

**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): September 23, 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 7.01. Regulation FD Disclosure.

Vaxart, Inc. (the “Company”) intends to present an updated corporate presentation at the SVB Leerink Virtual CybeRx Series Vaccine Forum on September 23, 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, September 23, 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: September 23, 2020

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



The Pill Against COVID-19

SVBLEERINK
2020 CybeRx Call Series

September 23rd 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 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.

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)



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

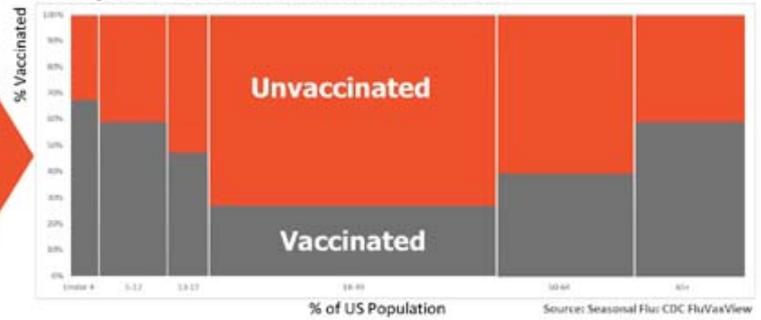
- ✦ No medical personnel needed
- ✦ No vaccination centers needed

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%

2017/18 US FLU VACCINATION BY AGE



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

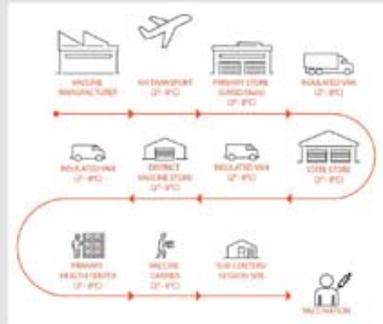
Significantly simpler and cheaper for national and local governments to distribute and stockpile a pill vs. an injectable



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 18th 2020

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

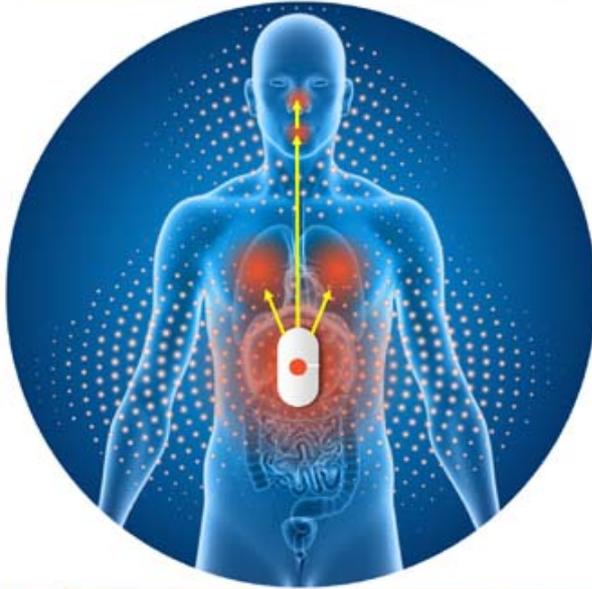
The New York Times, September 18th 2020

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

Politico, August 3rd 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 1st line of defense against airborne viruses



Protection against Airborne Viruses:

Oral vaccine activates immunity in the right places

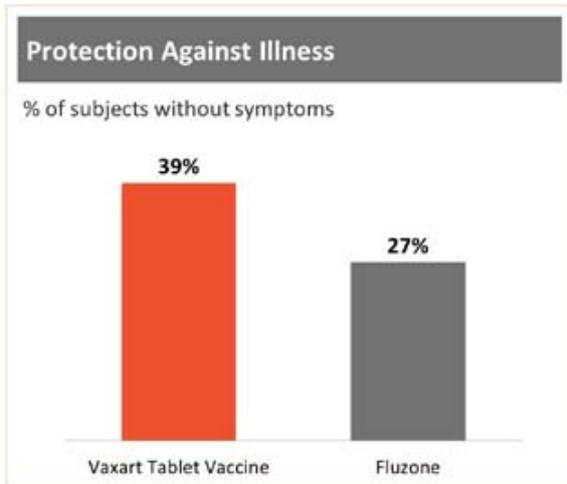
Vaxart's oral vaccine triggers a broad immune response, activating systemic and mucosal immunity:

- 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)

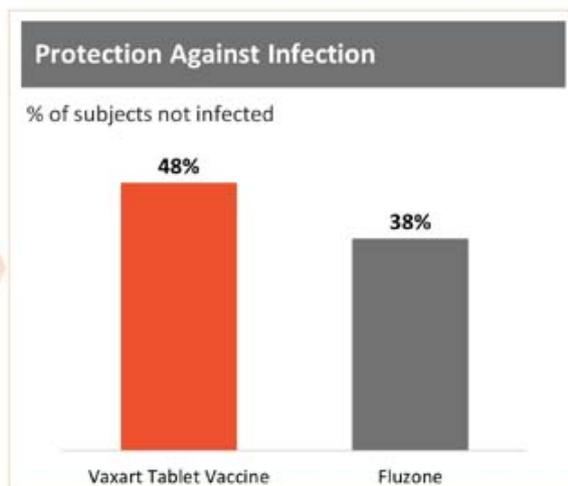
THE LANCET
Infectious Diseases

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**



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

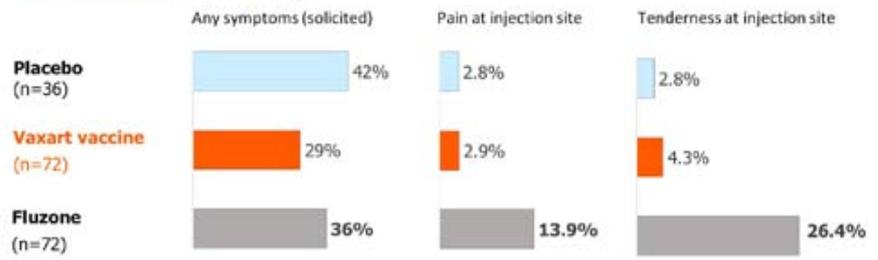
Long-term safety & tolerability:

462 subjects vaccinated

12 clinical trials

6 different viruses

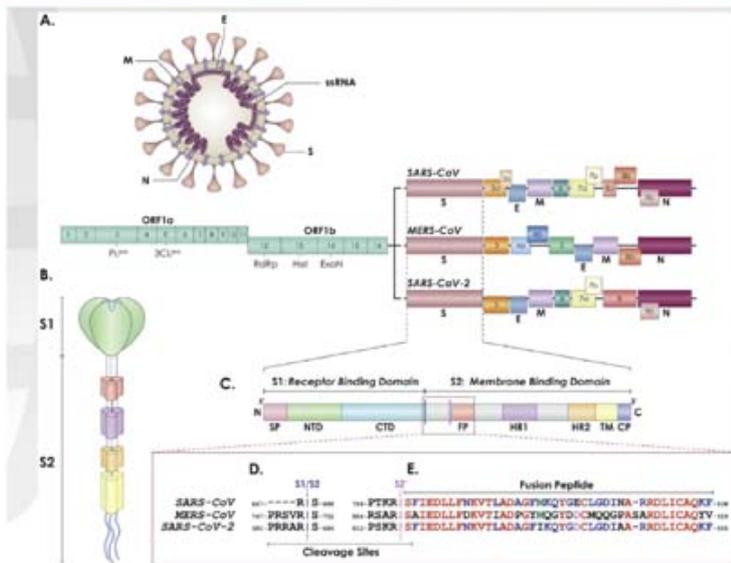
BARDA-funded flu study



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

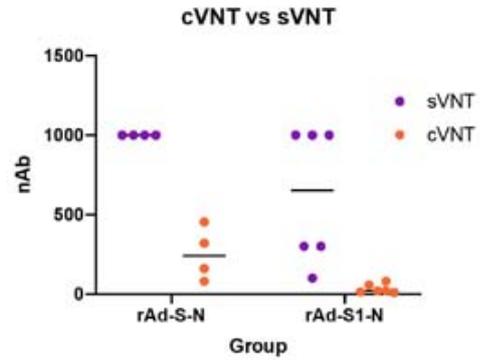
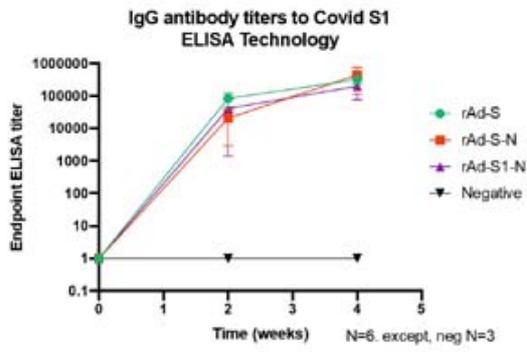
Source: Liebowitz et al., Lancet Infectious Diseases, Jan 2020

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



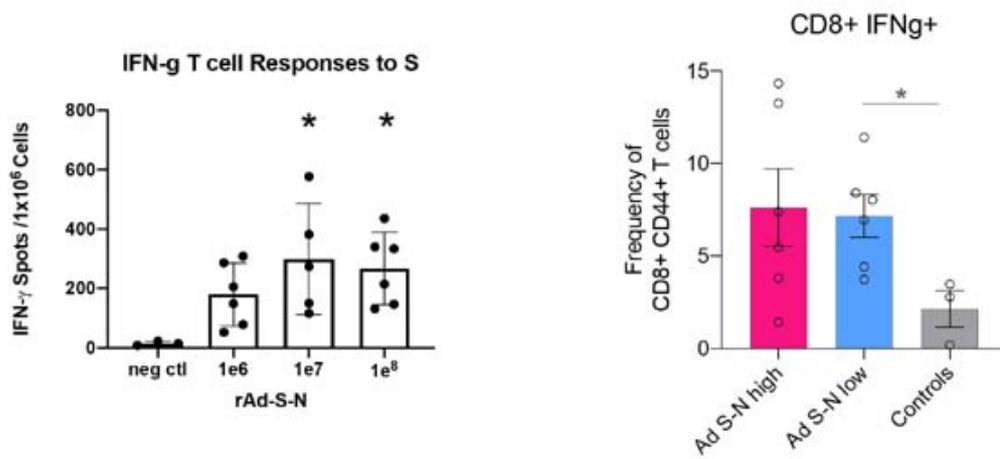
- **S Protein** is a surface protein, good target of neutralizing antibodies
- **N Protein** is well conserved, and a good target for T cell responses
- Construct is called rAd-S-N

Full-length S better for creating neutralizing antibody responses



Moore, et al, *BioRxiv*, 2020

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

emergent
biosolutions®

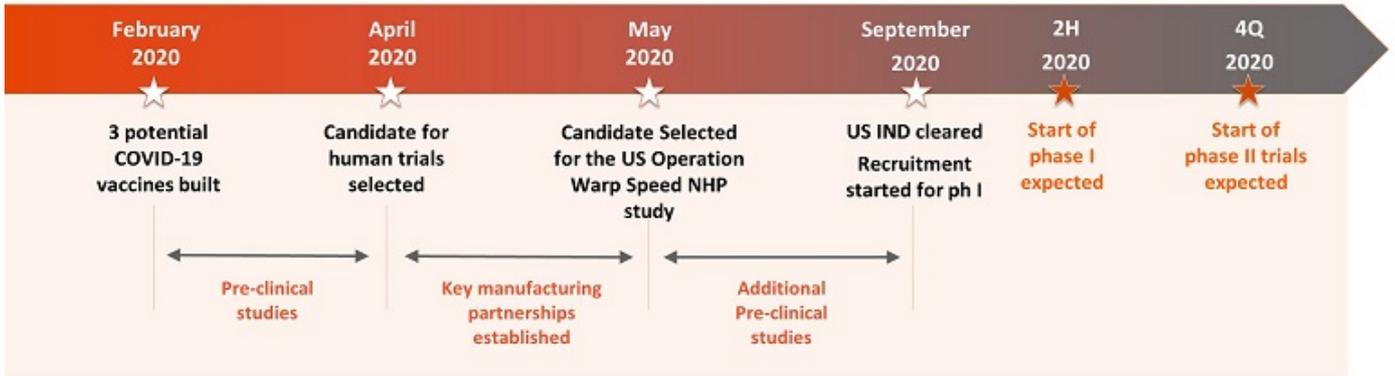
 KindredBio

 **AMS**
ATTWELL MEDICAL SOLUTIONS
ADVANCED TISSUE MEDICAL SOLUTIONS

Simpler manufacturing process than for injectables:

- No sterile fill and finish
- No need for vials

Vaxart COVID-19 vaccine timeline



Vaxart is the leading oral vaccine biotechnology company



Manufacturing



Research & Development



Clinical Trials



Commercial



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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vaxart.com
