

**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): June 18, 2020

Vaxart, Inc.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35285</u> (Commission File Number)	<u>59-1212264</u> (IRS Employer Identification No.)
<u>385 Oyster Point Boulevard, Suite 9A, South San Francisco, California</u> (Address of principal executive offices)		<u>94080</u> (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:

<u>Title of each class</u>	<u>Trading symbol</u>	<u>Name of each exchange on which registered</u>
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 Regulation FD Disclosure.
7.01.

Vaxart, Inc. (the “Company”) intends to present an updated corporate presentation at the Raymond James Human Health Innovation Conference on June 18, 2020. A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K. The corporate presentation will also be available on the Company’s website. 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 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 Financial Statements and Exhibits.
9.01.

(d) Exhibits

Exhibit Number	Description
99.1	<u>Vaxart, Inc. Corporate Presentation, June 18, 2020.</u>

SIGNATURES

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

Vaxart, Inc.

Dated: June 18, 2020

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



VAXART

The Pill Against Pandemics
A Disruptive Oral Vaccine Platform

Raymond James Virtual Human Health Innovation Conference

June 18, 2020

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 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 "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 may experience manufacturing issues and delays due to events within, or outside of, Vaxart's control, including the recent outbreak of COVID-19; 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.



Disruptive Oral Vaccine Platform



Convenient mode of administration

No needles, self administration (no appointments, no lines, social distancing)

Potential best-in-class efficacy against COVID-19 and other airborne viruses

Activates mucosal immunity, first line of defense, plus multiple immune system mechanisms

Environmentally friendly

No disposal of potentially billions of vials, syringes, needles, gloves, masks, cotton balls, etc.

Low cost distribution and storage

No refrigeration, room-temperature stable

Rapid Pandemic Response Platform

Plug-n-play platform, ready for future pandemics

Environmentally friendly vaccination campaigns

Even in large scale

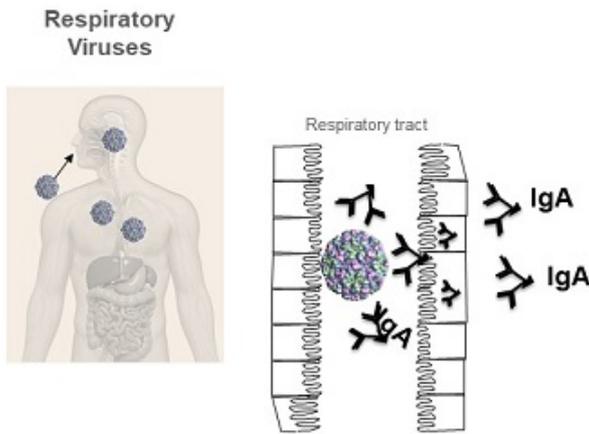
- A COVID-19 vaccination campaign would include ...
 - 200+ million in the US
 - 2-3+ billion globally



X 3 Billion

Protection by harnessing the multifunctionality of the mucosal immune system

Respiratory Viruses : The Vaxart platform gets the right molecule to the right place



Vaxart Generates Antigen Specific IgA at Nasal and Respiratory Sites

Evidence *suggesting* a Mucosal Correlate or Surrogate of Protection

- Influenza (IgA, $\alpha 4\beta 7$ IgA ASC*)
- RSV (Nasal IgA, Memory IgA)

We believe this may be the case for COVID-19 as well

References:

- Ambrose, et al., *Vaccine*, 2012
- Gould, et al., *Frontiers in Microbio*, 2017
- Habibi, et al., *Am J Resp and Crit Care Med*, 2015
- Joyce, et al., *Vaccine* 2018
- Kim, et al., *Sci Reports* 2016
- Liebowitz et al., *Lancet Infectious Diseases*, Jan 2020



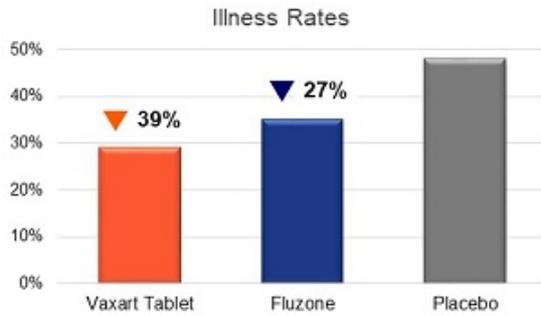
Proven Efficacy: Protection against a pandemic respiratory pathogen (2009 H1N1 influenza) after oral tablet delivery

H1N1 Pandemic vaccine made rapidly, tested in animals in a matter of weeks

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

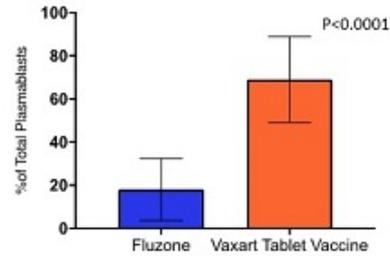


Reduction in Illness following challenge



Vaxart Tablet Vaccine: Protection Highly Correlated With Mucosal Response In Humans

% of B cells that express the mucosal homing receptor



Liebowitz, et al, *Lancet ID*, 2020



Safe, with Tolerability Comparable to Placebo

BARDA-funded flu study



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

460 patients in safety database, dosed across 3 viruses

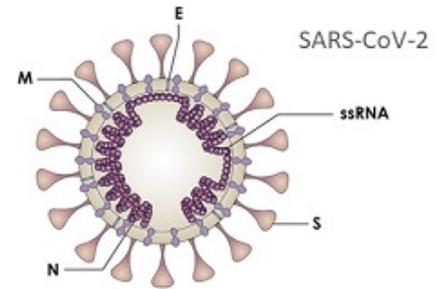
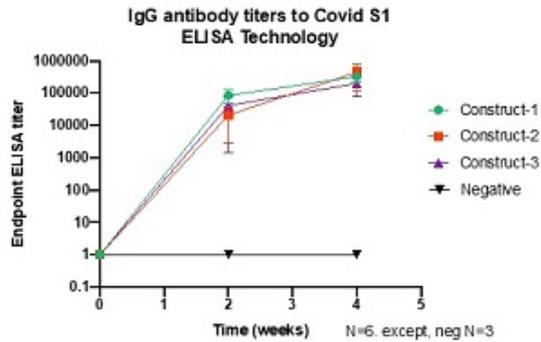
- Flu: 245
- Influenza: 46
- Norovirus: 171



Oral COVID-19 Vaccine Development

Vaxart Program is Advancing Exponentially

- Final vaccine candidate selected with the potential to generate broad responses
 - COVID-19 is a respiratory tract infection and this vaccine will promote *mucosal* and systemic immune responses



Advantages of our COVID-19 vs others

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

Oral COVID-19 Vaccine – Phase 1 Ready

CDMO Partners

- Tech Transfers Complete
- GMP Bulk Vaccine in Progress



- **Clinical/Regulatory Activities**

- IND submission in June
- Clinical Study FPI Summer 2020
 - *Phase 1 open label, dose ranging*



Prophylactic & Therapeutic Oral Vaccine Candidates

		Trials Conducted to Date or In Progress				Marketed
		Preclinical	Phase 1	Phase 2	Phase 3	
PROPHYLACTIC VACCINES						
Norovirus ¹	Bivalent					
Seasonal Influenza ²	Monovalent					
	Quadrivalent					
Influenza	Universal ³					
COVID-19						
RSV ⁴						
THERAPEUTIC VACCINES						
HPV ⁵	HPV, cervical dysplasia and/or cancer					

- 1) Bivalent Phase 1 demonstrated IgA ASC response rates of 90 – 93% for GI.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.

Norovirus Vaccine \$3B+ U.S. Market

Government Policy will Drive Demand

	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+



Development / Competitive Status

- Vaxart vaccine Phase 1 complete
- Phase 2 Ready
 - Challenge study
 - Safety and Immunogenicity study
- Partnering discussions ongoing



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

Management Team with Deep Experience in Vaccines

	<p>ANDREI FLOROIU, MBA Chief Executive Officer</p>	<p>Strategy, Corporate Finance, Biopharma Investing, Vaccines</p>			
	<p>SEAN TUCKER, PHD Founder and Chief Scientific Officer</p>	<p>Mucosal Immunology Gene Delivery</p>			
	<p>SHAILY JAINI GARG SVP, Clinical Development and Project Management</p>	<p>Global Clinical Development, Regulatory Affairs and Project Management</p>			
	<p>BRANT BIEHN SVP, Commercial Operations</p>	<p>Global Market Development, Sales and Business Development</p>			
	<p>MARGARET ECHERD, CPA MBA Vice President, Corporate Controller</p>	<p>Tech & Devices, Multiple Financings</p>			

Highlights

- **Disruptive Oral vaccine platform**
 - Validated approach: BARDA-funded flu challenge study
 - Could emerge as the ideal solution for COVID-19
 - Potentially best in class efficacy: mucosal & systemic immunity
 - Appeal of oral administration, low cost across supply chain, environmentally friendly
 - Advantages apply to other airborne & mucosal viruses - e.g., flu, norovirus, etc.)
- **Covid-19 program advancing rapidly**
 - Phase 1 to start in Summer 2020
 - Manufacturing in place
- **Norovirus program phase 2 ready**
- **Rapid response pandemic platform:** plug-n-play, ready for future pandemics
- **Strong balance sheet:** ~\$30M cash on hand per March 31



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