



Vaxart Announces Publication of Preclinical Study Demonstrating 100% Protection Against a Lethal Dose of H5N1 Avian Flu in a Ferret Challenge Model

October 8, 2026

Second-generation oral mucosal vaccine candidate (VXA-H5-02) induced robust cross-neutralizing antibodies, significantly reduced viral load, and completely protected against lethal clade 2.3.4.4b viral challenge

SOUTH SAN FRANCISCO, Calif., Oct. 08, 2026 (GLOBE NEWSWIRE) -- Vaxart, Inc. (OTCQX: VXRT), a clinical-stage biotechnology company developing oral recombinant vaccines administered via tablet, today announced the publication of positive preclinical study results evaluating its adenovirus-based oral mucosal vaccine platform against Highly Pathogenic Avian Influenza (HPAI) H5N1, a pathogenic virus that poses a significant threat to public health. The complete, peer-reviewed study results, which were published in [Frontiers in Immunology](#), demonstrate that Vaxart's second-generation vaccine candidate, VXA-H5-02, elicits both mucosal and systemic neutralizing antibody responses, offering comprehensive protection against lethal challenge with H5N1 clade 2.3.4.4b. The company previously reported [topline study results](#) in 2025.

"The potential spread of H5N1 avian influenza across livestock and mammals underlines the critical need for scalable, rapidly deployable vaccines," said Dr. Sean Tucker, CSO of Vaxart. "These data further support our oral mucosal vaccination technology and highlight the improved immune-stimulating activity of our second-generation H5 construct. The 100% survival rate following challenge with a lethal dose of virus underscores the robust immune protection our oral influenza vaccine candidates may be able to provide. This protection, combined with ease of self-administration and the elimination of complex cold-chain requirements required for injected vaccines, supports the potential of our platform in enabling a novel approach to influenza prevention and pandemic preparedness."

Key Study Highlights

- **100% Survival Rate:** All ferrets immunized with VXA-H5-02 survived a lethal challenge with H5N1 clade 2.3.4.4b, whereas 100% of unvaccinated control animals rapidly succumbed to infection by Day 6 post-challenge ($p < 0.001$).
- **Significant Viral Load & Shedding Reduction:** VXA-H5-02 vaccination produced a ~2.3-log reduction in infectious viral shedding by Day 3 post-challenge compared to controls. By Day 6–7, viable virus was below the limit of detection in nasal wash samples, and 7 out of 8 animals completely cleared viral RNA by Day 8/9.
- **Mucosal & Cross-Neutralizing Immunity:** Immunization with VXA-H5-02 elicited strong serum neutralizing titers and mucosal IgA/IgG responses in nasal wash fluid. Higher pre-challenge nasal IgA levels showed the strongest negative correlation with post-challenge viral shedding ($r = -0.6059$).
- **Cross-Clade Protection:** Serum from VXA-H5-02 immunized animals demonstrated cross-neutralizing activity against divergent H5 strains, including the recently emerged H5N1 clade 2.3.2.1e. Additionally, the clade-mismatched first-generation vaccine (ND1.1, encoding clade 2.1.3.2) conferred 37% survival against the clade 2.3.4.4b challenge.

About the Study

In the study, non-replicating recombinant adenovirus type 5 (rAd5) vectors expressing viral hemagglutinin (HA) were administered directly to the small intestine of ferrets via endoscopic delivery on Day 0 and Day 28. Ferrets cannot use human tablets, so a liquid formulation delivery method was used to simulate enteric-coated tablet release. On Day 56, animals were challenged intranasally with 1×10^5 TCID₅₀ H5N1 clade 2.3.4.4b virus. Protective efficacy, clinical symptoms, mucosal/systemic antibody titers, and viral shedding (measured by RT-qPCR and TCID₅₀) were systematically monitored.

About Vaxart

Vaxart is a clinical-stage biotechnology company developing a range of oral recombinant vaccines based on its proprietary delivery platform. Vaxart vaccines are designed to be administered using pills that can be stored and shipped without refrigeration and eliminate the risk of needle-stick injury. Vaxart believes that its proprietary pill vaccine delivery platform is suitable to deliver recombinant vaccines, positioning the Company to develop oral versions of currently marketed vaccines and to design recombinant vaccines for new indications. Vaxart's development programs currently include pill vaccines designed to protect against coronavirus, norovirus, and influenza, as well as a therapeutic vaccine for human papillomavirus (HPV), Vaxart's first immune-oncology indication. Vaxart has filed broad domestic and international patent applications covering its proprietary technology and creations for oral vaccination using adenovirus and TLR3 agonists.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Vaxart's strategy, prospects, plans and objectives, results from preclinical and clinical trials, commercialization agreements and licenses, and beliefs and expectations of management are forward-looking statements, including statements contained in the quotations of Vaxart's management in this press release. These forward-looking statements may be accompanied by such words as "should," "believe," "could," "potential," "will," "expected," "anticipate," "plan," "target," "seek," "intend," "may," "predict," "project," "would," and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements regarding the potential of VXA-H5-02 and Vaxart's oral mucosal vaccine platform to induce protective immune responses against H5N1 or other influenza strains in humans; the potential for the preclinical ferret results described in this press release to be predictive of, or replicated in, human clinical trials; the potential for the in vitro cross-neutralizing antibody responses observed in this study to confer cross-clade protection; the anticipated advantages of oral tablet administration, including self-administration and the absence of cold-chain requirements; Vaxart's plans, objectives and expected timing for further preclinical studies, regulatory submissions and clinical development of VXA-H5-02; Vaxart's ability to develop and commercialize its product candidates; and Vaxart's expectations regarding the role of its platform in influenza prevention and pandemic preparedness. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about the industry and markets in which Vaxart operates as well as management's current

beliefs and assumptions. 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 the risk that preclinical results in ferrets, generated using endoscopic delivery of a liquid formulation, will not be predictive of safety, immunogenicity or efficacy in humans administered an enteric-coated tablet; the risk that in vitro cross-neutralization against divergent H5 clades does not translate into protection against circulating or emerging clades; the fact that VXA-H5-02 has not been evaluated in humans, is not the subject of an investigational new drug application, and will require substantial additional funding to enter clinical development; 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; difficulties in production, particularly in scaling up initial production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations; 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 resolve pending legal matters; 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 and uncertainties described in the "Risk Factors" sections of Vaxart's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q filed with the U.S. Securities and Exchange Commission, which are available on the SEC's website at www.sec.gov. The forward-looking statements in this press release speak only as of the date of this press release. Vaxart undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by applicable law.

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