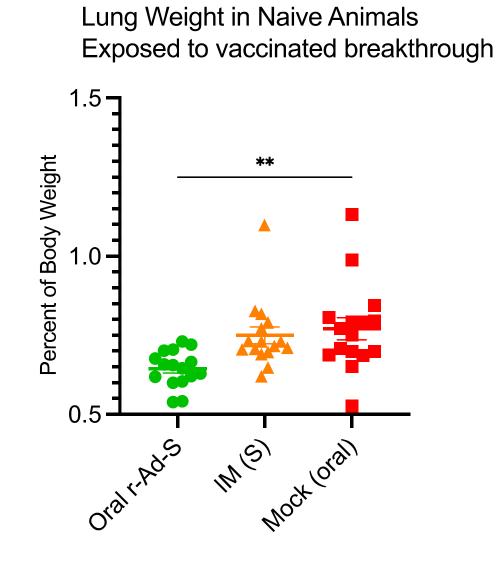
### **Protection Against Infection**





# Mucosal Vaccines can inhibit transmission via IgA in the mucosa (nose, mouth, intestine) In a Duke University-led study, Vaxart oral vaccine demonstrated inhibition of aerosol

### **Protection Against Illness**



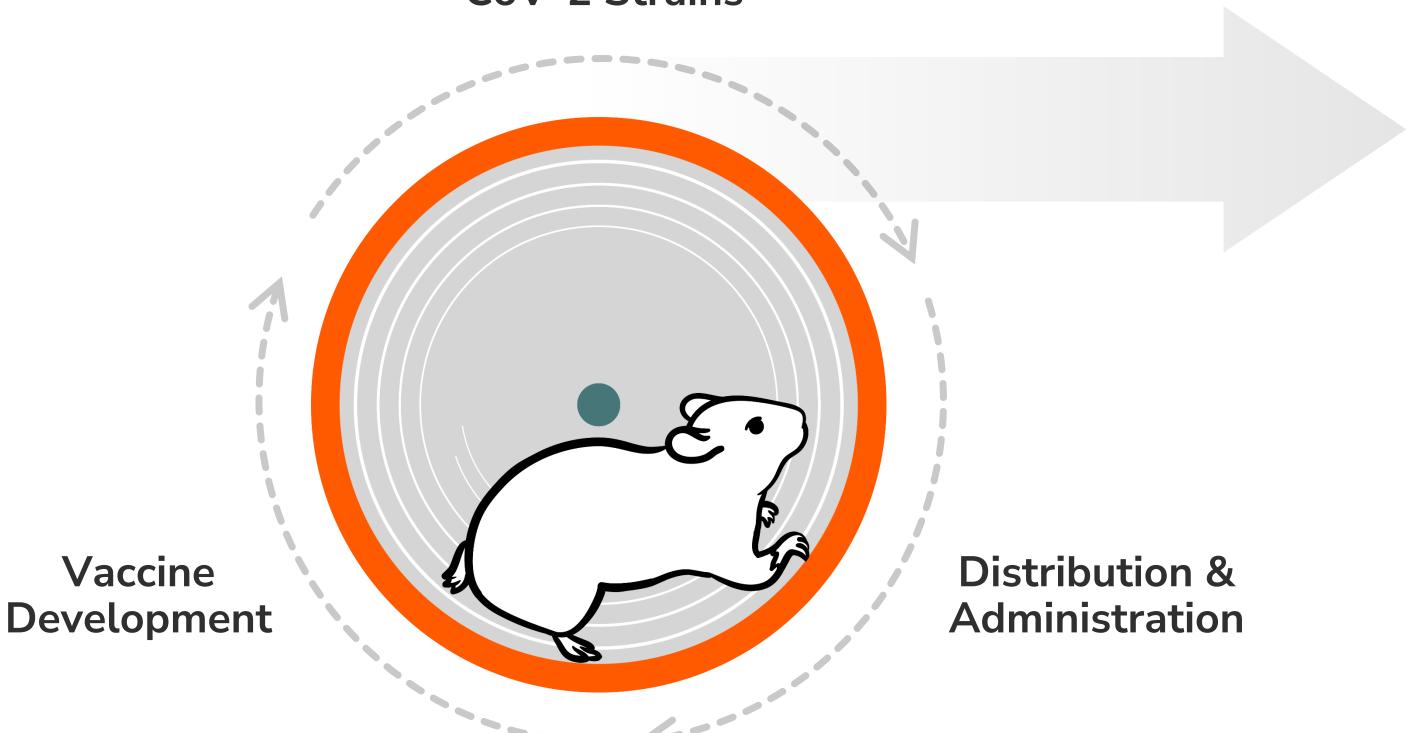
Langel, et al, Biorxiv 2021





# COVID-19 Injectable Vaccine Development and Distribution Efforts are Being Challenged by Rapidly Emerging Strains

### **Emergence of New SARS-CoV-2 Strains**



### We are currently chasing the virus with vaccines like a hamster on a wheel

VAXART

### The Variant Challenge:

- Short time to deploy new vaccines with each variant
- Radically shortening time needed for mass vaccine campaigns is essential to ending the hamster wheel paradigm







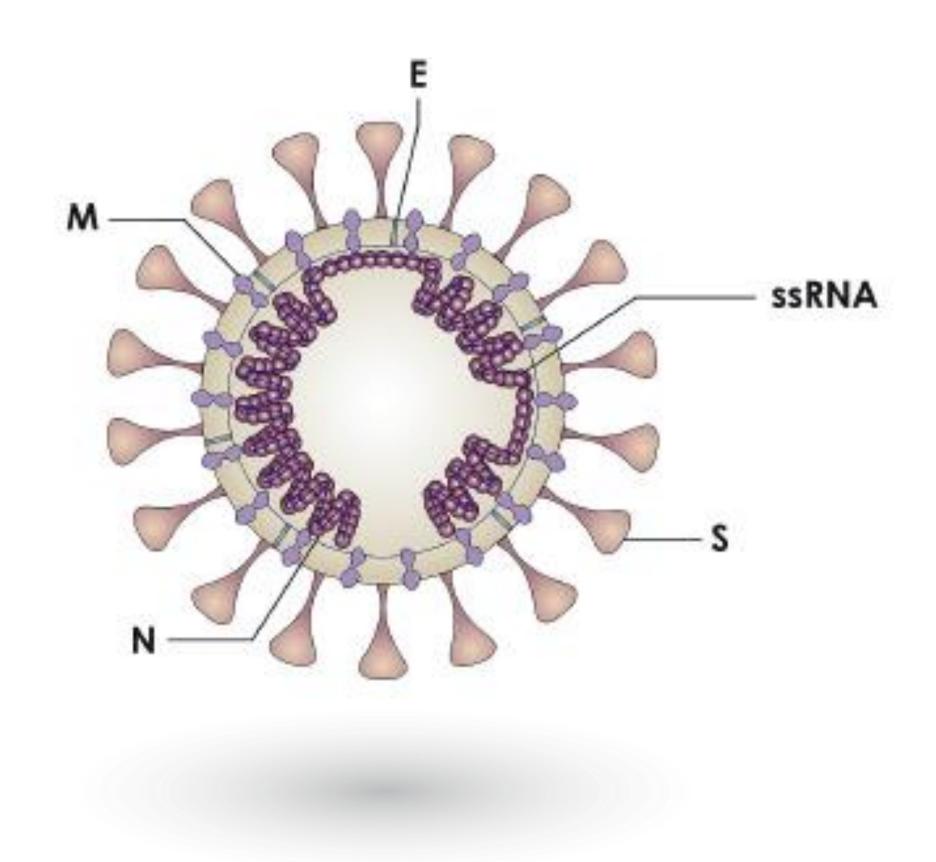
### Vaxart Has Two COVID-19 Vaccine Candidate Constructs

# VXA-CoV2-1.1-S (Expresses only S): phase II study ongoing

 Much higher serum antibody responses than the S&N in NHP study

### VXA-CoV2-1 (Expresses S+ N): completed phase I

- Highly immunogenic on eliciting T cells and mucosal IgA
  - T-cell responses to the S appear much higher than those of injectable mRNA vaccines



# Phase I COVID Study Results Support Potential of Single-dose Oral Tablet Vaccination: Trial Design and Safety Profile

	Vaccine	Dose	# of Doses	# of Sub
Cohort 1 (Sentinels)	VXA-CoV2-1	1x10 <sup>10</sup> I.U.	2	5
Cohort 2	VXA-CoV2-1	1x10 <sup>10</sup> I.U.	1	15
Cohort 3	VXA-CoV2-1	5x10 <sup>10</sup> I.U.	1	15



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Solicited Symptom Days (1 – 8)	Low Dose (n=20)	High Dose (n=15)	
No. (%) with Solicited Symptoms	4 (20)	10 (66.7)	
General Symptoms			
Malaise/Fatigue	2 (10)	2 (13.3)	
Myalgia (Muscle Pain)	1 (5.0)	1 (6.7)	
Anorexia	0 (00)	2 (13.3)	
Headache	3 (15)	2 (13.3)	
Fever	0 (00)	1 (6.7)	
Gastrointestinal Symptoms			
Diarrhea	0 (00)	4 (26.7)	
Nausea	0 (00)	5 (33.3)	
Vomiting	0 (00)	0	
Abdominal Pain	1 (5.0)	2 (13.3)	

• Most Solicited Adverse Events mild and transient; few moderates @ Days 2 to 6

• 6 Mild unsolicited AEs: sore throat, epistaxis, chills, dry sinus, back pain & testicular pain

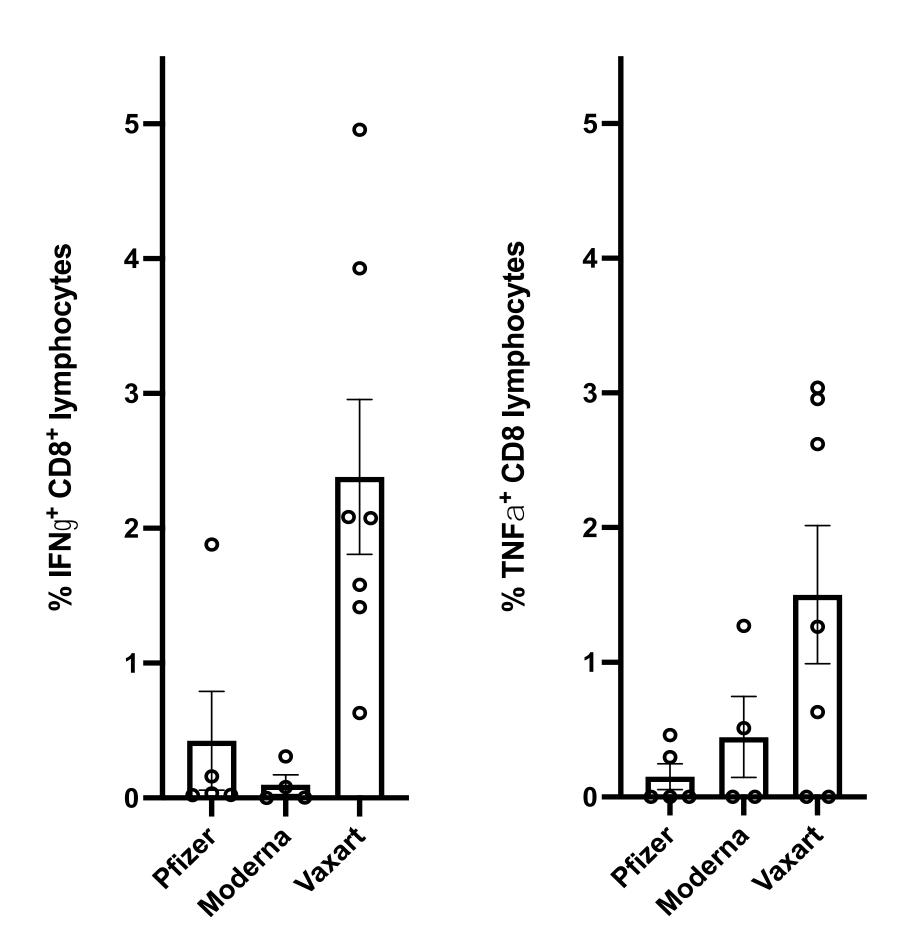
• No SAEs or MAAEs reported to date



# Phase I Results Support Potential of Single-dose Oral Tablet Vaccination: Robust Immune Responses

Induction of T cell responses measured 7 days after the first dose. Increase over day 1 for IFN-g and TNFa are shown

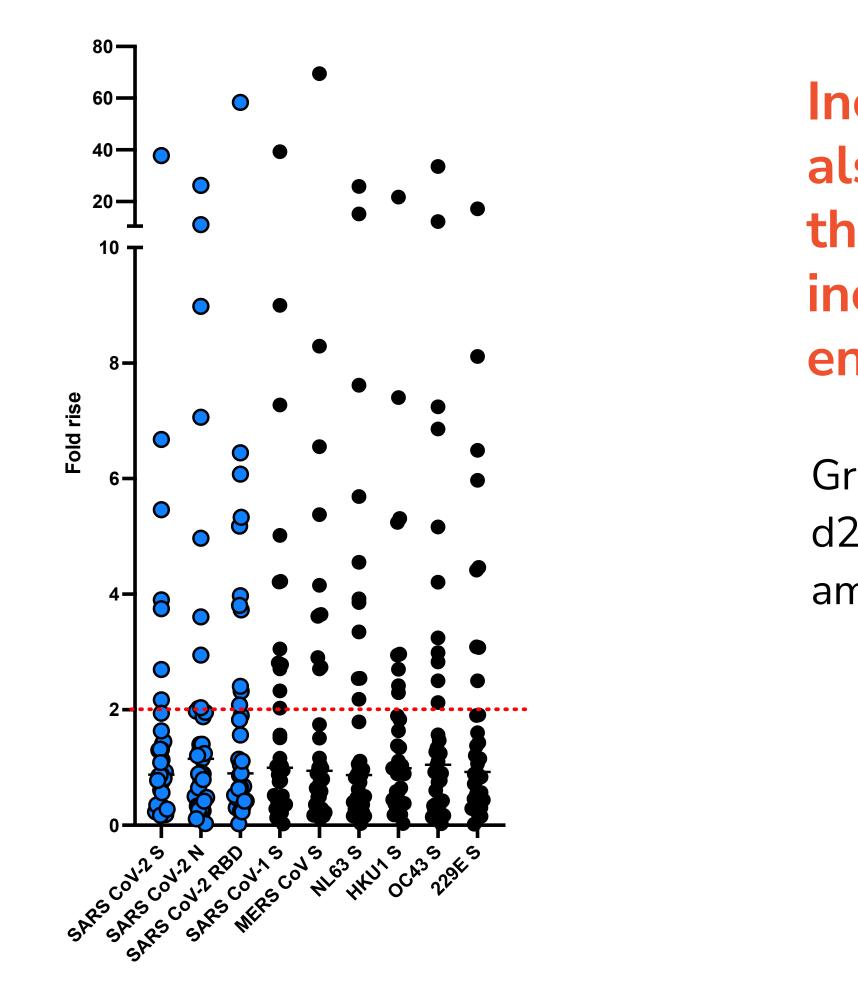
Frozen PBMC samples from Vaxart's Phase I trial were compared to PBMCs from volunteers that were immunized with the Pfizer or Moderna vaccines under EUA. Analysis was done at the same time points post immunization



Preliminary data



# Vaxart Immunized Subjects Have Increased Cross-reactive Nasal IgA Response to Other Coronaviruses



Preliminary data

Increased IgA antibodies to SARS-Cov-2 also led to increased antibody responses to the S protein of other coronaviruses including SARS-CoV-1, MERS, and endemic common cold viruses

Graph shows increase in nasal IgA at d29 over d1 sample, normalized for amounts of total IgA





# Phase I COVID Clinical Study Results

- Well-tolerated, no severe or serious adverse events reported
- Solicited symptoms of vaccine reactogenicity mostly mild and transient
- 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
- Dose-dependent responses observed with B cells
- IgA to SARS-CoV-2 induced in serum, nasal, and saliva
- T cell and IgA cross-reactivity to other coronaviruses observed, including with diverse endemic coronaviruses

May allow for future proofing against diverse variants



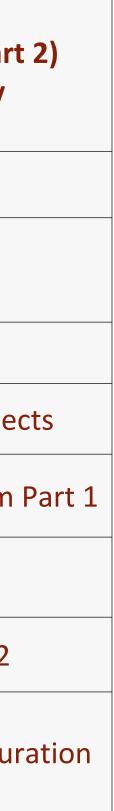
### Phase II Study Design and Timeline

- VXA-COV2-1.1-S Phase II Trial Design
- The Phase II study is designed to enroll 896 heathy adults aged 18 - 75 in a two-part protocol

Part 1

- Will enroll 96 subjects at US sites in an open-label manner
- 4 cohorts of 12 subjects each of prior vaccinated subjects, and
- 4 cohorts of 12 subjects each of naive, unvaccinated subjects \_\_\_\_ Part 2
- Will randomize 800 subjects in 1:1 ratio to either vaccine or placebo tablets, stratified by age, vaccination history and region
- All subjects will receive oral doses administered on Days 1 and 29
- Study endpoints are safety, immunogenicity and efficacy (Part 2)

Phase 2 (Part 2) Phase 2 (Part 1) **Dose/Age Escalation** Efficacy VXA-COV2-201 Naive & Naive **Prior mRNA vaccine** 18-75 yrs N=96 subjects N=800 subjects Dose: 1x10<sup>10</sup> IU and Dose: TBD from Part 1 1x10<sup>11</sup> IU 2 doses 1 month apart TBD Oct-2021 Q1-2022 4 months duration 6-8 months duration





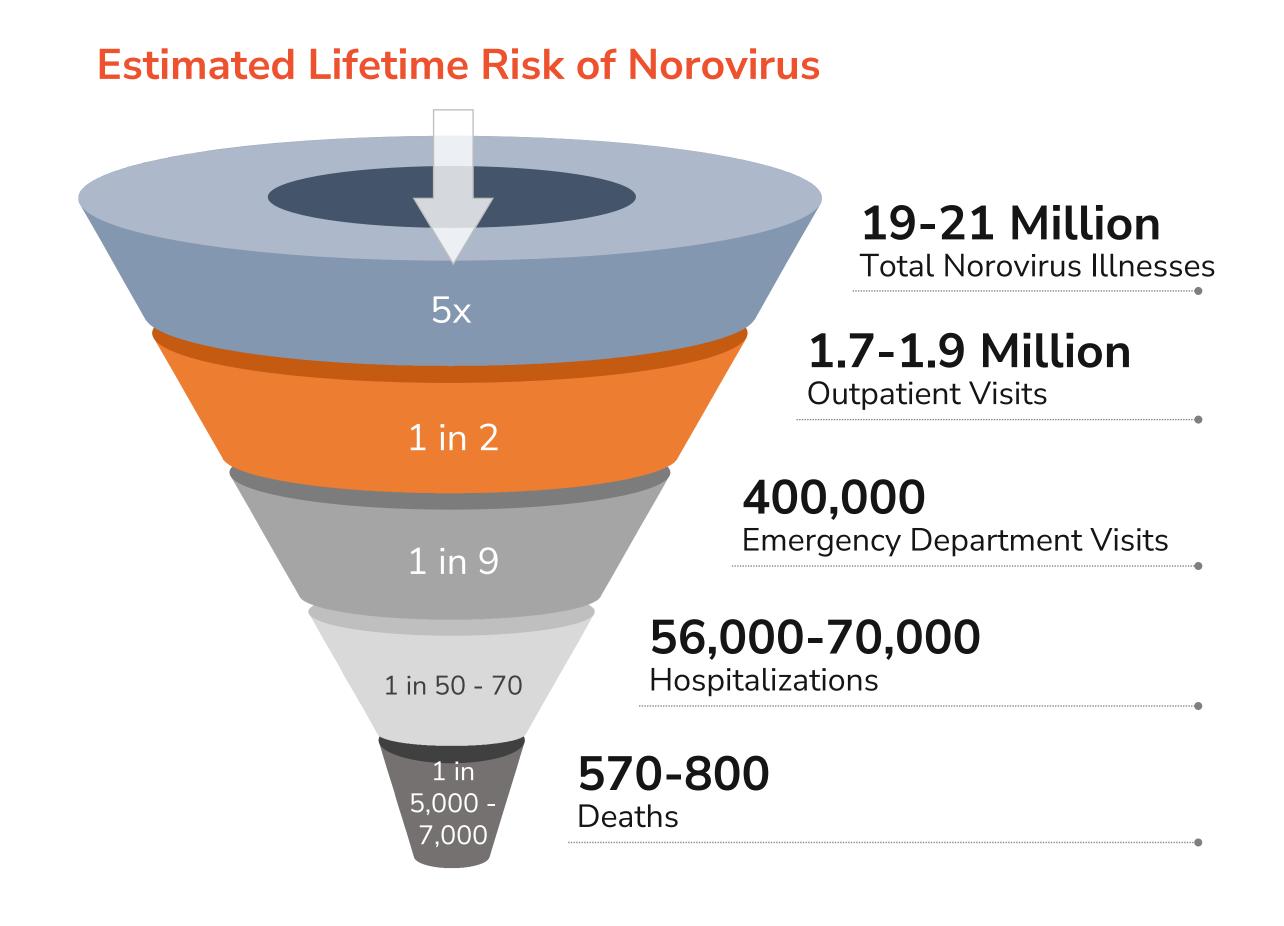
# Norovirus: Significant Unmet Need, \$10B Market Potential in the U.S. Alone

- Norovirus in the US causes ~20MM illnesses/year
- Annually 15% children under age 5 catch Norovirus
- 3MM sets of parents need to take time from work (2.2 days) to care for these children
- Annually ~7.5% of Age 65+ get sick, most hospitalizations in this group
- Economic burden of disease concentrated in these two groups

### \$10B market opportunity in U.S.

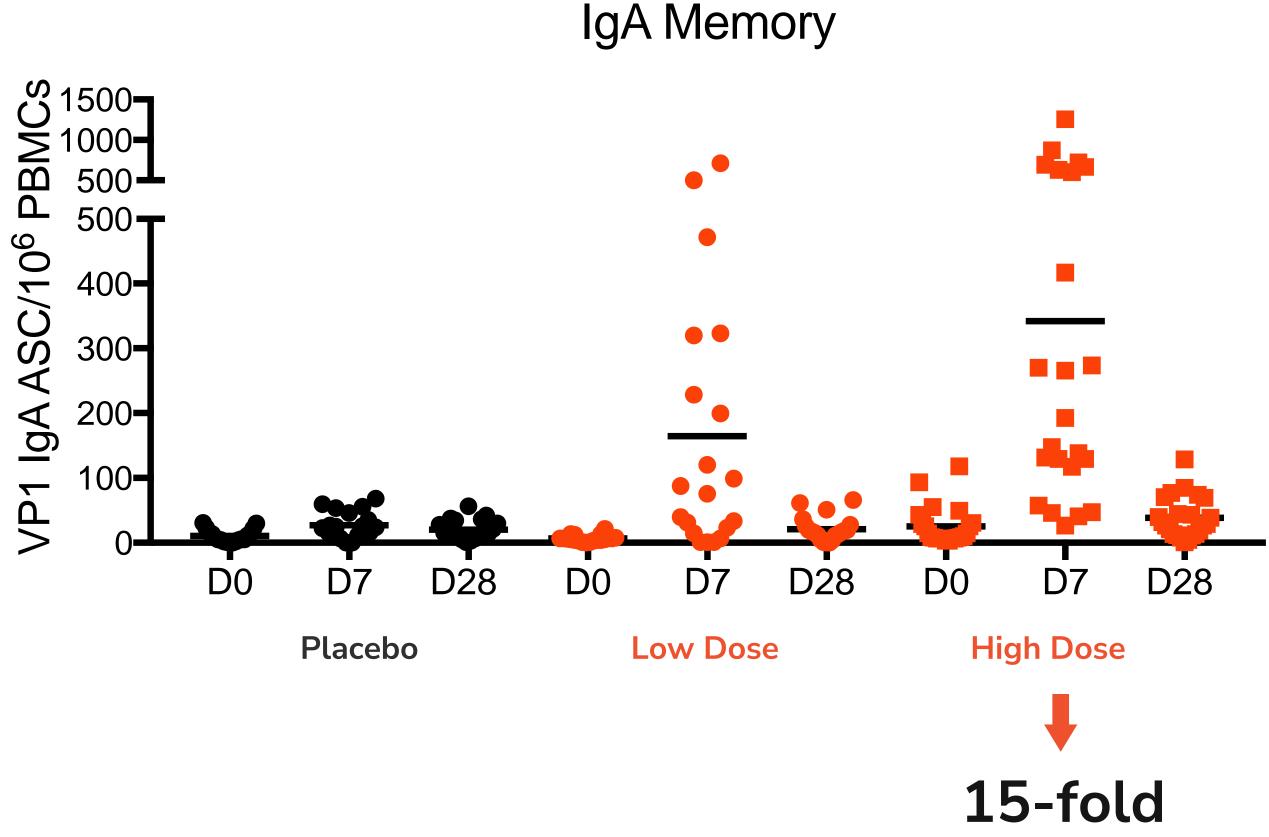
Source: Incidence of Norovirus and Other Viral Pathogens That Cause Acute Gastroenteritis (AGE) among Kaiser Permanente Member Populations in the United States, 2012–2013, Grytdal et al, PLOS 1, 2016





Source: CDC website (https://www.cdc.gov/norovirus/php/illness-outbreaks.html

# Potent Response from Vaxart's Oral Tablet Norovirus Vaccine: Memory and Effector Responses on the Same Order of Magnitude as Norovirus Infection

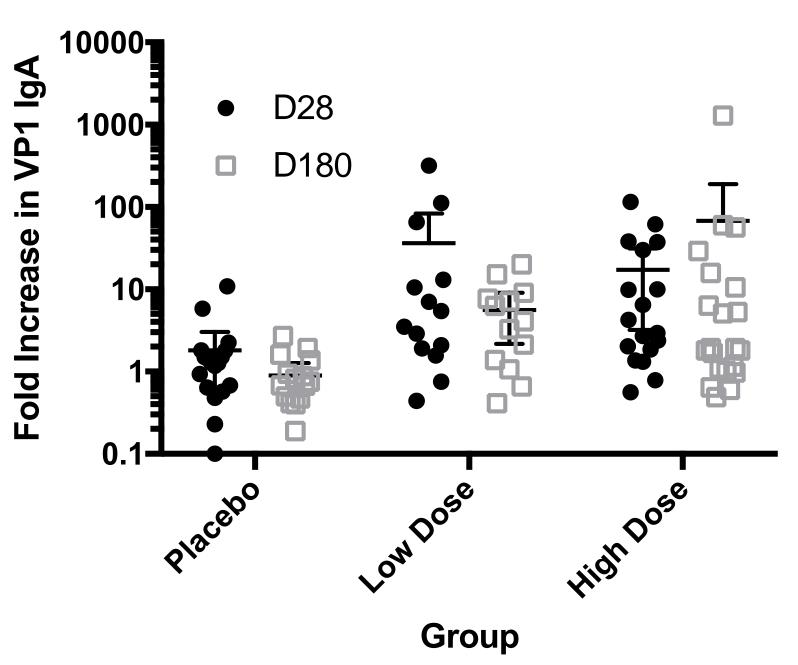


**GM** increase

Fecal IgA measured by Marcela Pasetti, U Maryland, Baltimore Kim, et al, JCI Insight, 2018



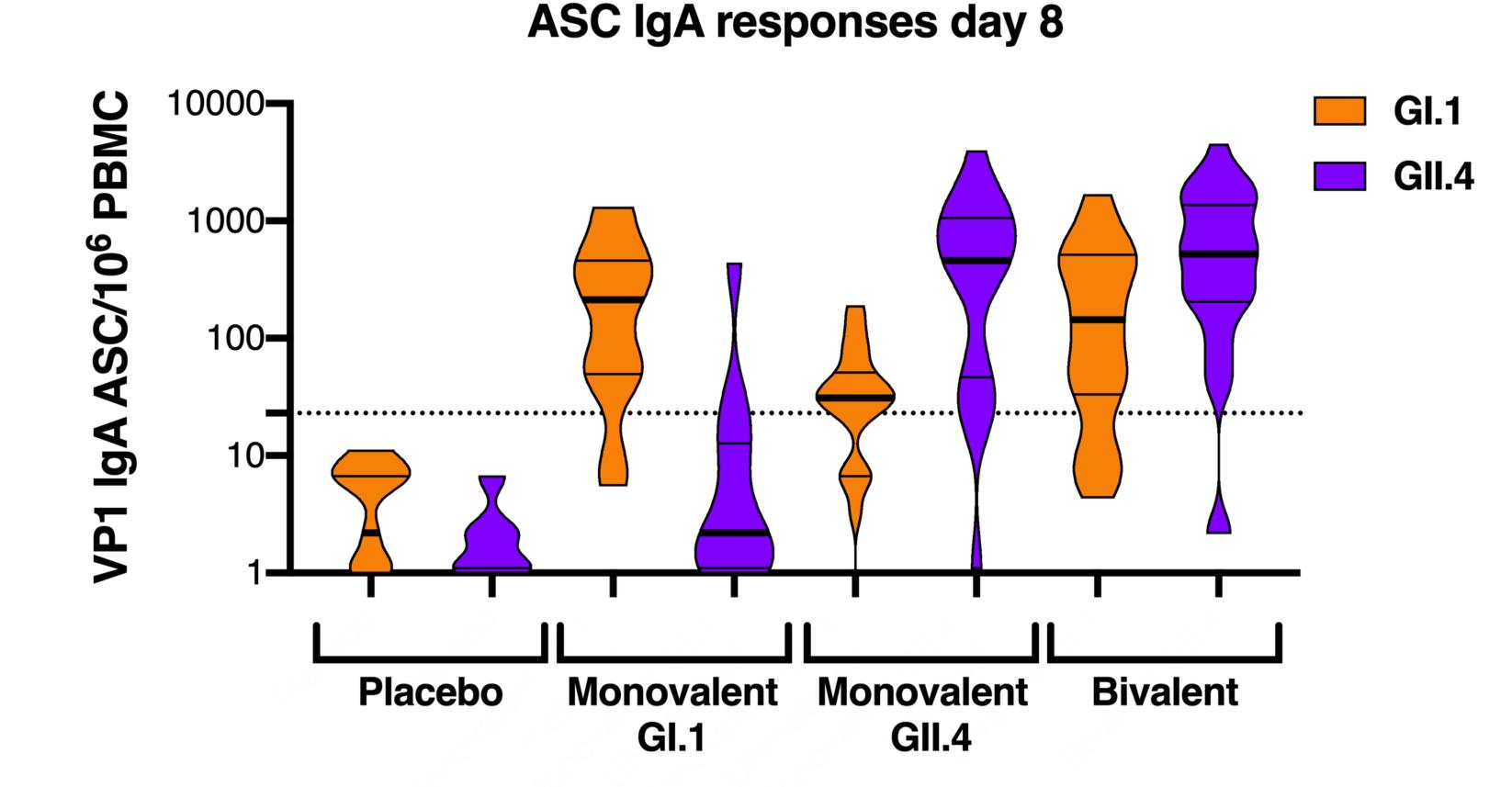
Fecal Samples show durable fecal antibody response



Fecal IgA response



# Vaxart's Bivalent Vaccine Shows No Interference, Strong Antigen-Specific B Cell Induction





# Significant Opportunity for Vaxart's Oral Norovirus Vaccine

### **Mucosal Immunity, Oral Delivery**

### **Development / Competitive Status**

- GI and GII genotypes cause majority of NV-disease
- Vaxart bivalent vaccine targets prevalent strain of each genotype
- Only Vaxart (oral tablet) & HilleVax (injectable) are in the clinic

### Mucosal Immunity May Be Important for Protection Against Norovirus

- Correlates of protection from human challenge studies shown with rapid induction of mucosal IgA, serum IgA
- Vaxart vaccine designed to activate mucosal immunity

### **Oral Tablet Vaccine**

Convenient room temperature-stable tablets are easier to distribute and administer than injectable vaccines

1) CDC Norovirus Illness: Key Facts 2) Atmar, et al, CVI, 2015. Ramani, et al, PlosPathogens 2016





# Several Norovirus Clinical Trials in 2021

### Phase I Age Escalation Study

- Dose-ranging study in elderly adults (55 80 years) evaluating safety and immunogenicity \_\_\_\_
- Expect to complete enrollment by end of Oct / Nov 2021
- Topline results expected in Q1 2022

### Phase Ib Boost Optimization Study

- Completed enrollment August 2021 \_\_\_\_
- Topline results expected December 2021

### Phase II Norovirus Challenge Study

Study set-up in Q4-2021 to allow initiation of vaccine phase dosing in January 2022 \_\_\_\_





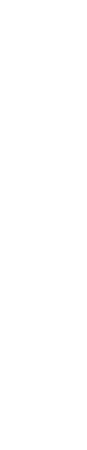


## Norovirus Phase I Age and Escalation Study Design

### **Study Design:**

- Randomize 66 subjects aged 55 to 80 years old in 2:1 ratio:
- Cohort 1: Low Dose (n=24)
  - 16 subjects to norovirus vaccine @ 1e10 I.U. and 8 placebo subjects
- Cohort 2: Medium Dose (n=24)
  - 16 subjects to norovirus vaccine @ 3e10 I.U. 8 placebo subjects
- Cohort 3: High Dose (n=18)
  - 12 subjects to norovirus vaccine @ 1e11 I.U. and 6 placebo subjects
- Study drug administration: Days 1 and 29
- Study Visits: Day 1, 8, 29, 36, 57, 210 and 390
- Topline results after all subjects complete Day 57 visit





### **Deep Expertise Provides Strong Foundation for Success**



### ANDREI FLOROIU, MBA

Chief Executive Officer





### SEAN TUCKER, PHD

Founder and Chief Scientific Officer





### **SHAILY JAINI GARG**

SVP, Clinical Development & Project Management





**RAJESH KAPOOR** 

SVP, Quality

Image: BDP&G Wyeth





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### MARGARET ECHERD, CPA MBA

SVP and Principal Accounting Officer







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