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): February 3, 2021

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.)**

170 Harbor Way, Suite 300, 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.

On February 3, 2021, Vaxart, Inc. (the "*Company*") presented the Phase 1 data as part of a clinical trial update at the New York Academy of Sciences Symposium "*The Quest for a COVID-19 Vaccine*". 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, dated February 3, 2021

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: February 3, 2021

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

Feb 2021

Vaxart's Oral Vaccine Candidate for Prevention of Covid-19

Hold the Needles and the Ice

VAXART

UNLOCKING THE FULL POTENTIAL OF ORAL VACCINES

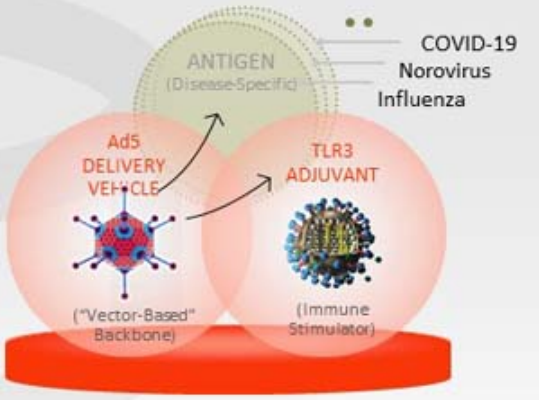
Forward-Looking Statement

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.

Proprietary Oral Vaccine Platform : Vaccine Tablets

VAXART

Intestinal Delivery + Targeted Immune Activation



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

VAAST™: Vector-Adjuvant-Antigen Standardized Technology

Manufacturing Standardized	Adjuvant & Antigen are Co-expressed: Potential Safety, Efficacy Benefits	Patents with Broad Composition of Matter and Method Claims

Platform has been tested in humans for a different respiratory pathogen

Double-Blind, Placebo-Controlled - with Active Comparator (Fluzone)

- **Funded by HHS/ASPR/BARDA[1] as innovative approach to develop more effective influenza vaccines**
- **Three Groups received a one-time administration of:**
  - **Vaxart Tablet**: Vaxart tablet vaccine + placebo IM injection
  - **Active Comparator**: Fluzone IM injection + oral placebo tablet
  - **Placebo**: Placebo IM injection + oral placebo tablet
- **Challenge at Day 90-120 post-randomization with A/CA/2009/pH1N1**
  - **Target 2:2:1 ratio (Vaccine groups vs placebo)**

READ-OUTS

- **Primary endpoint:**
  - Number and % of Vaxart subjects protected against **influenza illness** following challenge as compared to placebo and Fluzone
- **Secondary endpoint:**
  - Number and % of Vaxart subjects protected against **influenza infection**, as measured by qRT-PCR in nasal swabs following challenge as compared to placebo and Fluzone

1) HHS/ASPR/BARDA: U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response / Biomedical Advanced Research and Development Authority, Contract no.: HHSO 100201500034C

Favorable Safety and Tolerability Profile Observed

Solicited Symptom	Placebo	VXA-A1.1	Fluzone
	(n=36)	(n=70)	(n=72)
Number of Subjects with Solicited Symptom TEAEs	**15 (42%)**	**20 (29%)**	**26 (36%)**
General Disorders and Nervous System Disorders			
Malaise/Fatigue	5 (14%)	3 (4%)	5 (7%)
Headache	7 (19%)	5 (7%)	6 (8%)
Myalgia/body aches	1 (3%)	1 (1%)	0
Fever	0	2 (3%)	0
Gastrointestinal Disorders			
Diarrhea	5 (14%)	4 (6%)	0
Abdominal Pain	1 (3%)	0	1 (1%)
Nausea	1 (3%)	4 (6%)	3 (4%)
Vomiting	0	0	1 (1%)
Local Symptoms			
Pain at injection site	1 (2.8%)	**2 (2.9%)**	**10 (13.9%)**
Tenderness at injection site	1 (2.8%)	**3 (4.3%)**	**19 (26.4%)**

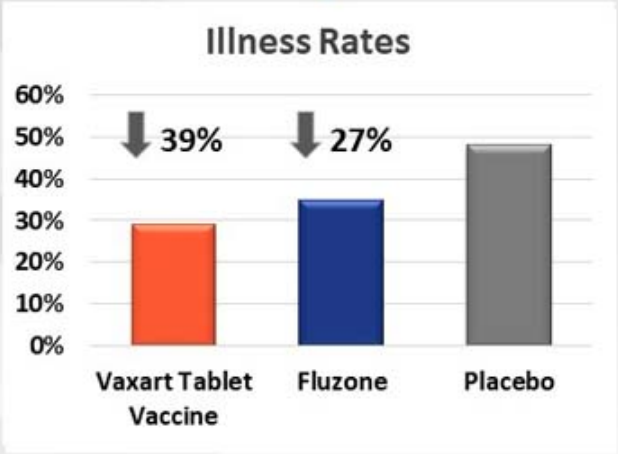
Liebowitz, et al, Lancet ID, 2020

Reduction in Illness and Infection Rates Similar to Fluzone

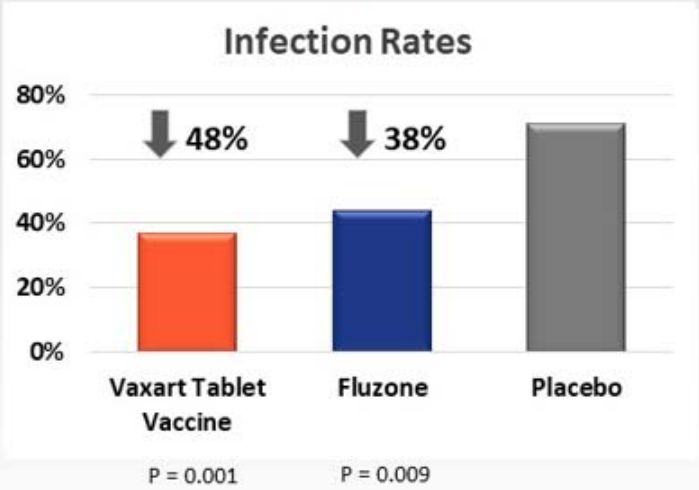
Reduction in Illness and Infection Rates Trended Superior to Fluzone

VAXART

Protection Against Illness



Protection Against Infection



P = 0.001 P = 0.009

Defined by % of subjects shedding 36 hours post challenge to remove pass-through virus

Vaxart Tablet Vaccine: Protection Highly Correlated With Mucosal Response

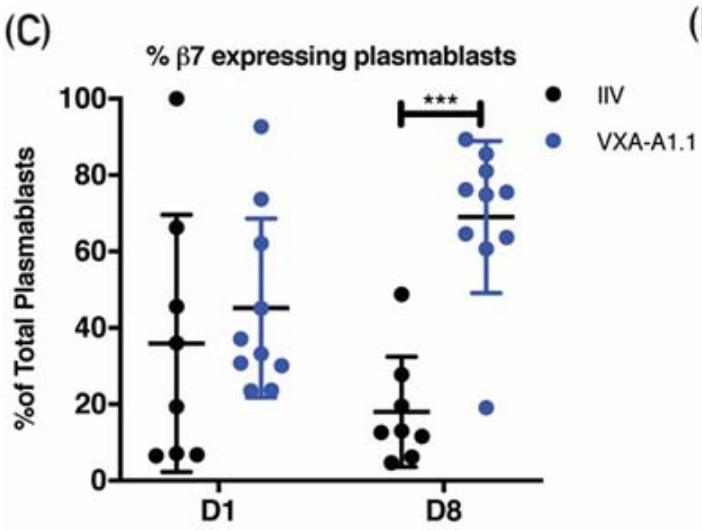
Liebowitz, et al, Lancet ID, 2020

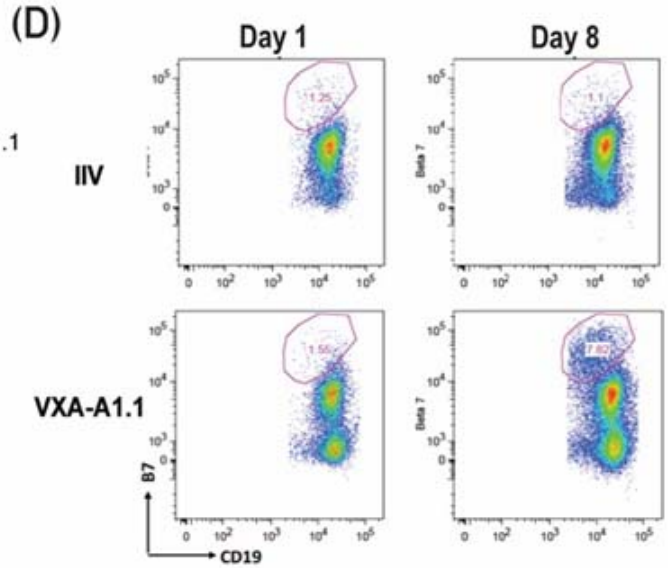
IgA ASC was the most important immune parameter to predict protection from oral immunization

- Random Forest Analysis
  - IgA ASC most important immunological feature for protection against shedding for the Oral Vaccine
  - HAI most important feature for protection against shedding for the QIV vaccine
- Logistic fit analysis (rough correlation between IgA ASC Counts and predicted protection rate for the oral influenza vaccine)

IgA ASC Count per 1e6	Predicted Protection Rate
2.3	50%
55.4	75%
108.4	90%
144.5	95%

Vaxart Vaccine Specifically Elicits Increased Expression of Mucosal Homing Receptor α4β7 on Activated Plasmablasts





*** P<0.0001

Liebowitz, et al, Lancet ID, 2020

COVID Vaccines – Where are we now?

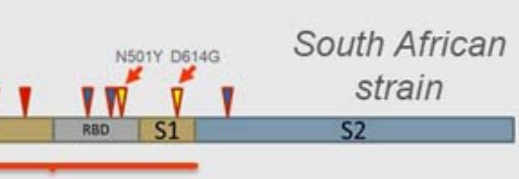
VAXART

- Vaccine developers have made advanced candidates at incredible speed
- Several needle-based vaccines have completed Phase 3
  - Expression of the S protein in people leads to substantial protection (symptomatic illness) against matched strains (Moderna, Pfizer, Astrazeneca, Janssen)
  - S Protein vaccine also protective (Novavax)
  - Drop-off in efficacy noted when the vaccine strain doesn't match the circulating strain
- Roll out >1.2M vaccinations a day in the US under EUA
  - 8 months to immunize 300 M people, 16 months to immunize 600M people
- Coronavirus S mutations are showing up without vaccine selective pressure, including mutations in the RDB
- Discussion about building new vaccine strains that match the new coronavirus mutants

COVID-19 Vaccine Development and Distribution Efforts are Being Outpaced by Rapidly Emergent Strains

VAXART

Rapid Emergence of new SARS-CoV-2 strains



- New mutations are starting to accumulate in the S1/RBD domain, where neutralizing antibodies generated by current vaccines bind

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

Rate Limiting Step is the time for injected large populations: Vaxart Takes Away the Needles

Rapid Emergence of new SARS-CoV-2 strains

Vaccine Development

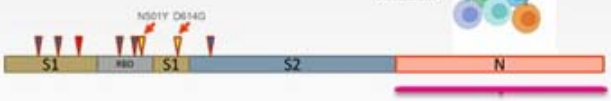
Rapid Distribution & Administration

Get Off The Wheel – Shorten the Time to Herd Immunity

Vaxart's solution

- Room temperature stable tablet, easy to produce, distribute, and administer

T cells



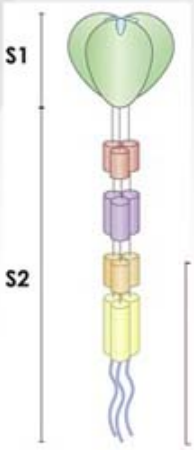
- More conserved across strains
- Strong target for T cells

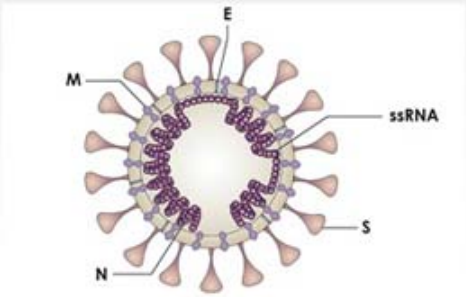
Goal: Drive CD8 T cell responses and mucosal responses with our Covid-19 vaccine candidate

VAXART

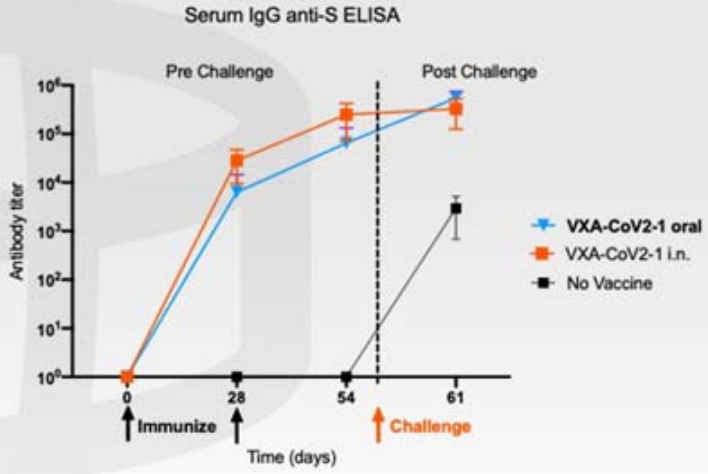
Candidate VXA-CoV2-1

- Expressing both S and N proteins
  - S is good antibody target, but also has a lot of T cell epitopes
  - N is more conserved and a good target for T cell responses
- Made several different vaccine candidates
  - Chose construct that made highest lung IgA responses in mice
- rAd + TLR3 should drive T cell responses toward Th1





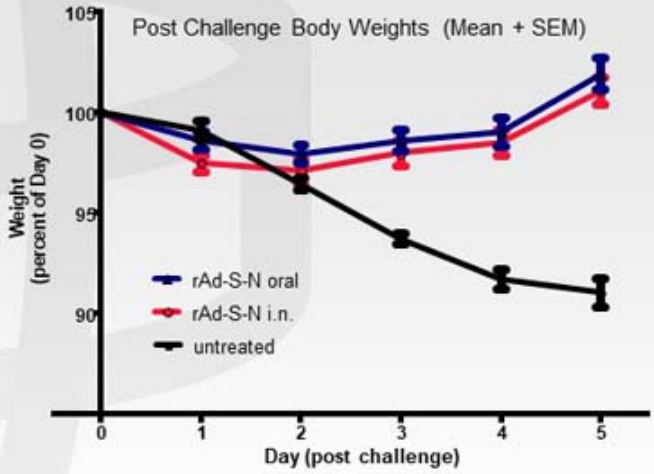
Oral COVID-19 vaccine candidate induces potent antibody responses in hamsters



- Oral administration induced specific antibody titers above 10,000 over background
- Oral administration performed as well as intranasal

- Vaxart rAd vaccine candidate expressing the S and N protein used at 1:10/1:100 of the human dose
- Two doses given, 0 and 4 weeks. rAd given at 1e9 IU. Challenge at week 8.
- Administered orally and intranasally (i.n.)

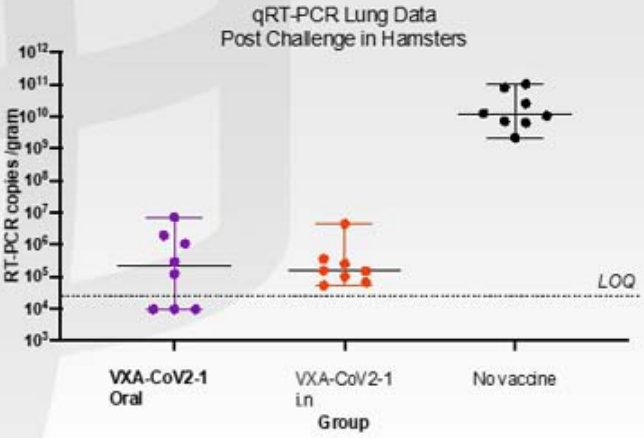
Oral COVID-19 vaccine protects against a key clinical outcome, weight loss, in a hamster challenge model



- The Syrian hamster is a very sensitive COVID-19 model
- Syrian hamsters have an ACE2 receptor that can bind SARS-CoV-2
- Hamsters challenged nasally with COVID-19 virus have similar disease as humans
- Clinical symptoms of COVID-19 infection include weight loss

Orally vaccinated hamsters protected against lung COVID-19 infection as measured by qRT-PCR

4-5 logs reduction in lung viral load in hamsters that received two oral vaccine doses as compared to non-vaccinated animals



Oral administration performed as well as intranasal vaccination after intranasal viral challenge as assessed by several different quantitative measures of COVID disease and infection

VXA-COV2-101 Phase 1 Study Design and Schema

- Single Dose, Oral Tablet Study at Low and Medium Doses
- Small Sentinel Cohort that was boosted
- **Primary (Safety) and Secondary (Immunogenicity) Endpoints Met**

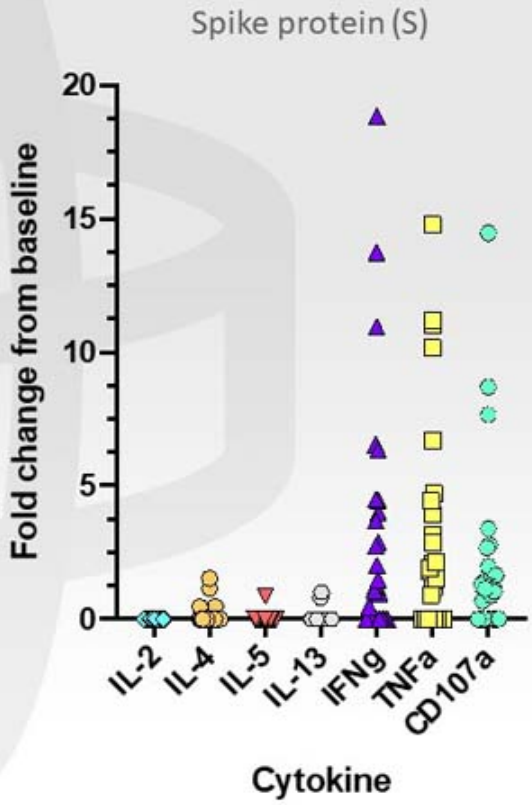
Treatment Group	Vaccine	Dose (±0.5 log)	No. of Doses	No. of Subjects
Cohort 1 (Sentinels)	VXA-CoV2-1	$1x10^{10}$ I.U.	2	5
	SMC Review of Safety Data through Day 8 Visit			
Cohort 2	VXA-CoV2-1	$1x10^{10}$ I.U.	1	15
Cohort 3	VXA-CoV2-1	$5x10^{10}$ I.U.	1	15
			Total	35

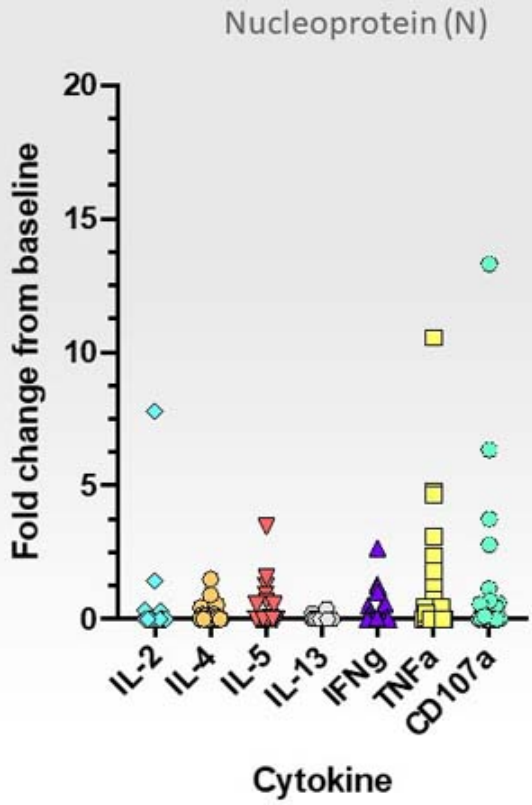
Solicited Symptoms Post Vaccination

Solicited Symptom Days (1 – 8)	Low Dose (n=20)	High Dose (n=15)
No. (%) with Solicited Symptoms	4 (20)	10 (66.7)
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)
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)

- 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

Vaxart's oral vaccine shows preferential Th1 responses, inducing a strong CD8 cytotoxic response

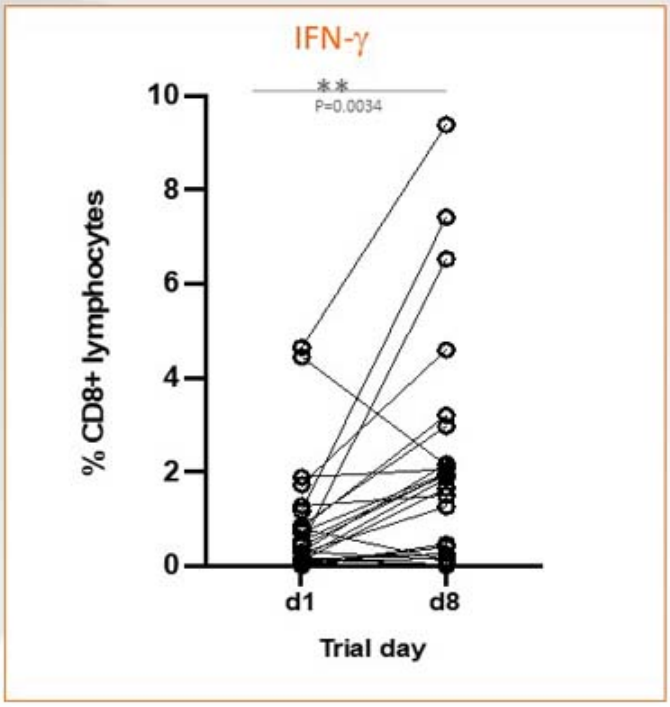


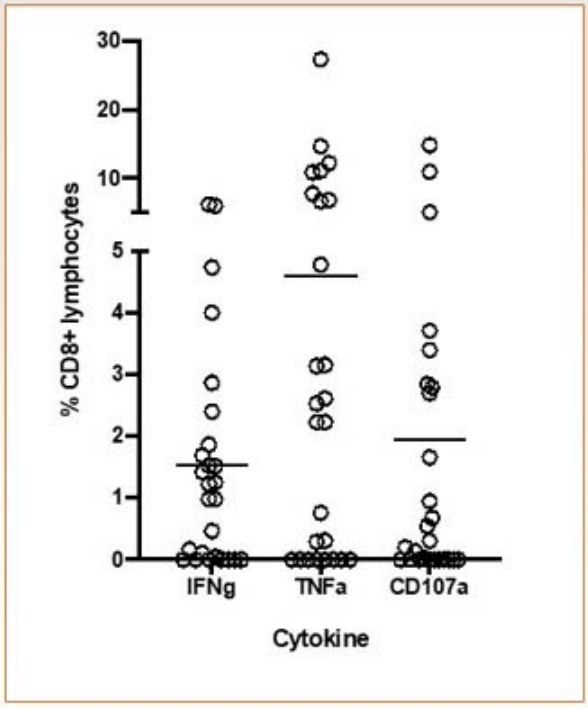


Restimulation with S or N peptide pools on PBMCs from pre and post vaccination. Th2 cytokines are CD4+ T cells, Th1 cytokines are CD8+ T cells. Fold change is calculated over the pre-vaccination sample.

Vaxart's Oral Vaccine generates robust CD8 T cell responses

Vaxart's Oral Vaccine generates high numbers of S specific IFN-γ, TNFα and CD107a producing T cells post immunization.





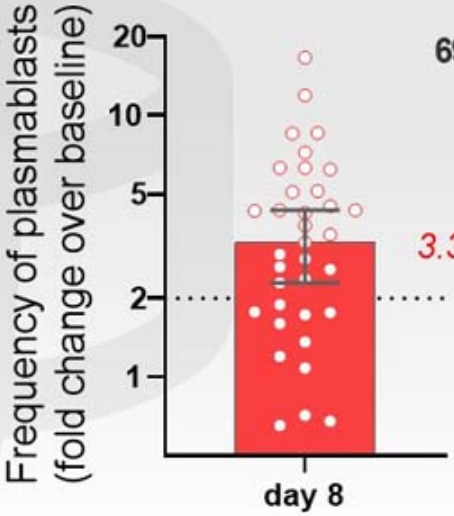
Why T cells may be important for COVID

- Cross-protective
- Long-lasting
- Reduces severity and length of the infection
- Mucosal T cells may be capable of blocking shedding and transmission
- Higher T cell responses correlated to protection against COVID disease in in prospective study of first responders (Wylie, et al, Medrxiv, 2020)
- Broader antigenic repertoire than antibody responses - T cell responses recognize at least 30-40 epitopes in each donor, as measured in 99 subjects. (Tarke, Cell Reports Medicine, Jan 21)

B cell Responses to Oral Immunization

VAXART

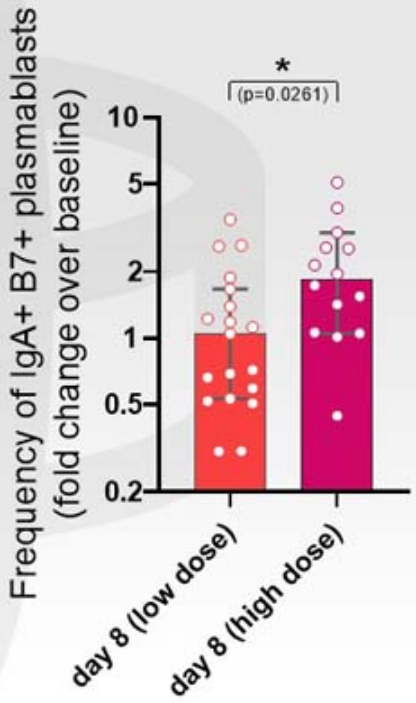
Sharp increase in plasmablast frequencies on day 8 after vaccination

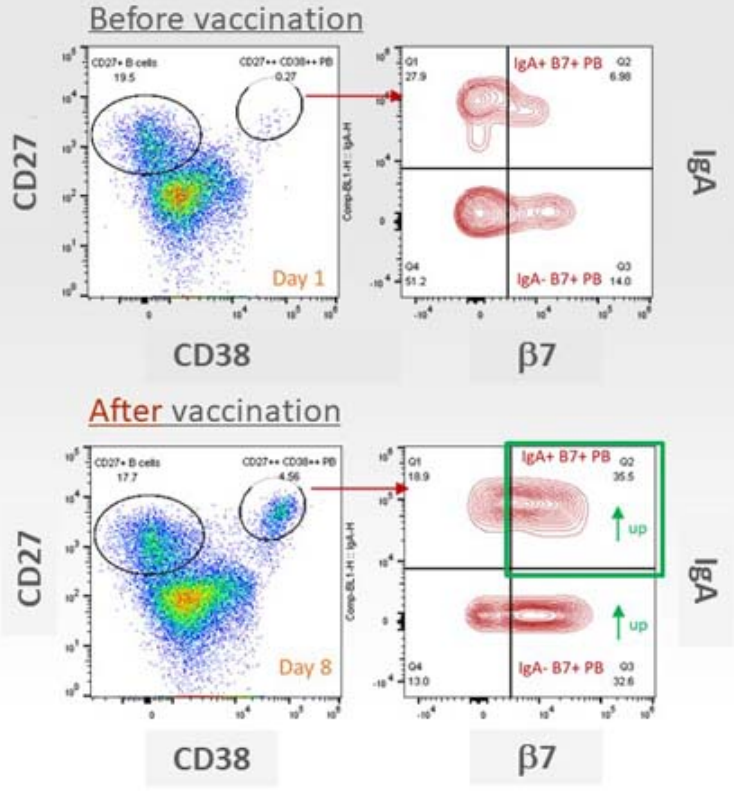


69% *percentage of vaccinees with >2 fold increase in PB frequencies*

3.3 median fold change

Vaccine-induced plasmablasts preferentially express IgA and upregulate the Mucosal Homing Receptor α4β7, particularly at higher dose





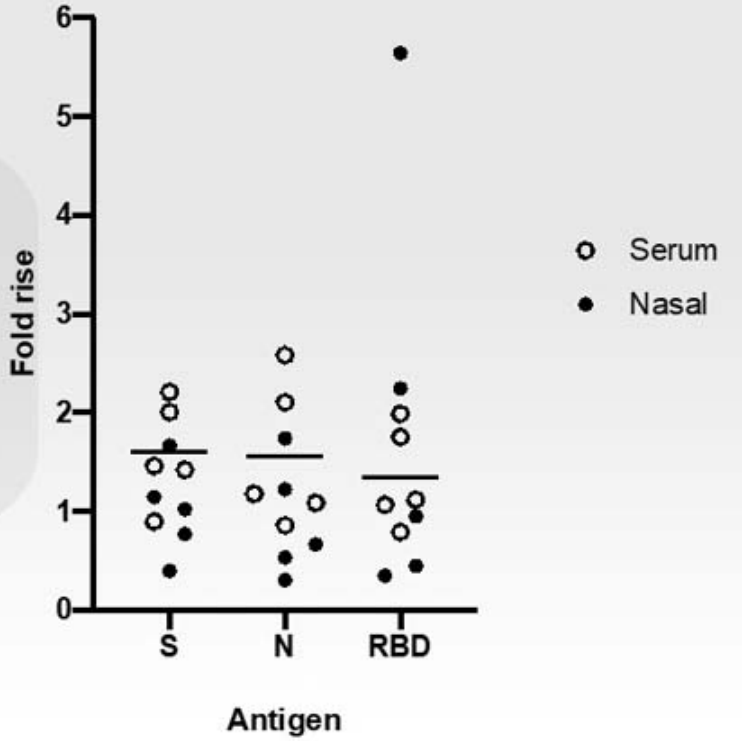
52% of participants showed 2-fold or above increase in specific IgA to RDB, S, or N

RBD responses	S responses	N responses	Any response
16/35	11/35	13/35	18/35

Preliminary Data

Responses calculated as a 2 or higher fold increase at d29 above pre-vaccination baseline measured in nasal, saliva, or serum samples.

100% of participants given two doses had an increase in specific IgA in one or more compartments



Preliminary Data

Fold rise d1 to d57 in serum and nasal IgA. 100% had a fold rise above 1.5 times pre-vaccination levels in at least one of serum or nasal samples.

Vaxart Strategy for COVID

Summary for VXA-CoV2-1

- Met Primary and Secondary Endpoints
  - Well-tolerated
  - Easy to distribute and administer (Tablets)
  - Highly immunogenic on eliciting T cells
  - Dose dependent responses observed with B cells
- Formulation and dosing will be evaluated in subsequent clinical studies to increase antibody responses

US will be immunized in 6 months

- Next generation vaccine approaches will need to be able to boost prior immunized people
- Evaluate cross-reactivity and potentially building new vaccines that address emerging escape mutants