



# The Pill Against COVID-19

**SVBLEERINK** 

*2020 CybeRx Call Series*

September 23<sup>rd</sup> 2020



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# Key Investment Highlights



## 01 Transformative Oral Vaccine Platform

Potential to disrupt the vaccine ecosystem



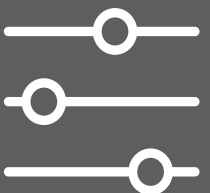
## 02 Oral COVID-19 Program may offer the Best Practical Global Solution to Pandemic

Oral convenience, potential superior efficacy due to mucosal immunity, ease of distribution – room temp. stable



## 03 Validated Clinical Platform with Benign Safety and Tolerability profile

Clinical data from 12 trials against 6 viruses



## 04 Pipeline focused on several very large opportunities besides COVID-19

Norovirus, HPV, influenza & RSV



## 05 Resources to aggressively continue clinical advancement and commercialization

Cash: \$140M (as July 2020)



# Groundbreaking technology: An Oral COVID-19 Vaccine



## Vaccine as a pill

**Convenient mode of administration, rapid and painless:** no needles, self administration (no appointments, no lines, social distancing)

**Potentially more protective than injectable vaccines:** activates mucosal immunity – the first line of defense, plus multiple immune system mechanisms

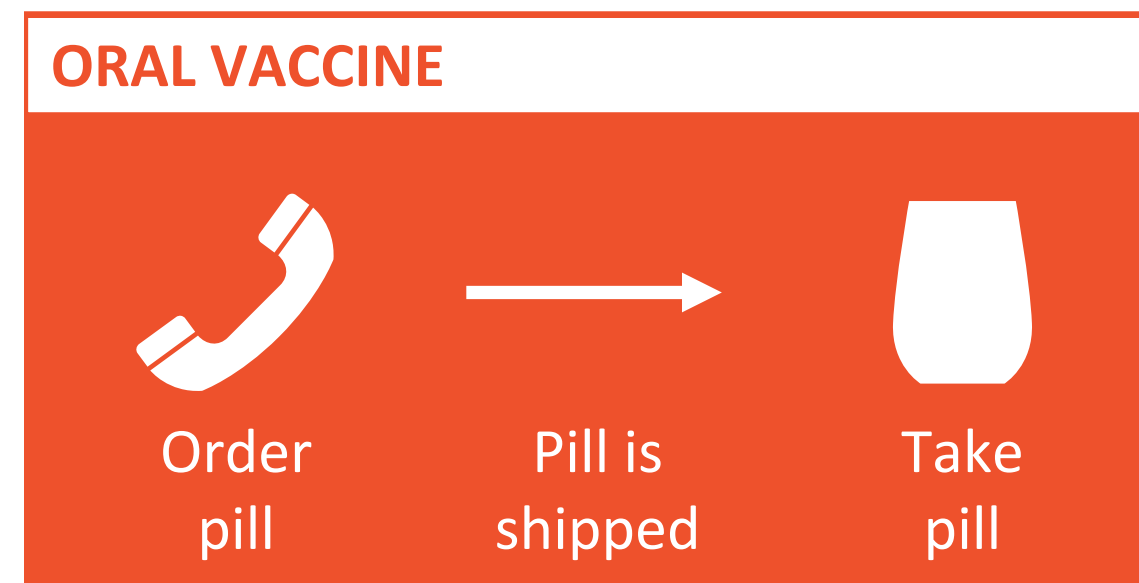
**Ease of distribution and storage, globally:** room temperature stable tablet – no cold chain, no needles, no waste

**Vaxart's COVID-19 vaccine is ...**

The only oral COVID-19 vaccine among leading programs

The only mucosal vaccine in the U.S.'s Operation Warp Speed NHP challenge study

# An oral vaccine would have huge advantages in mass COVID-19 vaccination campaigns



VS.



**The pill =  
more people  
vaccinated faster**



## Higher adoption – more people vaccinated

- ❖ Convenient, painless, self-administered
- ❖ Facilitates social distancing during a pandemic
- ❖ Appealing to those who dislike injections & needles

## Fastest way to conduct mass vaccination campaigns

- ❖ 1-2 months to vaccinate large populations with injectables
- ❖ 2-3 days with a pill

## Not taxing on healthcare system & local resources

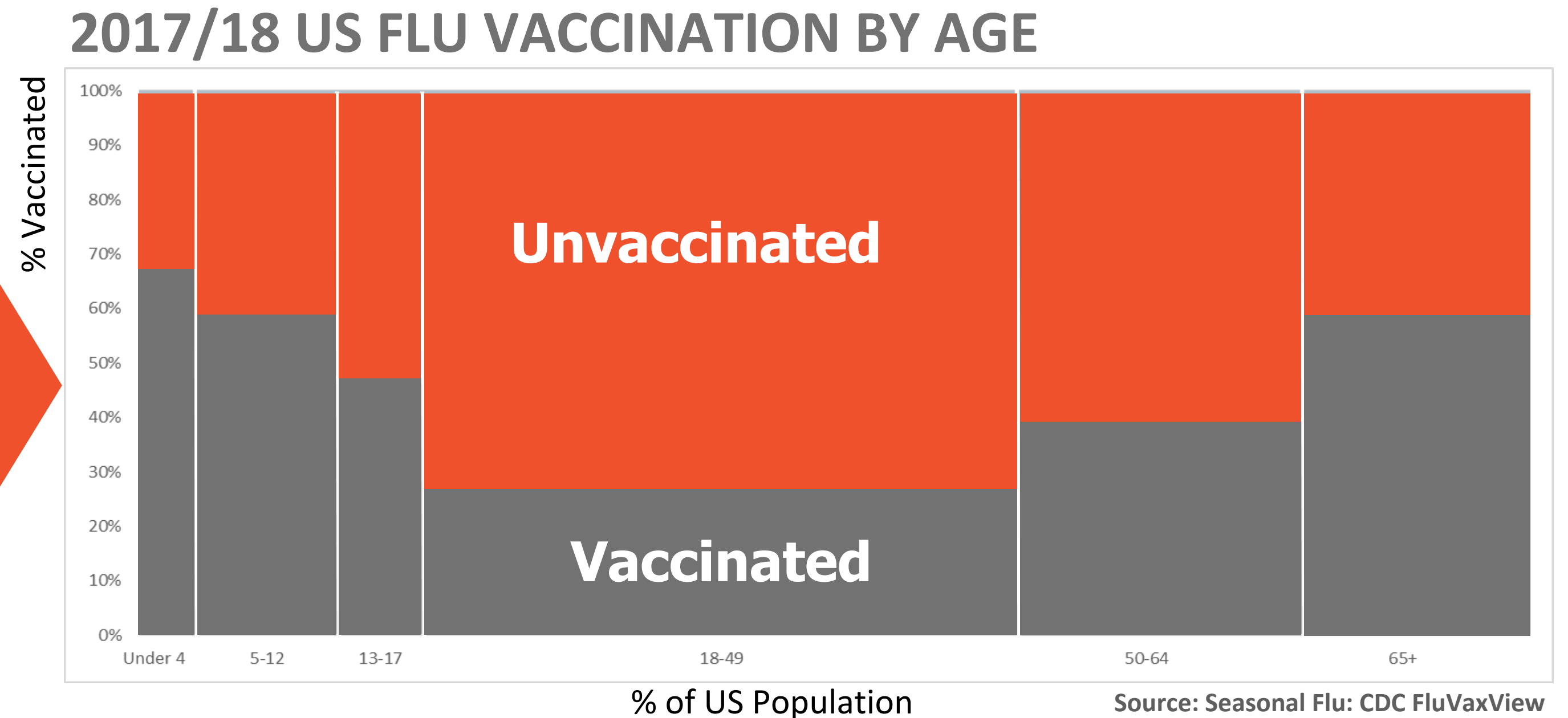
- ❖ No medical personnel needed
- ❖ No vaccination centers needed



# Needles and having to go to the doctor's office are the main reasons why not enough people get vaccinated



only 42%  
vaccinated\*  
despite U.S. CDC  
recommendation  
for 100%



## Similarly low uptake expected with COVID-19 vaccines:

- “*As few as 50%* of people in the United States are committed to receiving a vaccine, with another quarter wavering” – Science Magazine, Jun. 2020
- “*Less than half* of American adults say they would get a government-approved coronavirus vaccine” – NBC, Aug 2020
- “*Two-thirds of Americans say they won't* get COVID-19 vaccine when it's first available” – USA Today / Suffolk, Sep. 2020

\*Over 6 months old



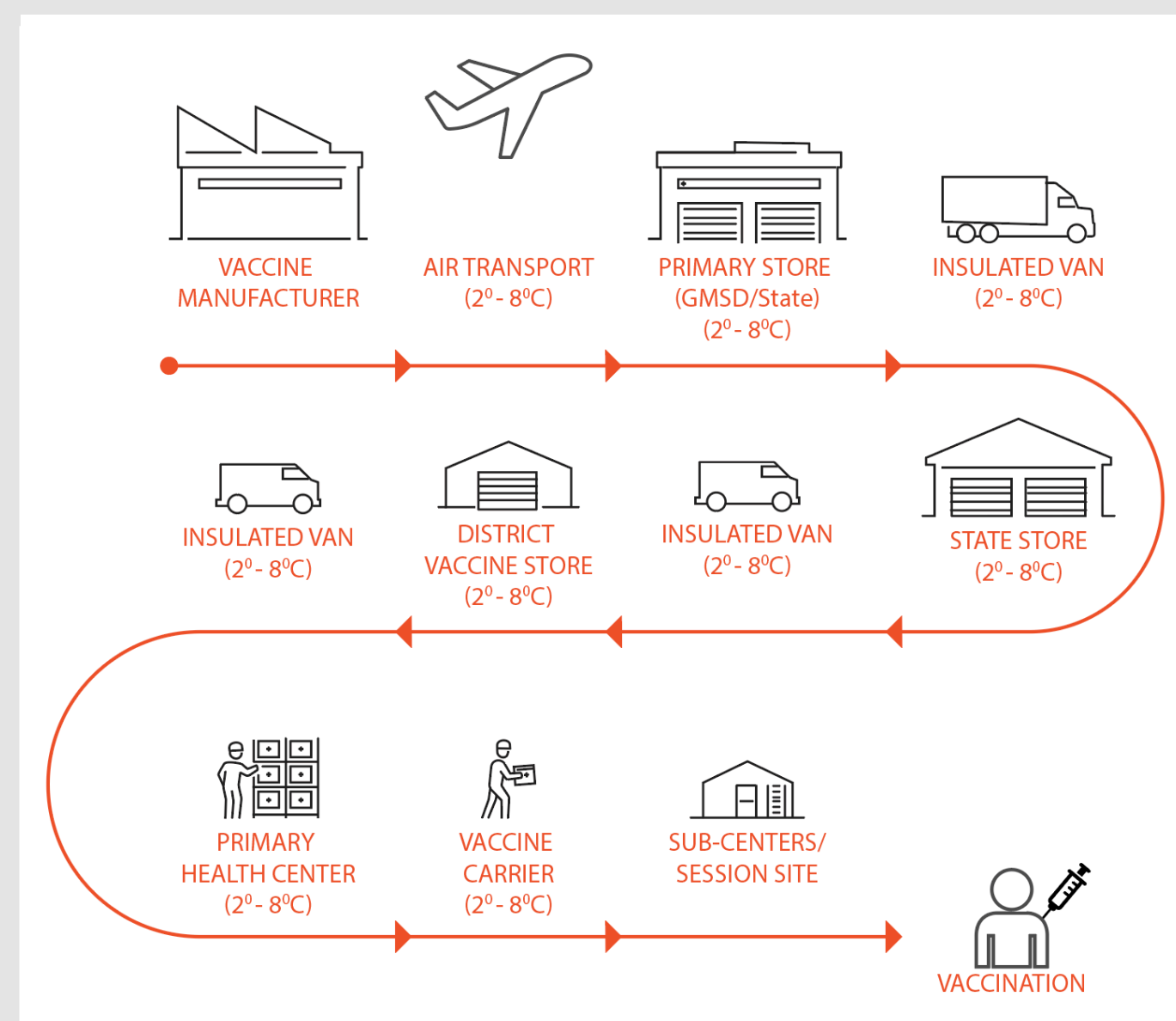
# Significantly simpler and cheaper for national and local governments to distribute and stockpile a pill vs. an injectable



## Vaxart's oral vaccine is room temperature stable

- ❖ **No refrigeration for storage** – major cost & space savings
- ❖ **No refrigeration for distribution** – significantly simpler & cheaper, eliminates potential bottlenecks
- ❖ **Can be shipped cheaply** to any corner of the US or the Globe

## Cold Chain: very complex & expensive



## The New York Times, September 18<sup>th</sup> 2020

Strict temperature requirements “will make it very difficult for community clinics and local pharmacies to store and administer.” - Kathleen Dooling, C.D.C

## The New York Times, September 18<sup>th</sup> 2020

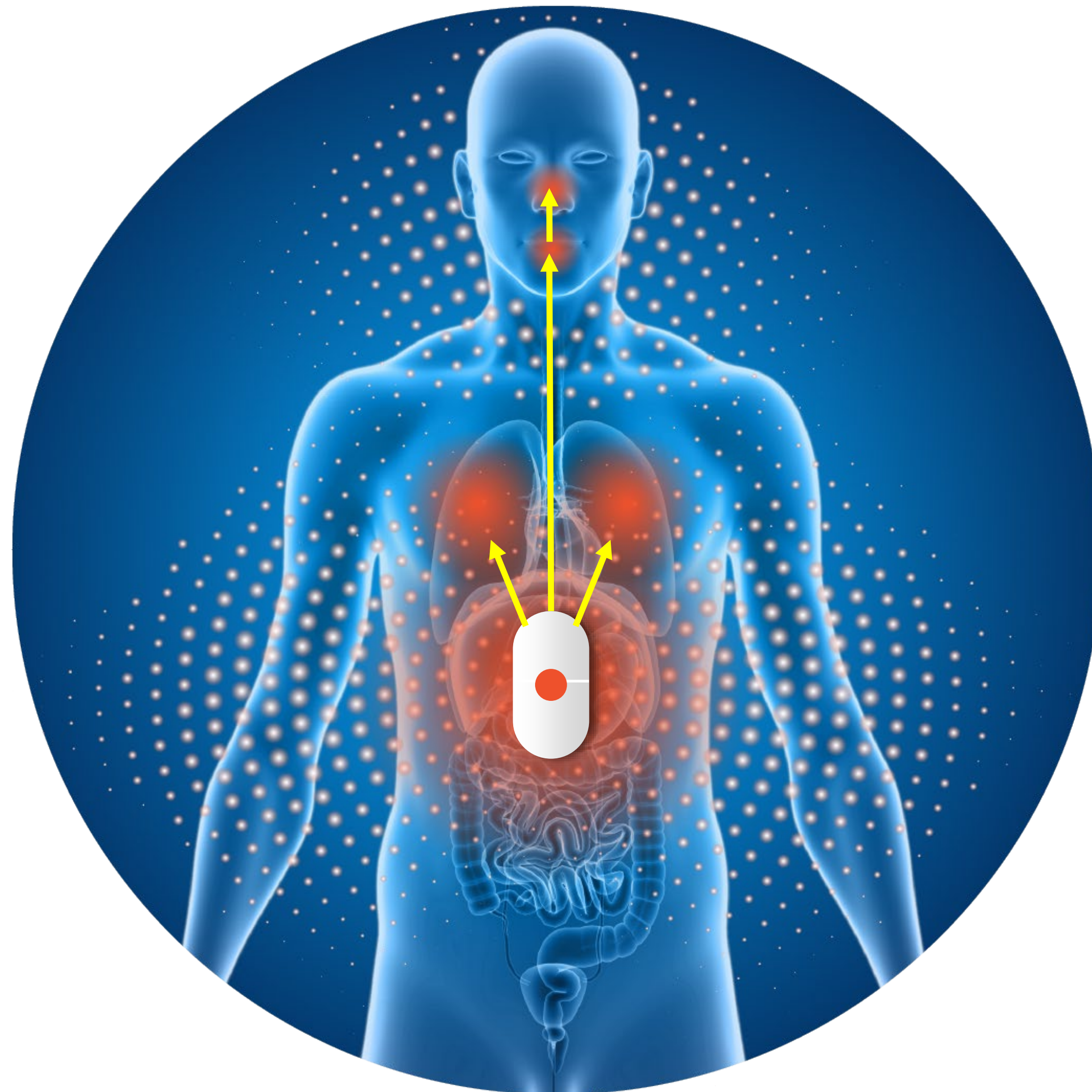
Large parts of Africa, South America and Asia, where super-cold freezers are sparse, would be left out – DHL, McKinsey study

## Politico, August 3<sup>rd</sup> 2020

**U.S. lacks plan for getting vaccine to communities of color devastated by virus**



# Vaxart's oral vaccine activates the mucosal immune system: the 1<sup>st</sup> line of defense against airborne viruses



**Protection against Airborne Viruses:**  
**Oral vaccine activates immunity in the right places**

*Vaxart's oral vaccine triggers a broad immune response, activating systemic and mucosal immunity:*

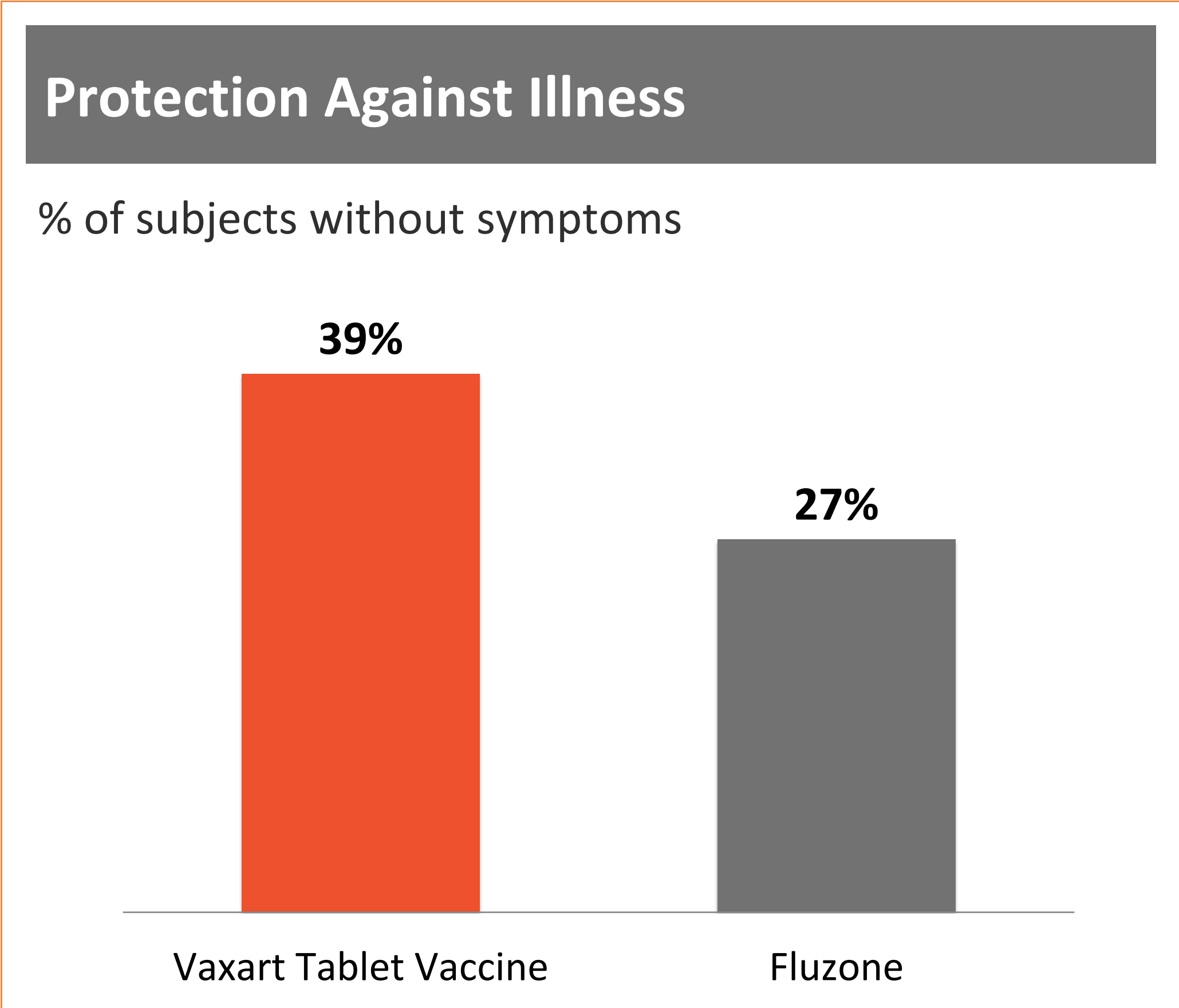
- ✧ *Mouth*
- ✧ *Nose*
- ✧ *Lungs*
- ✧ *Intestine*

*Injectable vaccines only activate systemic immunity*



# Proven efficacy against an airborne virus: Vaxart pill likely to protect better against flu than leading injectable in BARDA-funded clinical trial

Phase II trial comparing Vaxart’s oral tablet vaccine and Sanofi’s Fluzone injectable flu vaccine



Liebowitz, et al, *Lancet ID*, 2020



Clinical study funded by the U.S. Biomedical Advanced Research and Development Authority (BARDA)

THE LANCET  
Infectious Diseases

Results published  
in January 2020

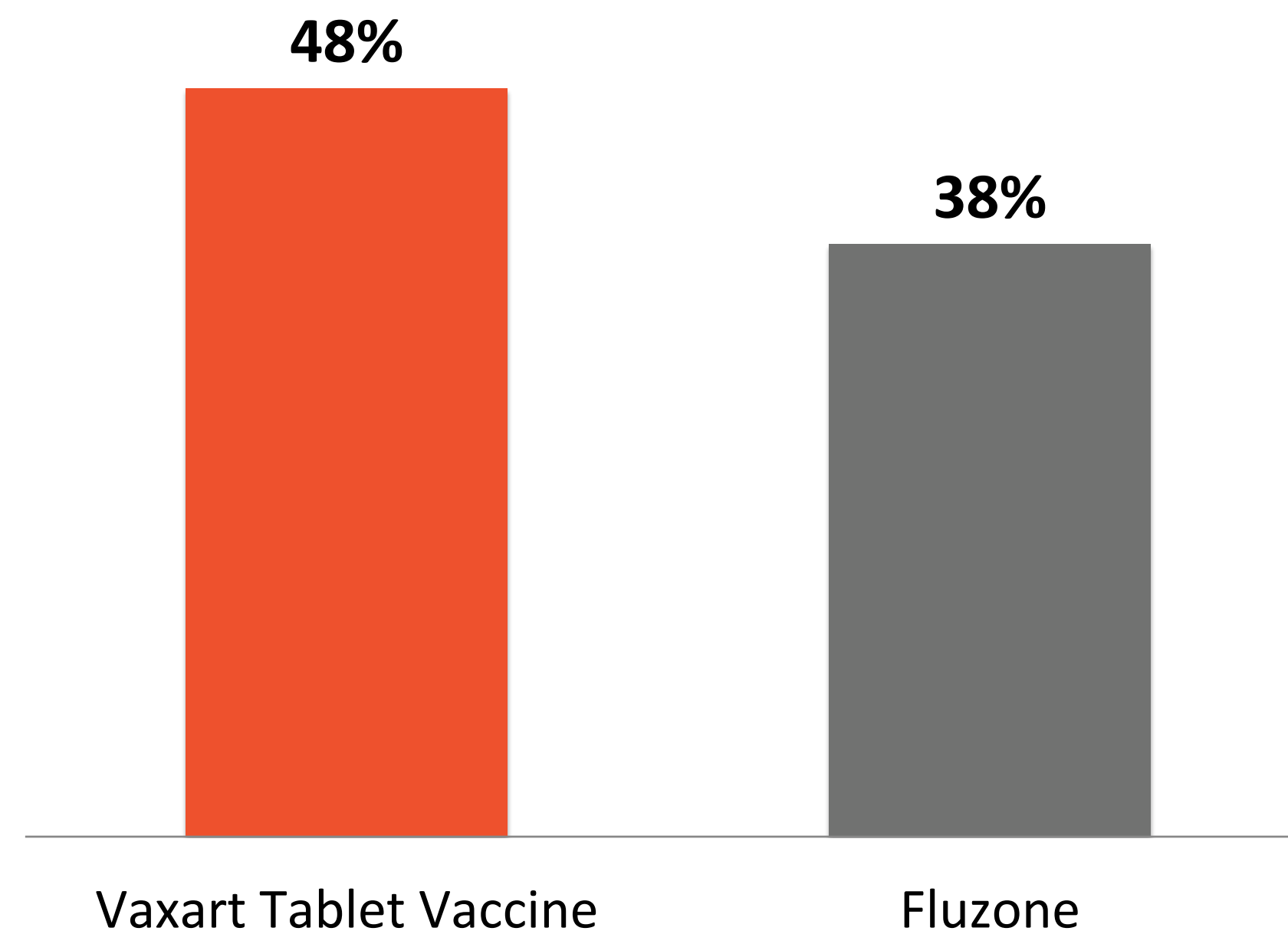
# Oral vaccines have the potential for sterilizing immunity against airborne pathogens such as COVID-19 and flu – preventing infection altogether

## Phase II trial comparing Vaxart's oral tablet vaccine and Sanofi's Fluzone injectable flu vaccine

By triggering a strong enough **mucosal immunity**, Vaxart's oral vaccine has the **potential to prevent infection altogether**

### Protection Against Infection

% of subjects not infected



More people who got the Vaxart oral vaccine were protected against flu compared to those who got Fluzone



THE LANCET  
Infectious Diseases

Liebowitz, et al, *Lancet ID*, 2020



# Safe, with Tolerability Comparable to Placebo

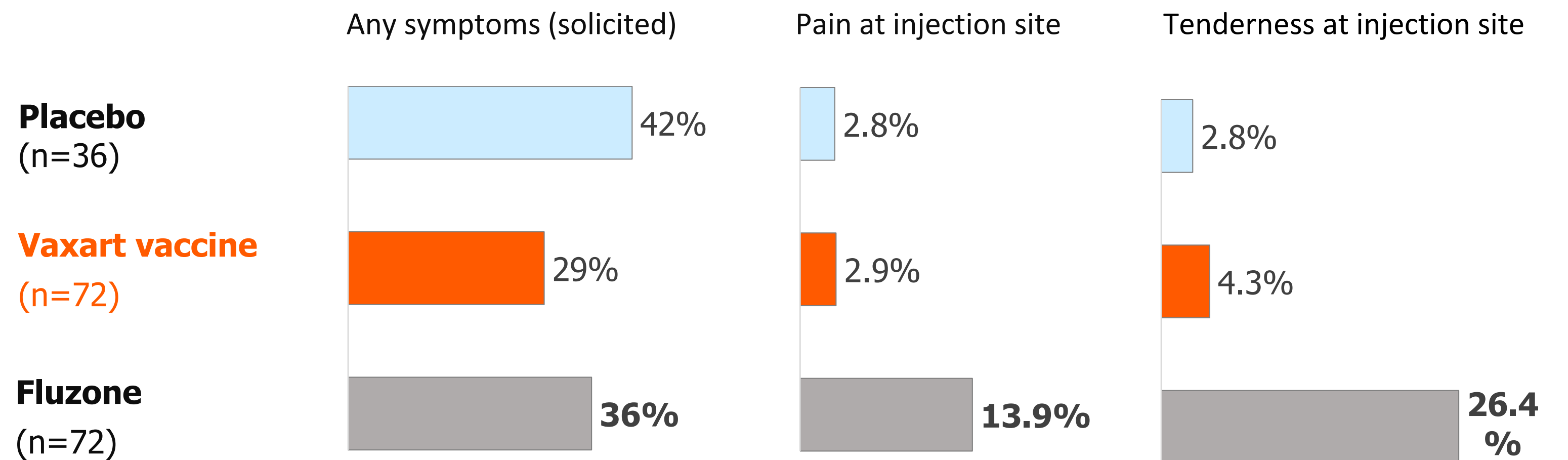
**Long-term safety & tolerability:**

**462** subjects vaccinated

**12** clinical trials

**6** different viruses

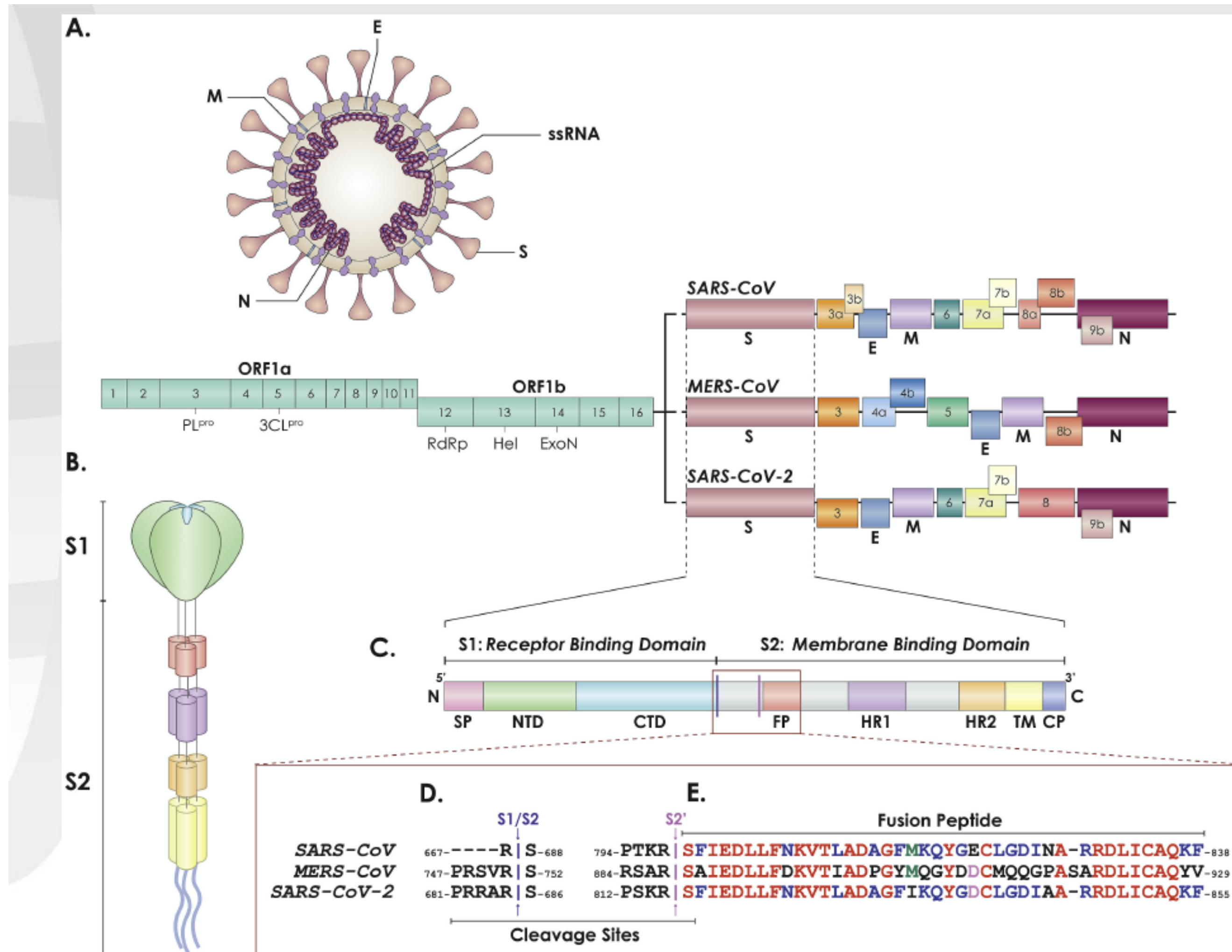
## BARDA-funded flu study



*Pain: a key reason for which people don't like needles*

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

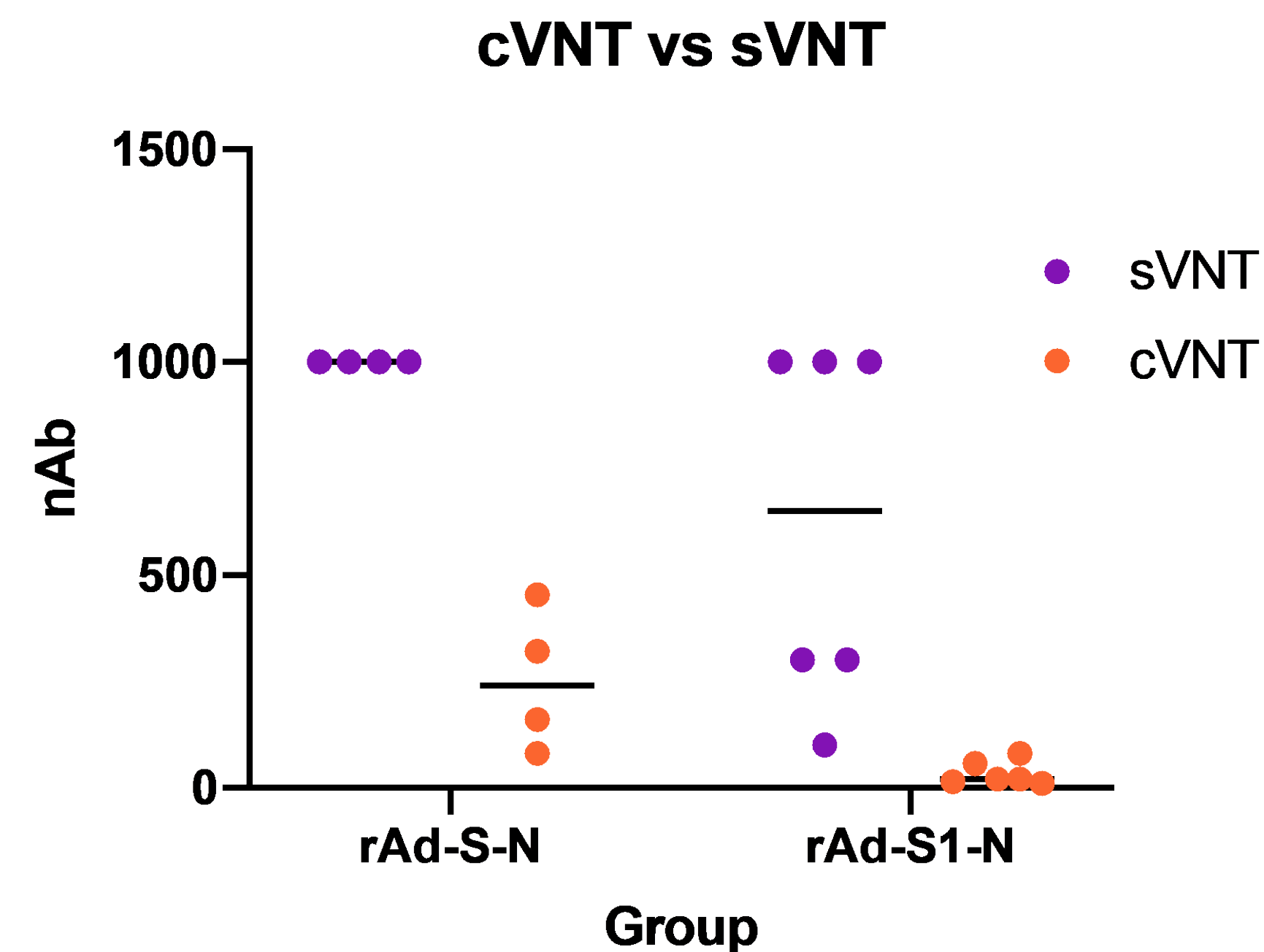
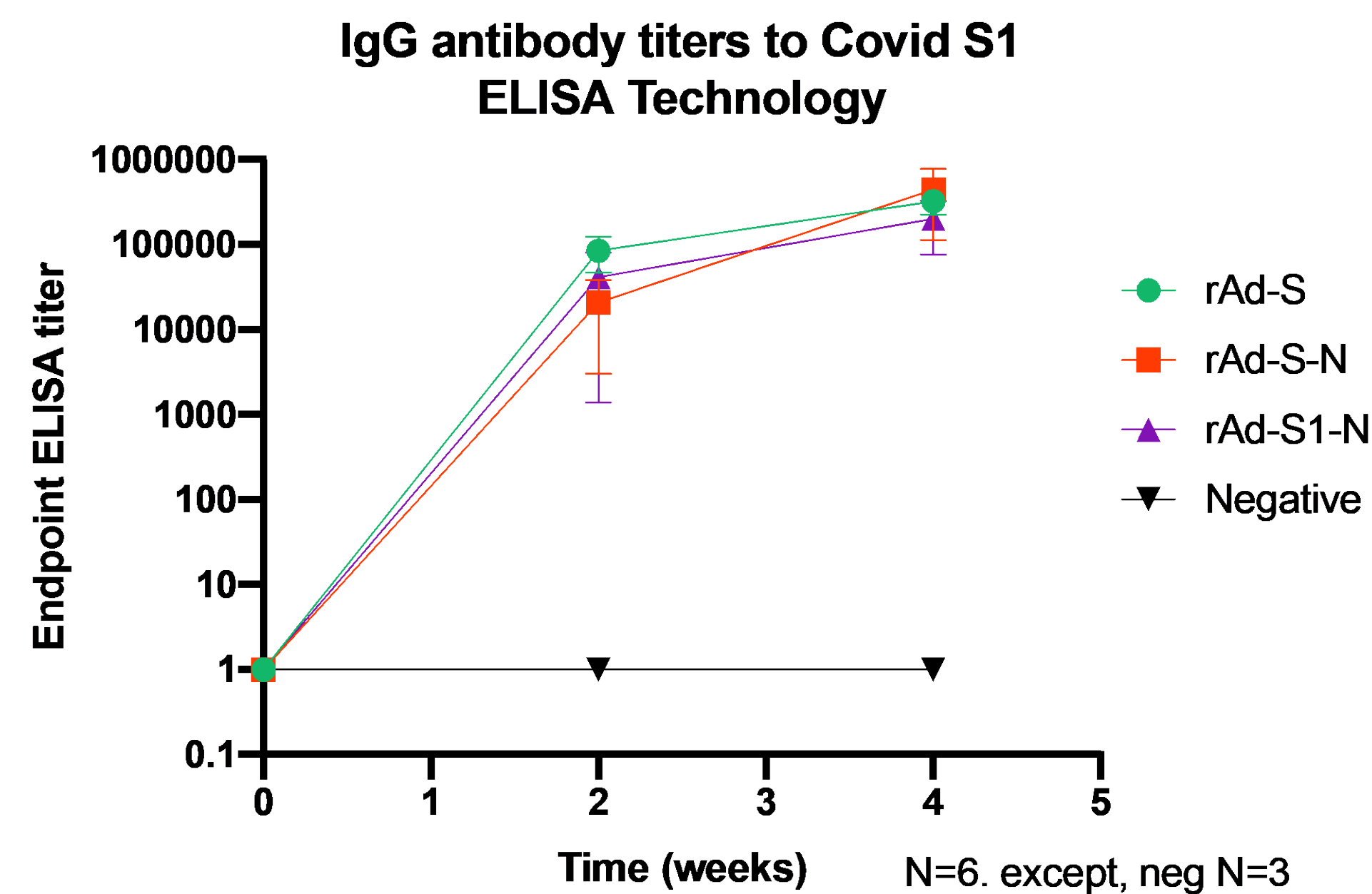
# Vaxart vaccine contains both the S and N genes from SARS-CoV-2



- S Protein is a surface protein, good target of neutralizing antibodies
- N Protein is well conserved, and a good target for T cell responses
- Construct is called rAd-S-N

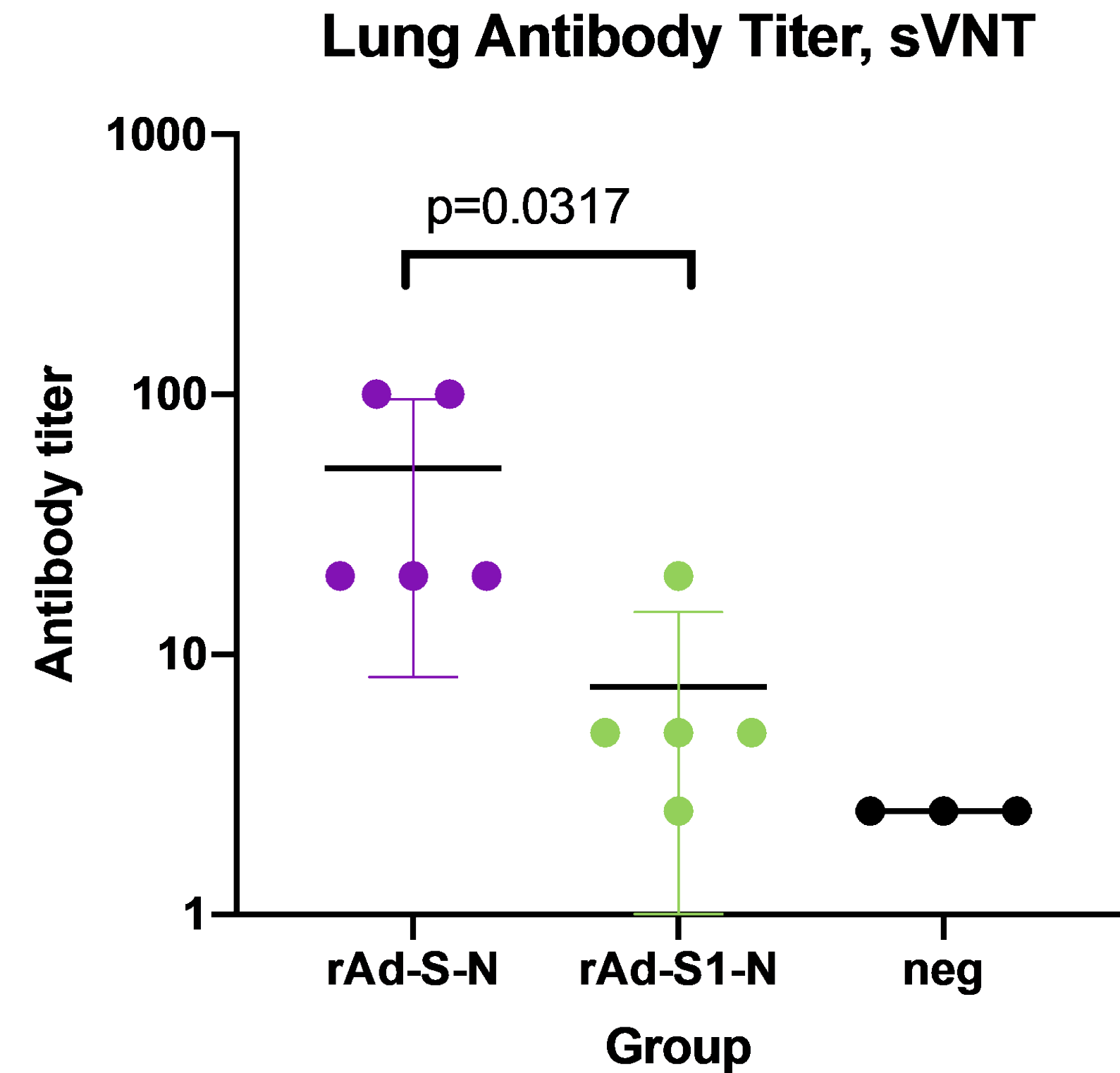
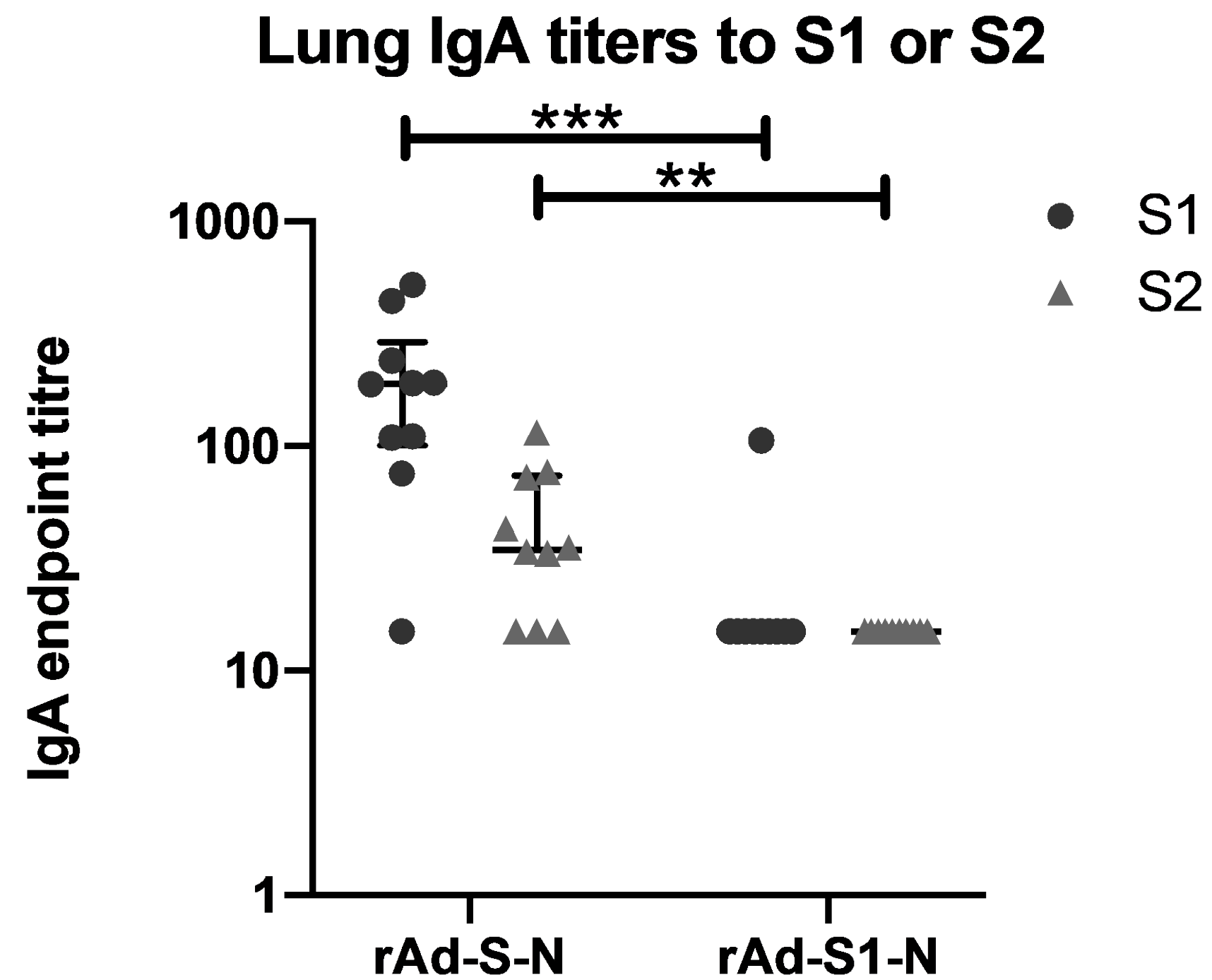


# Full-length S better for creating neutralizing antibody responses



Moore, et al, *BioRxiv*, 2020

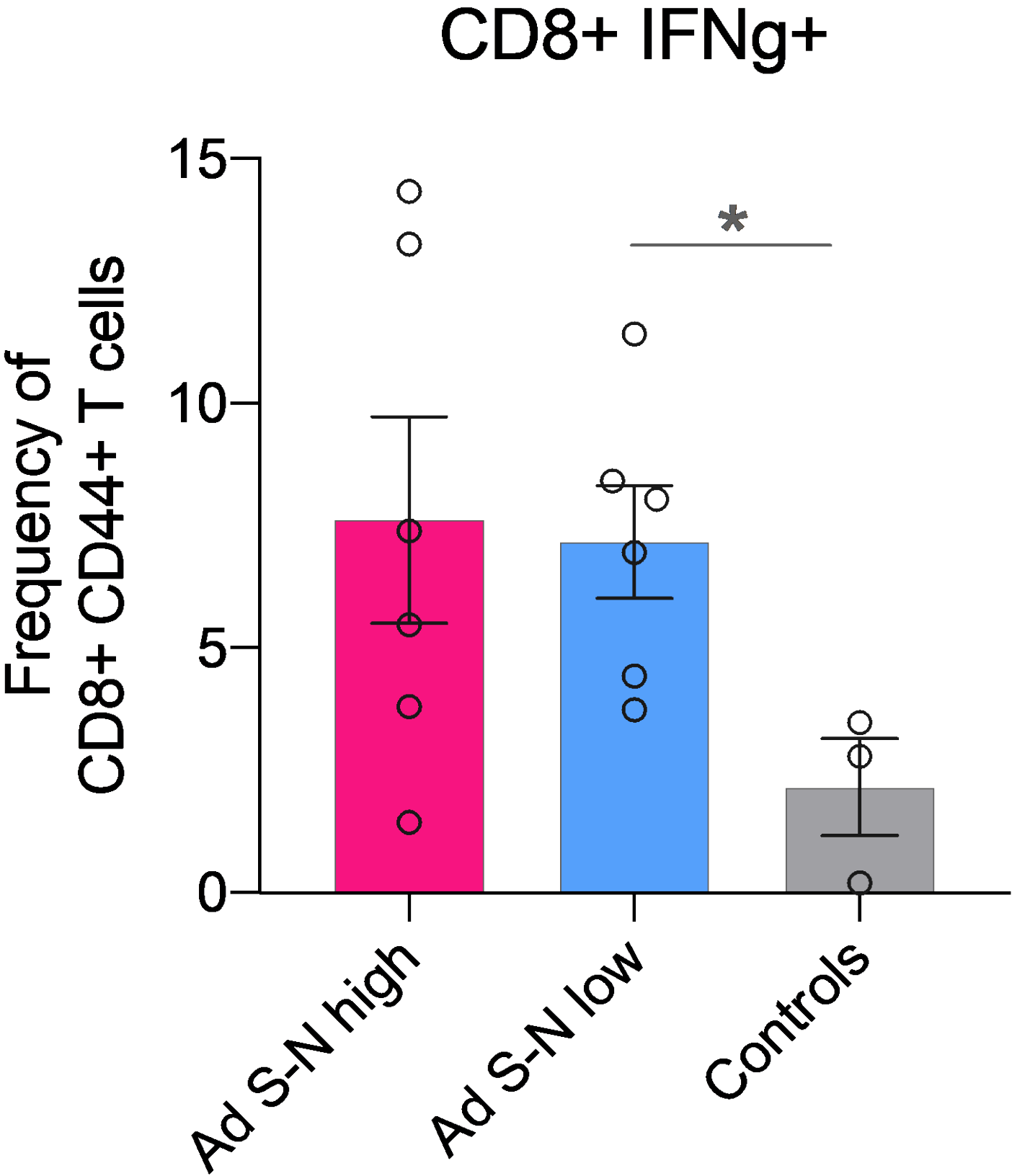
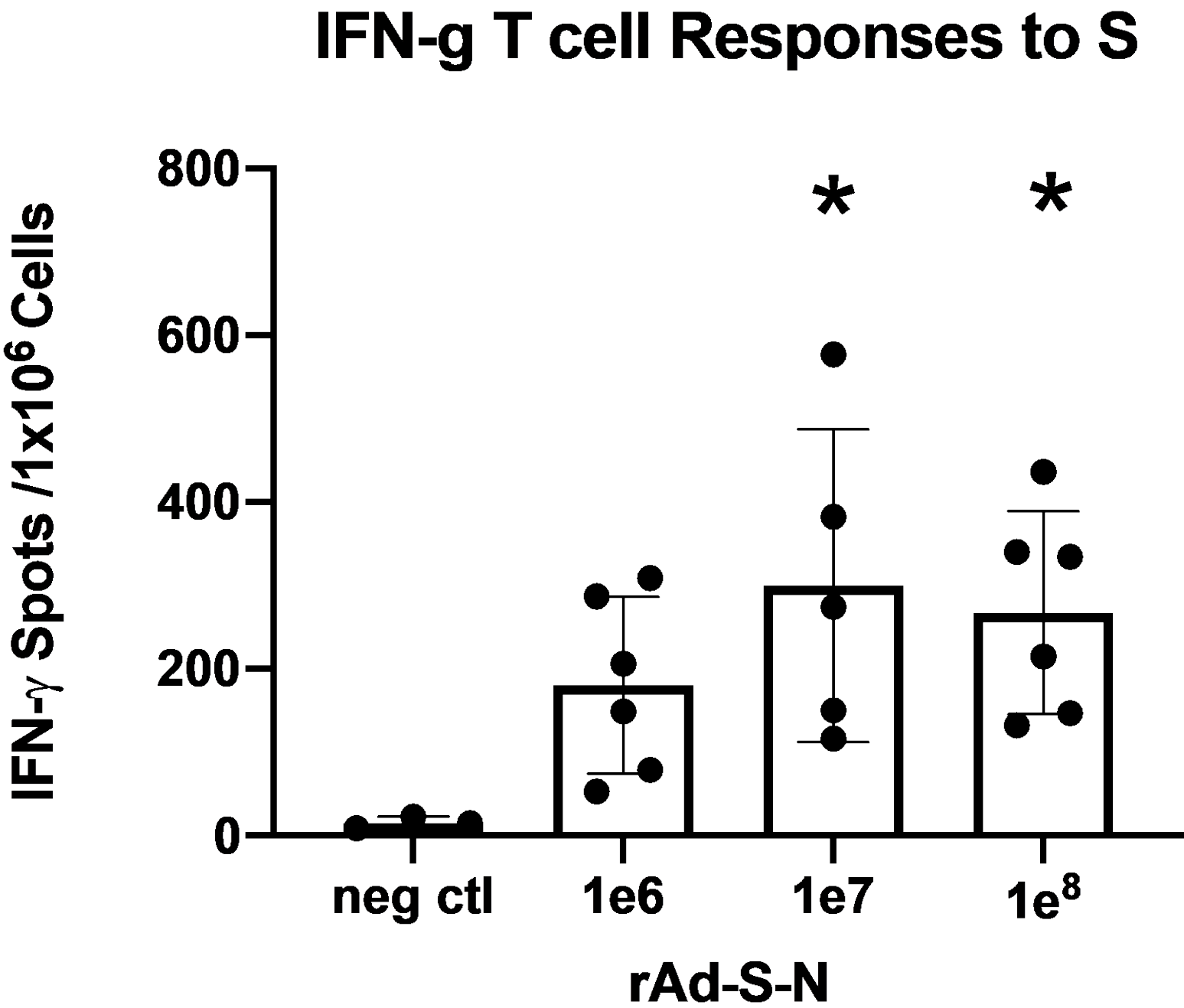
# Vaxart COVID vaccine induces lung antibody responses, IgA and neutralizing antibodies



Moore, et al, *BioRxiv*, 2020



# Potent T cell Responses to the S protein, at low doses of vaccine



Moore, et al, *BioRxiv*, 2020

# Conclusions

- Well tolerated vaccine platform
- Potent immune responses even at low vaccine doses
- Mucosal Immunity might be *really important*
  - Both mucosal IgA and mucosal T cells have been shown to contribute to sterilizing immunity in other respiratory diseases
  - Can't be adequately addressed by an injected vaccine
  - High degree of neutralizing antibody responses in lung
- IgA is not only a more potent neutralizing isotype for viruses, but can block transmission



# Vaxart's oral COVID-19 vaccine has several advantages vs. leading injectable vaccine candidates

|                 | Technology          | Limitations         | Likely Immune  | Needles | Cold chain |
|-----------------|---------------------|---------------------|----------------|---------|------------|
| Vector-based    |                     |                     |                |         |            |
| CanSinoBio      | rAd5 injected       | Antivector Immunity | nAb, T cells   | Yes     | Yes        |
| AZ/ Oxford      | Chimp rAd           |                     |                |         |            |
| Janssen         | rAd26 injected      |                     |                |         |            |
| DNA/RNA         |                     |                     |                |         |            |
| Moderna         | Stabilized RNA      | New technology      | nAb            | Yes     | Yes        |
| Pfizer/BioNTech | RNA                 |                     |                |         |            |
| Protein         |                     |                     |                |         |            |
| Novavax         | Insect cell culture | Only makes Ab       | Ab             | Yes     | Yes        |
| Sanofi/PS       |                     |                     |                |         |            |
| Oral Vaccine    |                     |                     |                |         |            |
| Vaxart          | rAd5 oral tablet    | Lower profile co.   | IgA, Mucosal T | No      | No         |

# Vaxart and its manufacturing partners have been gearing up for mass production



## Experienced Manufacturing Partners

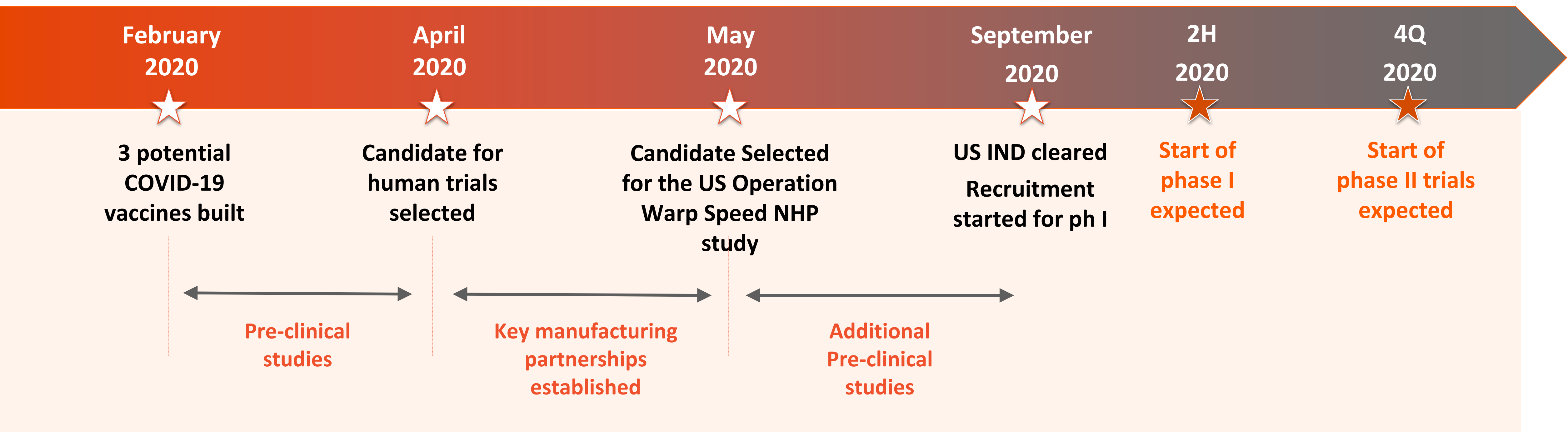


**Simpler manufacturing process than for injectables:**

- No sterile fill and finish
- No need for vials



# Vaxart COVID-19 vaccine timeline



# Pipeline focused on large indications includes prophylactic and therapeutic oral vaccine candidates

|                                 |                                       | Trials Conducted to Date or in Progress |         |         |         | Marketed |
|---------------------------------|---------------------------------------|---|---------|---------|---------|----------|
|                                 |                                       | Preclinical                             | Phase 1 | Phase 2 | Phase 3 |          |
| PROPHYLACTIC VACCINES           |                                       |   |         |         |         |          |
| Norovirus <sup>1</sup>          | Bivalent                              |   |         |         |         |          |
| Seasonal Influenza <sup>2</sup> | Monovalent                            |   |         |         |         |          |
|                                 | Quadrivalent                          |   |         |         |         |          |
| Influenza                       | Universal <sup>3</sup>                |   |         |         |         |          |
| COVID-19                        |                                       |   |         |         |         |          |
| RSV <sup>4</sup>                |                                       |   |         |         |         |          |
| THERAPEUTIC VACCINES            |                                       |   |         |         |         |          |
| 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.
- 4) RSV program to be partnered with new antigen partner.
- 5) HPV therapeutic pre-IND feedback received.



# Vaxart is the leading oral vaccine biotechnology company



## Manufacturing



## Research & Development



## Clinical Trials



## Commercial



San Francisco

# Management Team with Deep Experience in Vaccines



**ANDREI FLOROIU, MBA**  
Chief Executive Officer



**SEAN TUCKER, PHD**  
Founder and Chief Scientific Officer



**RICHARD SCHWARTZ, PHD**  
SVP, Technical Operations



**SHAILY JAINI GARG**  
SVP, Clinical Development  
and Project Management



**BRANT BIEHN**  
SVP, Commercial Operations



**MARGARET ECHERD, CPA MBA**  
Vice President, Corporate Controller





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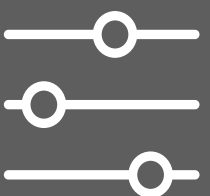
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[vaxart.com](http://vaxart.com)