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): November 19, 2020

Vaxart, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35285**	**59-1212264**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

385 Oyster Point Boulevard, Suite 9A, South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 550-3500

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	Name of each exchange on which registered
Common stock, $0.0001 par value	**VXRT**	**The Nasdaq Capital Market**

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 7.01. Regulation FD Disclosure.

Vaxart, Inc. (the "*Company*") intends to present an updated corporate presentation at a Key Opinion Leader panel for investors entitled "*An Oral Tablet Vaccine – A Potential Global Solution to COVID-19 and Norovirus?*" on November 19, 2020. A copy of the updated Corporate Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The corporate presentation will also be available on the Company's website.

The information furnished with this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

By furnishing the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, the Company makes no admission as to the materiality of such information. The information contained herein is intended to be considered in the context of the Company filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	**Description**
99.1	Vaxart, Inc. Corporate Presentation, November 19, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Vaxart, Inc.

Dated: November 19, 2020

By: /s/ Andrei Floroiu
Andrei Floroiu
President and Chief Executive Officer

November 2020

KOL Event

VAXART

UNLOCKING THE FULL POTENTIAL OF ORAL VACCINES

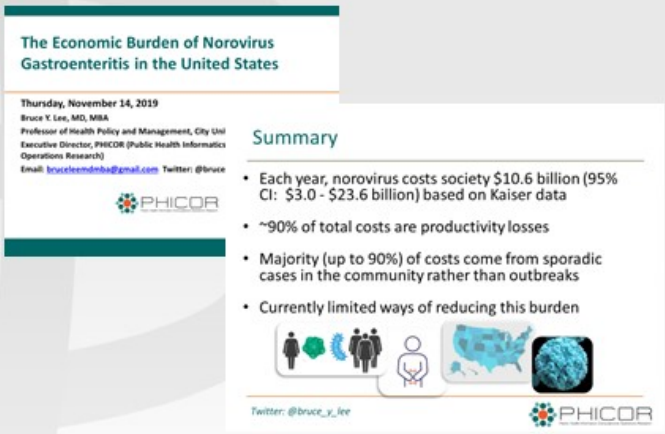
Forward-Looking Statement

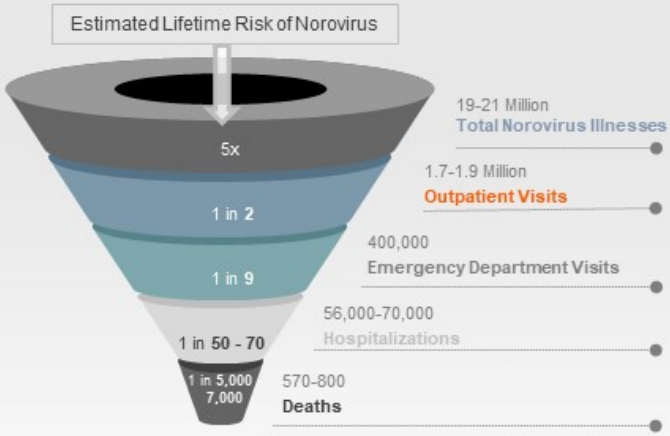
This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this presentation regarding Vaxart's strategy, prospects, plans and objectives, results from predinical and clinical trials, commercialization agreements and licenses, beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "believe," "could," "potential," "expect," "will" 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 and commercialize its product candidates; expected clinical results and trial data (including plans with respect to the proposed COVID-19 vaccine program); Vaxart's intention to continue its efforts to advance its oral tablet seasonal flu vaccine; Vaxart's expectations with respect to the important advantages it believes its oral vaccine platform can offer over injectable alternatives, particularly for mucosal pathogens such as norovirus, flu and RSV, as well as coronaviruses such as SARS, MERS and COVID-19; and Vaxart's expectations with regard to the vaccination market. 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, 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 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; that Vaxart or its partners 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.

2

Norovirus is a Significant Cause of Disease in the U.S.

Median cost to U.S. Healthcare system (2013-2017): $10.6 Billion annually[1]





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

1) Bruce Lee, MD, Vaxart KOL Day, November 14, 2019
2) CDC Norovirus Illness: Key Facts & Figures 2019

Government Policy Expected to Drive $3B+ U.S. Market

CDC (Viral Gastroenteritis Branch) Highly Engaged with Norovirus Disease

1. HECON modeling, multiple publications for burden of disease
2. Form working group to inform **Advisory Committee of Immunization Practices (ACIP)**

ACIP Recommends U.S. Vaccine Policy to Director of CDC

Broadly disseminated through professional organizations, insurance providers, directly to Health Care Providers and Patients

Age	0-4	5 – 64	65+
Population US	20M	260M	50M
Price Target	$100[1]	$50[1]	$50[1]
Prospect of ACIP recommendation	High	Low	High
Percent vaccinated[2]	70%[3]	4%	65%[4]
Market potential	$1.4B+	$0.5B	$1.6B+

1) US Disease burden, Bartsch S et al., Vaccine 2012 30(49):7097; 2) Assumes ACIP recommendation; 3) US Rotavirus complete series vaccination rate; 4) US Influenza Vaccine Age 65+ vaccination rate

How Vaccines Work with the Immune System

- Recognizes the germ component in the vaccine as being foreign.
- Responds by making antibodies and T cells to the germ component in the vaccine, just as it would for the real germ. **Effector Response**
- Remembers the germ and how to destroy it. That way, if you are ever exposed to the disease-causing germ in the future, your immune system will be able to quickly destroy it before it has a chance to make you sick. This is how you get immunity from vaccines. **Memory Response**

Adopted from Immunize BC
https://immunizebc.ca/how-do-vaccines-work

Oral Vaccines Based on VAAST Platform

Selected Mucosal Adjuvant "Hard Wired" in Vector Delivery System

Non-replicating adenovirus with molecular adjuvant

ORAL VACCINE OFFERS IMPORTANT ADVANTAGES

- **Potentially disruptive impact across vaccine supply chain**
  - *Room temperature stable tablets*
  - *Ease of distribution*
- **Allows increased vaccination rates**
  - *Ease of administration*
  - *Patient acceptance*

INNOVATIVE PLATFORM SYSTEMIC AND LOCAL IMMUNITY

- **Designed for wide range of recombinant antigens**
- **Local immunity is potential key differentiator**
  - *Protection at the mucosa of the gastrointestinal, respiratory tract*
  - *First line of Defense*

VAAST Oral Vaccines – Validated Platform In Humans

Approximately 500 Subjects Dosed to Date

Clinical Trials

Tablet Vaccines

Purpose:

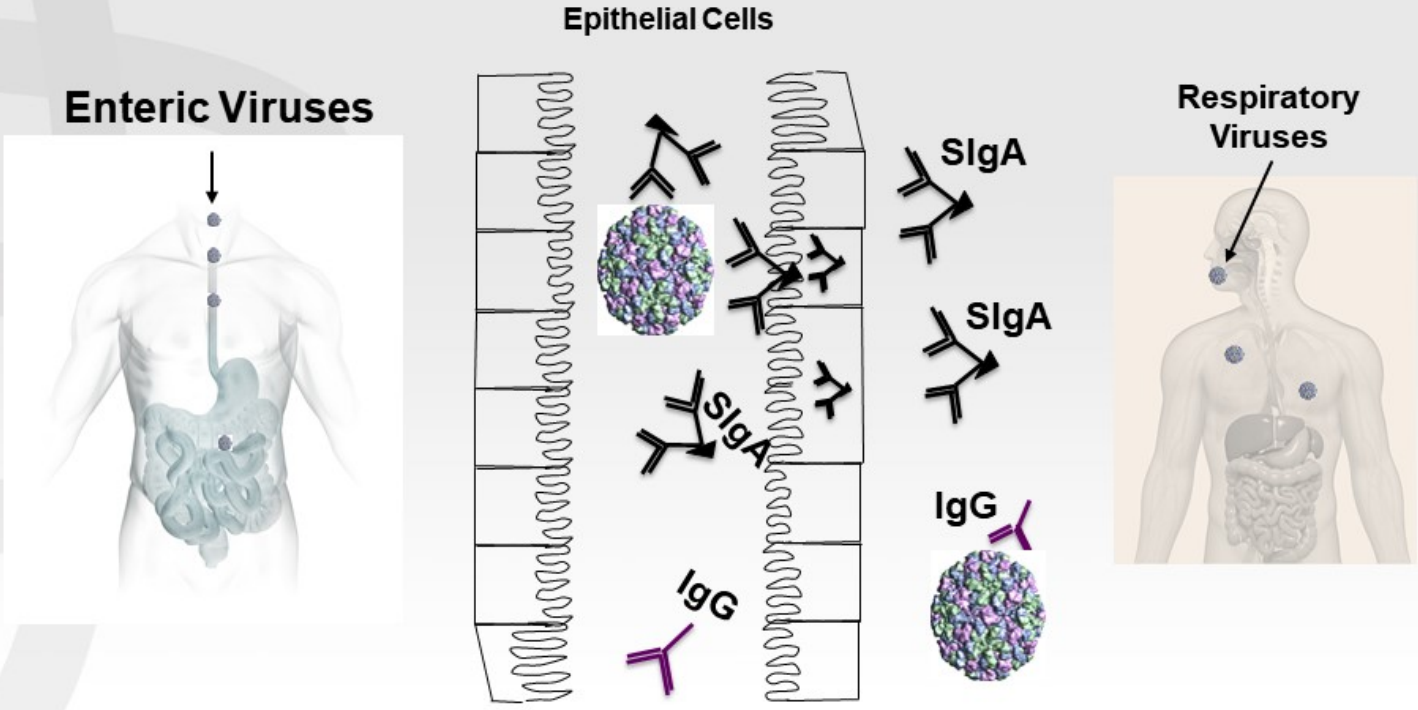
- Safety
- Immunogenicity
- Dose ranging
- Efficacy

	Flu	RSV	Norovirus	COVID-19
SUBJECTS DOSED	245	46	171	35
SAFETY				
Favorable safety and tolerability profile				
EFFICACY				
Reduction in influenza illness comparable with the leading marketed quadrivalent intramuscular influenza vaccine				
BROAD IMMUNE RESPONSES				
Serum neutralizing antibodies (IgG), Systemic T cell responses				
MUCOSAL HOMING CELLS				
T cells, IgA positive B cells				

Two Layers of Protection

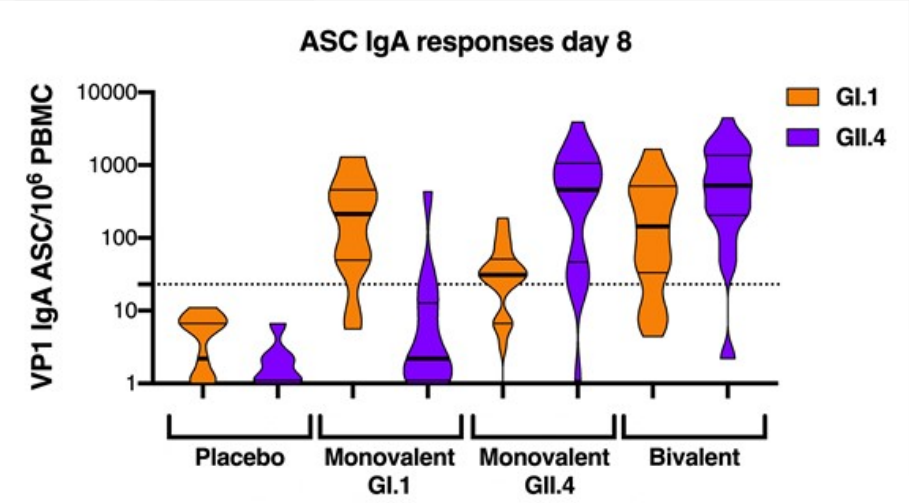
Mucosal SIgA and Serum IgG

Mucosal Response may be able to block infection more effectively at the site of infection

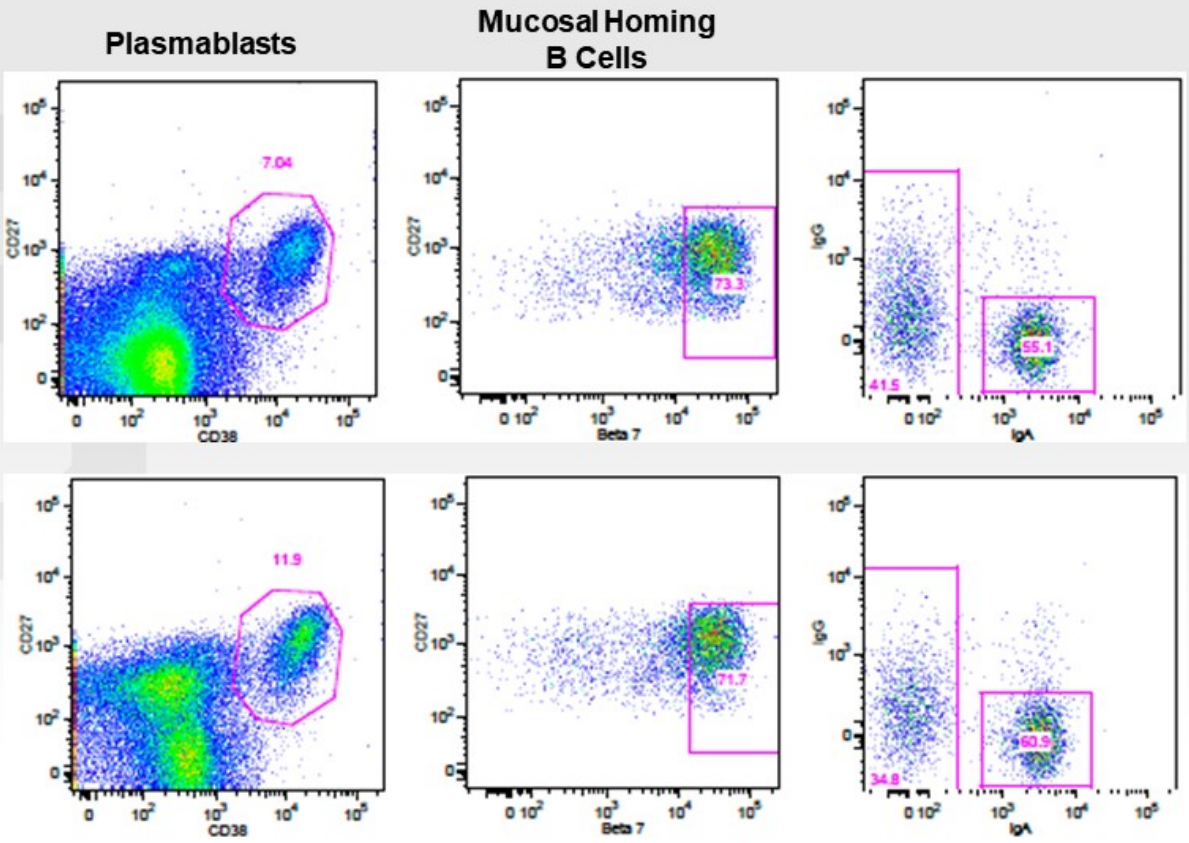


Human Norovirus Bivalent Trial (Oral tablets)
Similar B cell Response - Bivalent vs Monovalent

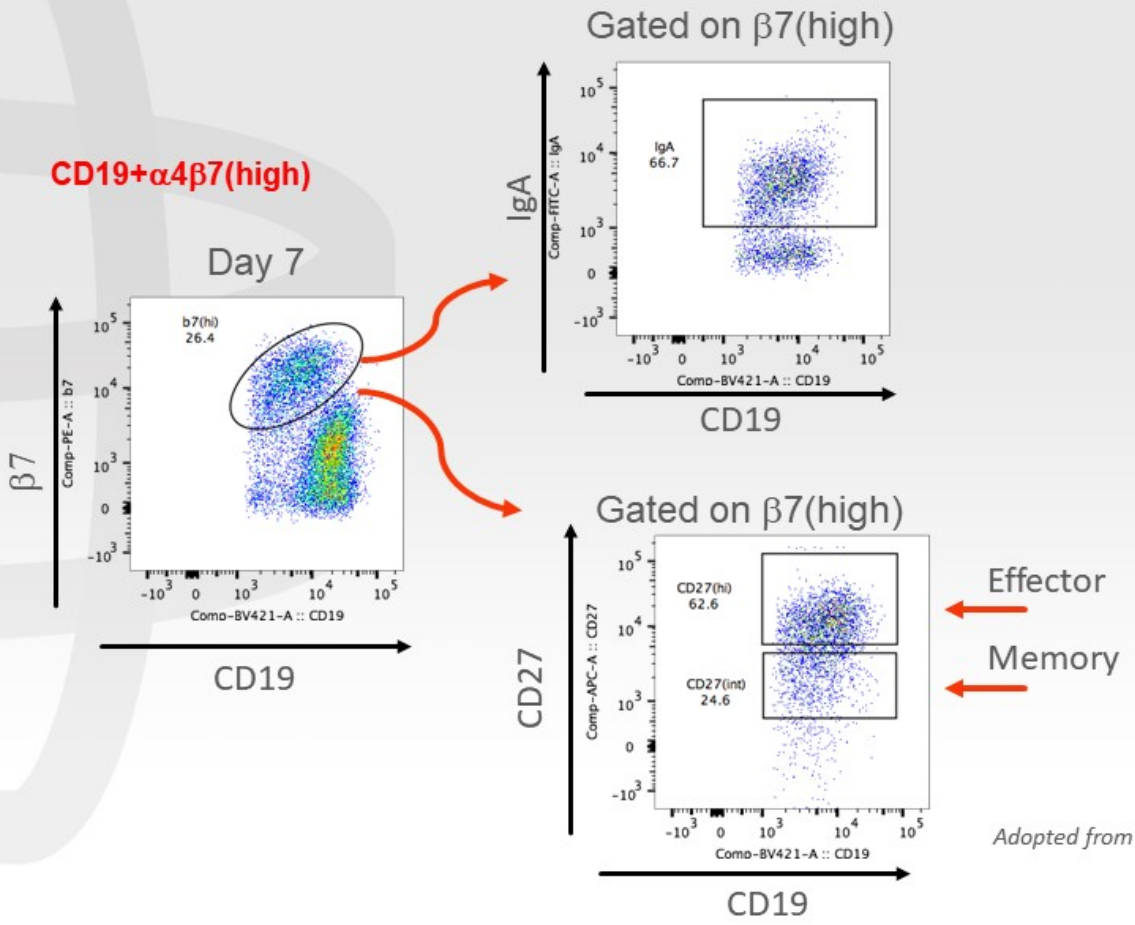
- Norovirus specific B cells (plasmablasts) are induced by vaccination.
- Counted by Antibody Secreting Cell (ASC) assay
- IgA ASC have correlated to protection in other enteric pathogen studies as well as our influenza vaccine study



Oral Vaccination Generates an Immune Response Similar to Infection



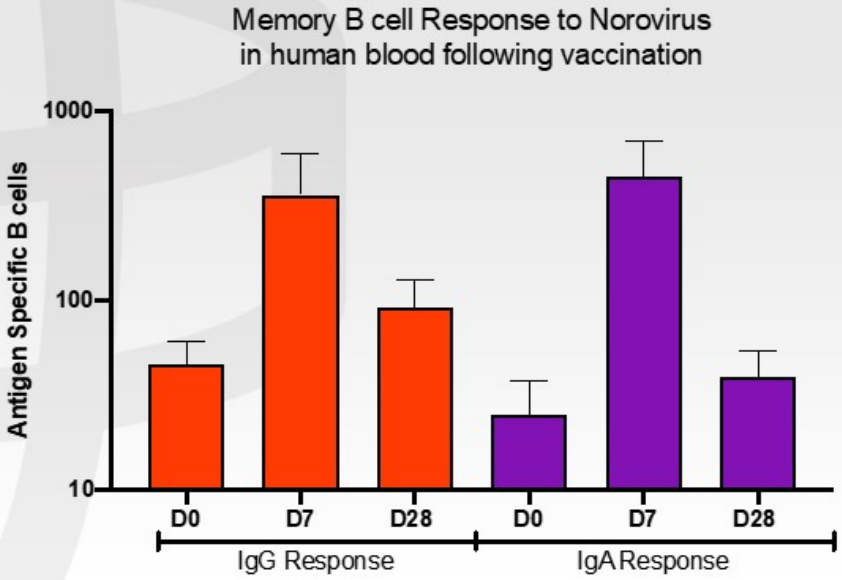
Vaccines work by “Memory” and “Effector” Responses; We can generate mucosal homing cells of both types.



Adopted from Kim, at al, JCI Insights 2018

Vaxart Norovirus Tablet Vaccine Increases Memory B cells

- IgG and IgA Memory B cells both increase in blood with vaccination
- The IgA memory B cells are likely leaving circulation by day 28 whereas significant numbers of IgG are still present



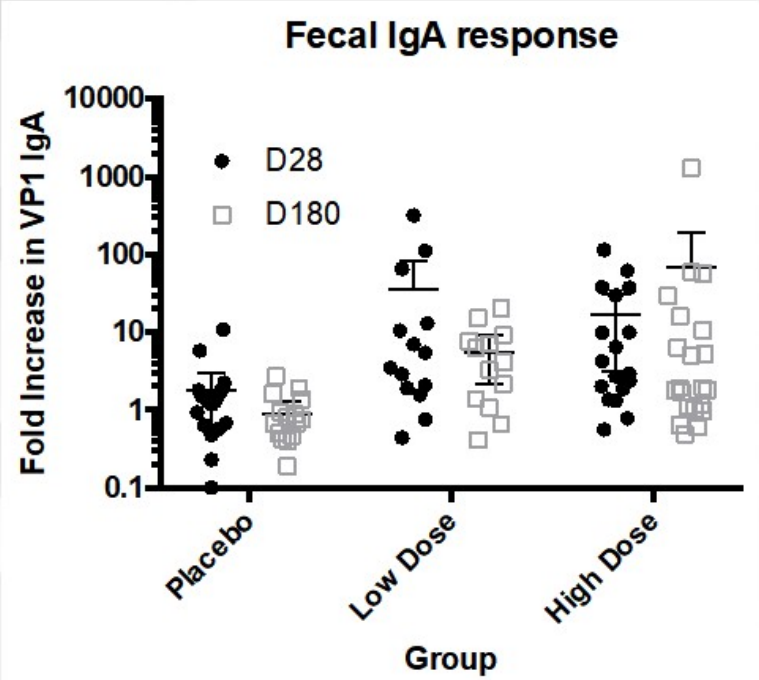
Memory Responses measured by cell treatment with IL-2 + R484 followed by measuring Antigen Specific B cells by ASC Assay

Adopted from Kim, at al, JCI Insights 2018

Increase in Mucosal IgA to VP1 can be found in Fecal Samples Post Immunization

VAXART

Substantial Effector B cells Homing to Mucosal Sites induce Local IgA Response to VP1 Post Immunization



Fecal IgA measured by Marcela Pasetti, U Maryland, Baltimore

Norovirus Oral Tablet Results

- Strong Induction of antigen specific B cells
- No interference between the two strains detected
- Memory Cell Induction, both IgA and IgG
- Migration of the memory cells out of the peripheral blood
- Induction of mucosal IgA
- Vaxart has restarted the norovirus vaccine program and will continue clinical studies by early next year

Vaxart – COVID Vaccine Issues

- Covid-19 is a significant health problem. A vaccine solution is possible. Lots of injected vaccine solutions are in late-stage trials

- Several limitations for roll-out of a needle solution during a pandemic
  - Need a qualified health care provider to administer
  - Many of the leading vaccines need to be kept frozen
  - We are all supposed to sequester and avoid contact
  - *All of this make the process of creating long-term herd immunity challenging*

- Mucosal Immunity might have advantages for COVID-19
  - Local immune responses might be able to do a better job of blocking actual infection at the site of infection
  - Subjects with gastrointestinal symptoms shed virus longer
  - Mucosal IgA and mucosal T cells have been shown to be able to inhibit viral shedding for mucosal pathogens. Should also substantially lower the rate of transmission
  - *Mucosal Immunity isn't really induced by an injected vaccine*

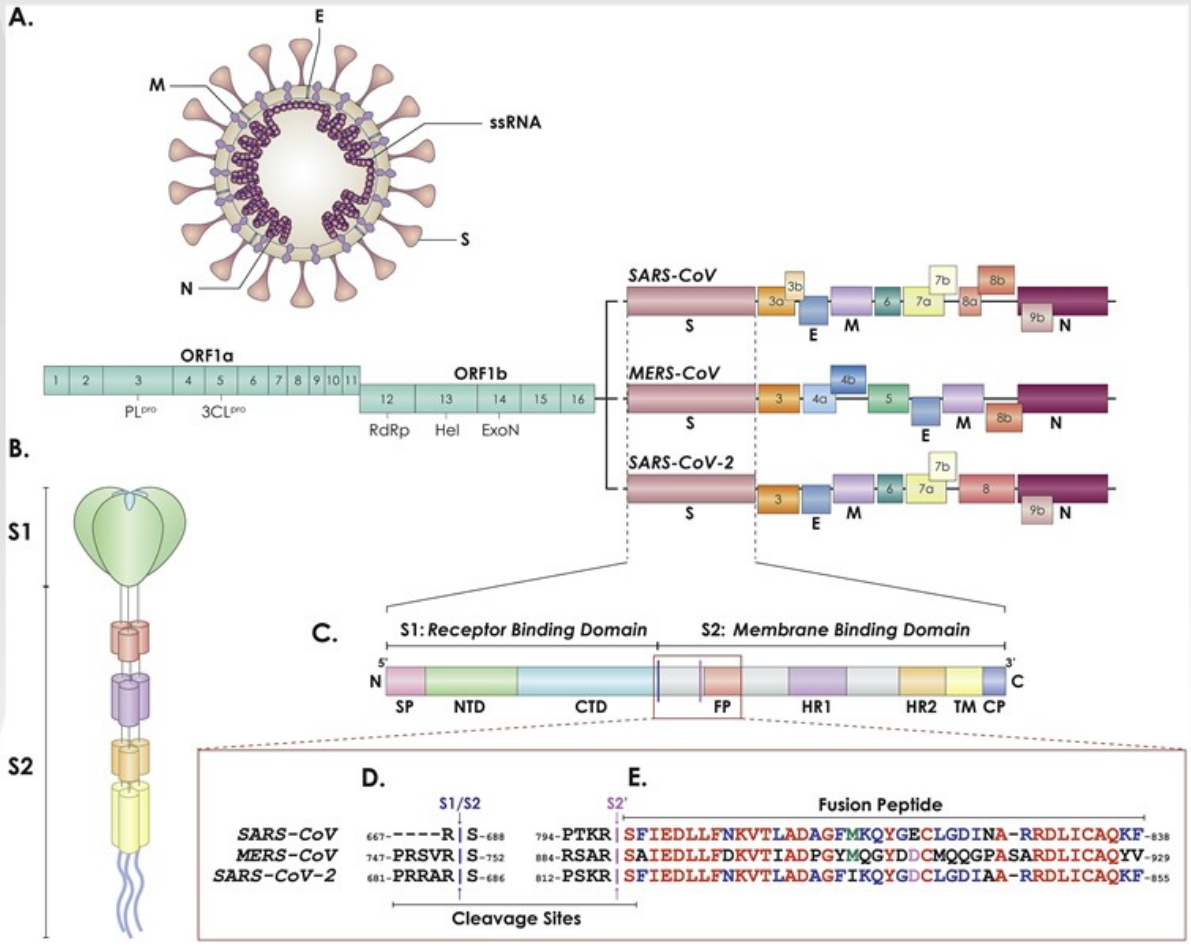
Vaxart – Oral Tablet COVID Vaccine Program

- **Goal**: Make a candidate that can induce robust antibody and T responses both systemically (blood) as well as *mucosally* (lungs, intestine, etc)
  - *Oral delivery should induce a broader immune response than an injected vaccine*

- Made several clinical candidates
  - Selected candidate with highest serum and lung neutralizing antibody responses
  - Currently evaluating these in animal efficacy studies in parallel with the human clinical trial
  - Plan is to move to a Phase II efficacy study in a region of the world with high SARS-CoV-2 infection rate

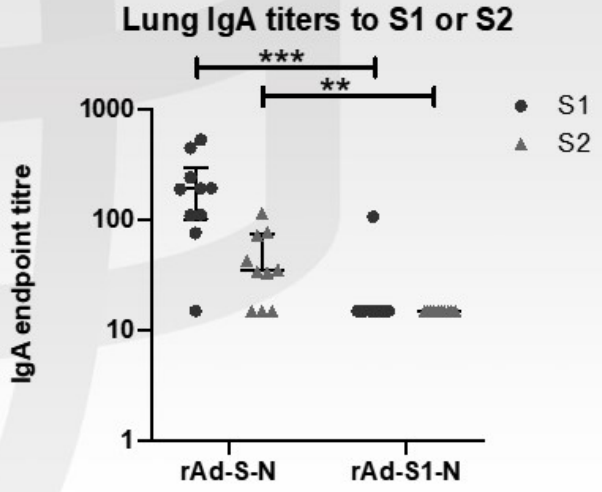
- Our candidate expresses both the S and the N protein from SARS-CoV-2
  - N is more highly conserved and has immunodominant T cell epitopes
  - S protein is great antibody target, but more variable among beta-coronaviruses. Possible that escape mutations will emerge that the S based vaccines cannot protect against

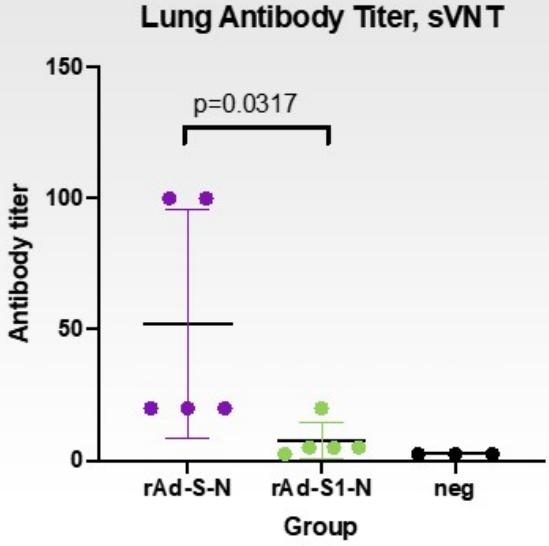
Coronaviruses – Large RNA viruses



Vaxart's rAd-S-N (VXA-CoV2-1) was superior to truncated forms of the S protein in mice

- S- Binding antibody responses equivalent for several different candidates
- Neutralizing antibody responses were better with the rAd-S-N (VXA-CoV2-1)
- Lung Antibody Titers better with full-length S protein (see below)

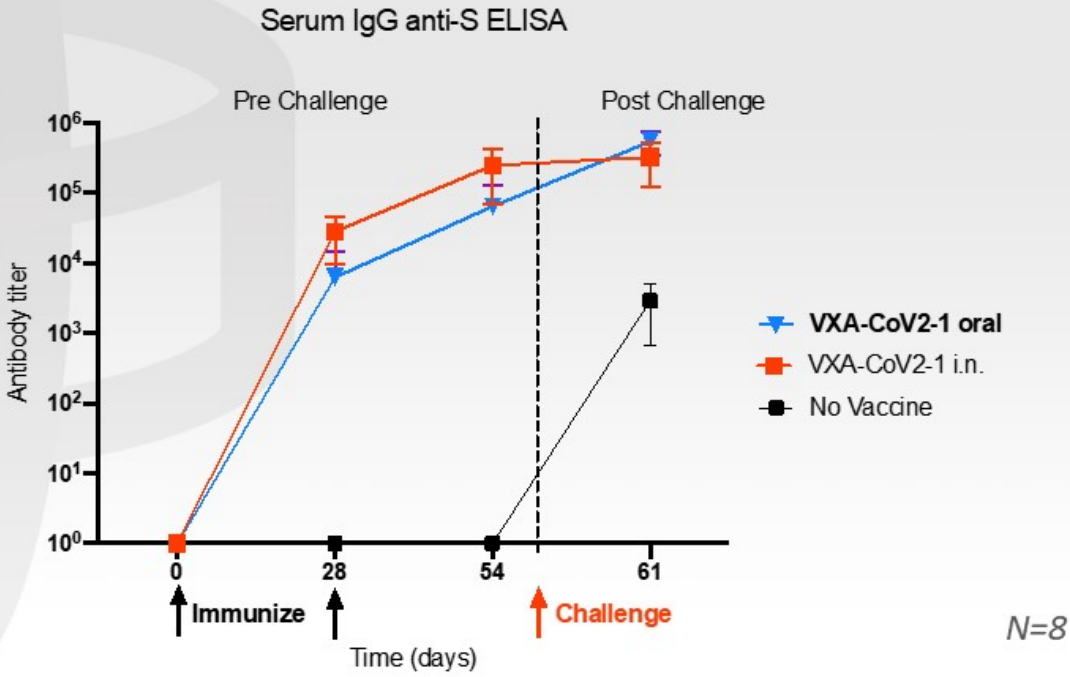




Moore et al, Biorxiv, 2020

Vaxart's Vaccine induces potent antibody responses in hamsters

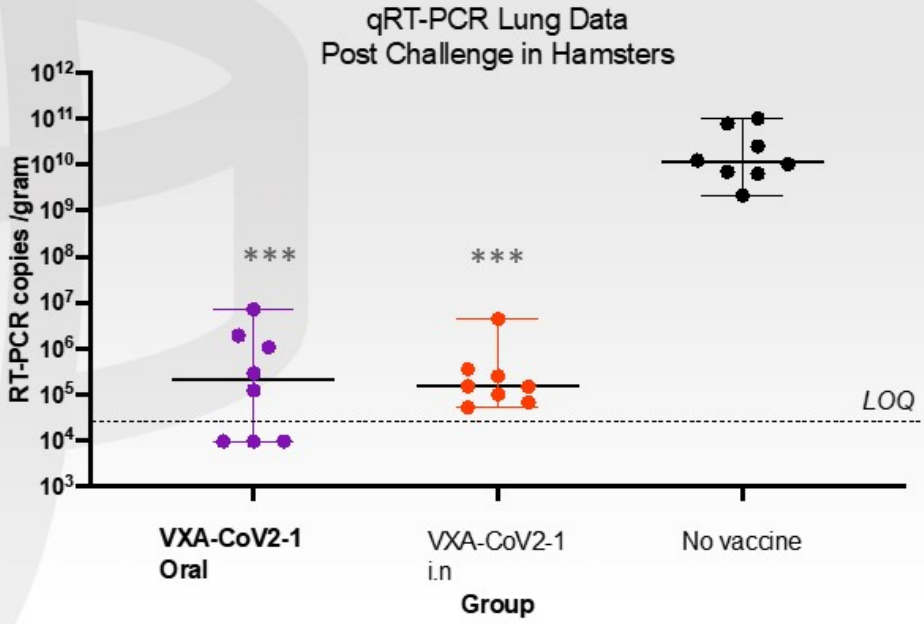
- Oral and intranasal delivery of VXA-CoV2-1 produced a similar antibody response with titers above 10,000



N=8

Vaxart's Oral Vaccine substantially protects against lung infection in a hamster challenge model

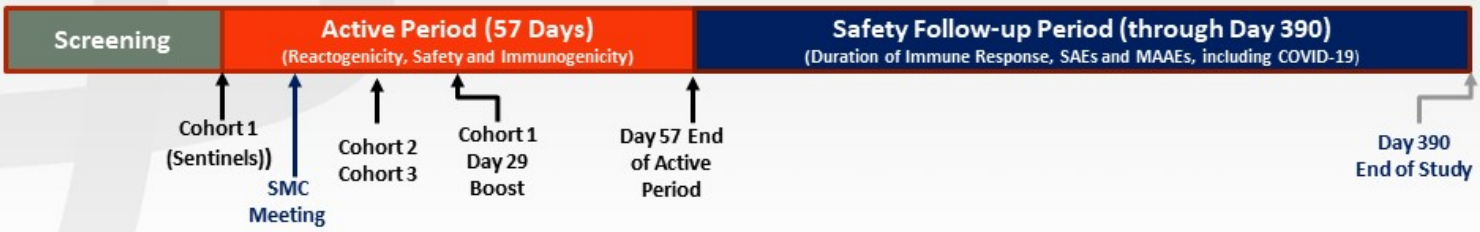
- Viral load in lungs reduced by >10,000 fold



*** P<0.001 compared to the no vaccine group

VXA-COV2-101 Phase 1 Study Design and Schema

Treatment Group	Vaccine	Dose (±0.5 log)	No. of Doses	No. of Subjects
Cohort 1 (Sentinels)	VXA-CoV2-1	$1x10^{10}$ I.U.	2	5
	SMC Review of Safety Data through Day 8 Visit			
Cohort 2	VXA-CoV2-1	$1x10^{10}$ I.U.	1	15
Cohort 3	VXA-CoV2-1	$5x10^{10}$ I.U.	1	15
			Total	35



Solicited Symptoms Post First Vaccination

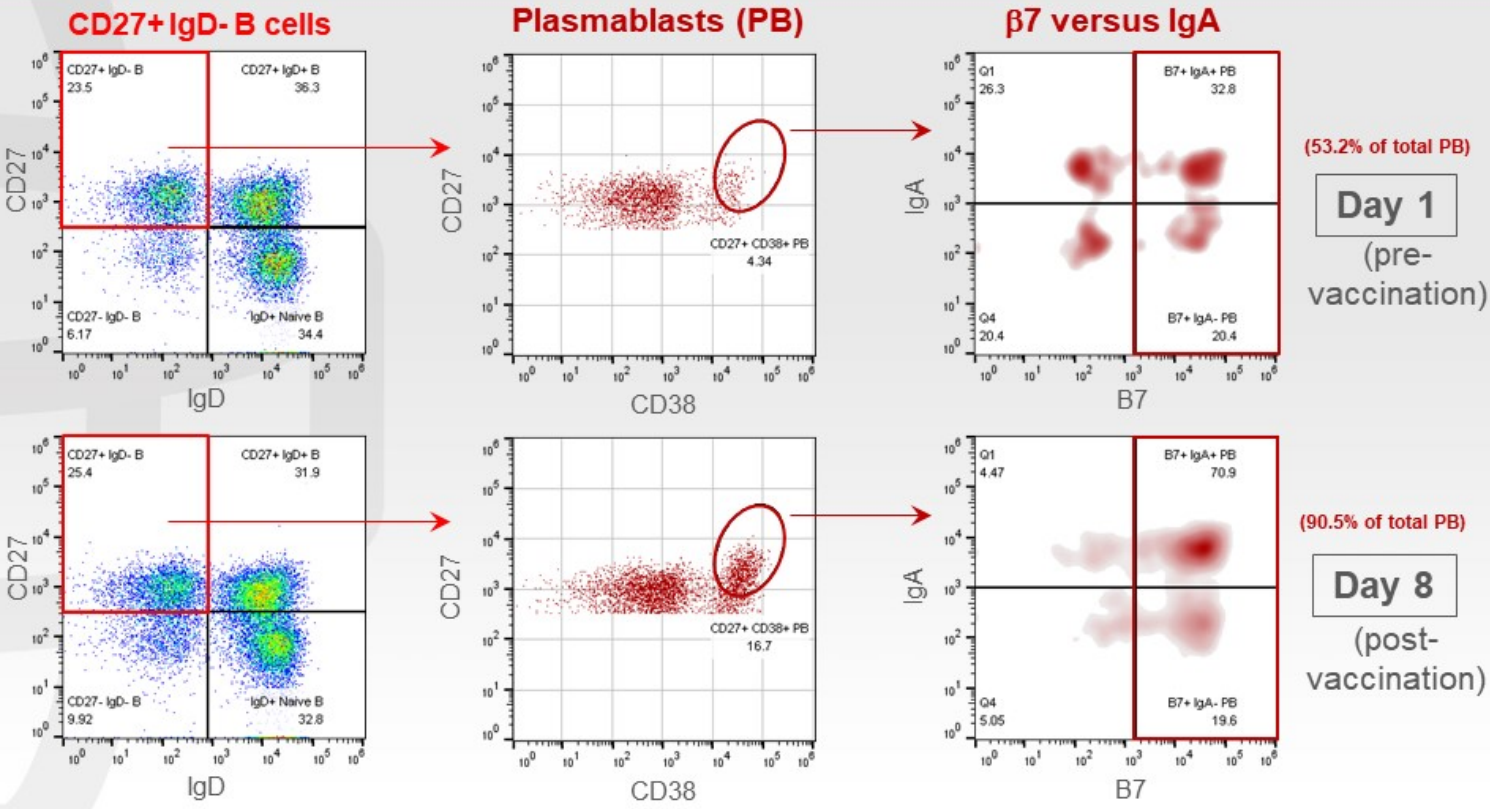
Solicited Symptom Days (1 – 8)	Low Dose (n=20)	High Dose (n=15)
No. (%) with Solicited Symptoms	4 (20)	4 (26.7)
Gastrointestinal Symptoms		
Diarrhea	0 (00)	1 (6.7)
Nausea	0 (00)	3 (20)
Vomiting	0 (00)	0 (00)
Abdominal Pain	1 (5.0)	0 (00)
General Symptoms		
Malaise/Fatigue	2 (10)	0 (00)
Myalgia (Muscle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

- Most Solicited Adverse Events mild and transient; few moderates @ Days 5 or 6
- No SAEs or MAAEs reported to date

Sentinel Analysis – Day 8 Post Vaccine Samples

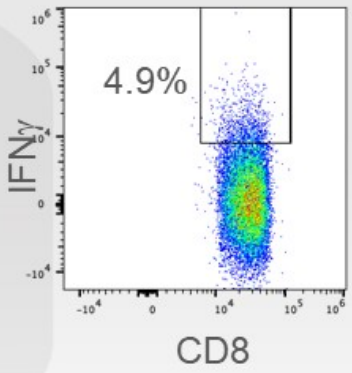
- Immune Responses in all subjects tested to date (N=4)
- Expansion of the plasmablast population (B cells that will eventually make vaccine specific antibodies)
- Increased ASC responses
- T cell responses
  - Heavy bias toward TH1 not TH2
  - S protein specific responses expanded in all subjects tested to date; majority of subjects have N specific responses as well
  - CD8 responses are particularly robust, polyfunctional in nature

Increase in plasmablast frequencies on day 8 after vaccination



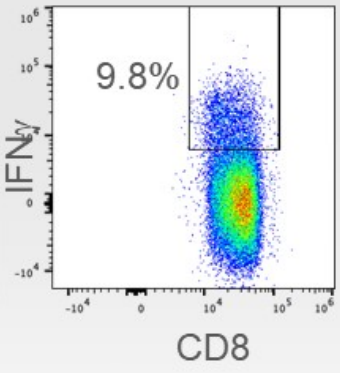
Increase in CD8 T cell responses on day 8 after vaccination

CD8 T cells measured by intracellular cytokine staining post stimulation of PBMCs with the S – protein Peptide library



Day 1

(pre-vaccination)



Day 8

(post-vaccination)

Summary – COVID vaccine results

- Vaxart's clinical candidate selected based on increased mucosal immune responses in mice
- Proven efficacious in a hamster challenge study
- Human phase I trial is completely enrolled
  - Well-tolerated safety profile based on solicited adverse events
  - Early signs of immune cell activation in the sentinel subjects based on day 8 flow cytometric analysis of peripheral blood mononuclear cells

Acknowledgements

- Vaxart Research
  - Mario Cortese
  - Susan Johnson
  - Emery Dora
  - Karen Lin
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  - David McIlwain
- University College Cork
  - Anne Moore
- Visimederi
  - Laura Palladino
  - Emanuele Montomoli