# AVIRAGEN THERAPEUTICS, INC.

## FORM 8-K
(Current report filing)

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# 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 Earl iest Event Reported): November 29 , 2017**

# Aviragen Therapeutics, Inc.

**(Exact name of registrant as specified in its charter)**

| **DELAWARE** | **001- 35285** | **59-1212264** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

| **2500 Northwinds Parkway, Suite 100 Alpharetta, GA** | **30009** |
|---|---|
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant 's telephone number, including area code (678) 221-3350**

**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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 8 .01 Other Events .**

On November 29, 2017, Aviragen Therapeutics, Inc. issued a press release announcing completion of patient enrollment in its Phase 2 CT4 clinical trial evaluating teslexivir (BTA074) for the treatment of condyloma. A copy of the press release is attached as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated November 29, 2017 |

**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.

**Aviragen Therapeutics , Inc.**

Date: November 30, 2017

/s/ Joseph M Patti

Name: Joseph M Patti
Title: Chief Executive Officer and President
(Duly Authorized Officer)

**Exhibit 99.1**

# PRESS RELEASE

IMMEDIATE RELEASE

**Aviragen Therapeutics Announces Completion of Patient Enrollment in Phase 2 Clinical Trial of Teslexivir (BTA074) for the Treatment of Condyloma**

**ATLANTA, GA – November 29 , 2017** – Aviragen Therapeutics, Inc. (NASDAQ:AVIR), a company focused on the discovery and development of direct-acting antivirals to treat infections that have limited therapeutic options, today announced the completion of patient enrollment in its Phase 2 CT4 clinical trial evaluating teslexivir (BTA074) for the treatment of condyloma. The Company expects to report top-line data from this trial in the second quarter of 2018.

" The enrollment and randomization of over 210 patients in the CT4 trial represents a significant milestone in the development of teslexivir," said Joseph Patti, Ph.D., President and Chief Executive Officer of Aviragen. "We believe the direct-acting antiviral mechanism of action of teslexivir has the potential to both enhance clearance rates and reduce condyloma recurrence rates compared with currently approved treatments."

CT4 is a Phase 2 double-blind, randomized, multi-center, placebo-controlled trial designed to evaluate the safety, tolerability and efficacy of teslexivir 5% gel in male and female patients with condyloma, or anogenital warts. Patients were randomized 2-to-1 (teslexivir to placebo gel) and dosed twice daily for up to 16 weeks. The primary efficacy endpoint is the complete clearance rate for baseline anogenital warts from the commencement of therapy to the end of the treatment period. Secondary efficacy endpoints include various efficacy assessments of clearance and wart area reduction for both baseline warts and post-baseline emergent warts, as well as the assessment of condyloma recurrence over a 3 month follow-up period, in patients who experience clearance.

Teslexivir is a topical antiviral agent that is a potent and selective inhibitor of the interaction between two essential viral proteins, E1 and E2, an interaction that is a necessary step for Human Papilloma Virus (HPV) 6 and 11 DNA replication and thus viral production. HPV types 6 and 11 are responsible for more than 90% of anogenital condyloma.

**About Condyloma (Anogenital Warts)**

Condyloma infections from HPV represent the most frequent viral sexually transmitted disease in adults worldwide. In the United States, approximately one to two percent of sexually active adults between the ages of 15 to 49 develop condyloma as the primary clinical manifestation of HPV infection. Currently available treatments for anogenital warts typically are divided into two categories, ablative/destructive therapies and topical therapies. Existing topical therapies are associated with significant mucosal toxicities manifesting as erosions and ulcerations, which can result in therapy discontinuation. Ablative options can be painful and scarring, and can lead to sexual dysfunction. Another significant limitation with current therapies is a high incidence of recurrence after successful primary treatment.

**About Aviragen Therapeutics**

Aviragen Therapeutics is focused on the discovery and development of the next generation of direct-acting antivirals to treat infections that have limited therapeutic options and affect a significant number of patients globally. It has three Phase 2 clinical stage compounds: BTA074 (teslexivir), an antiviral treatment for condyloma caused by human papillomavirus types 6 and 11; vapendavir, a capsid inhibitor for the prevention or treatment of rhinovirus upper respiratory infections; and BTA585 (enzaplatovir), a fusion protein inhibitor in development for the treatment of respiratory syncytial virus infections. Aviragen also receives royalties from marketed influenza products, Relenza ® and Inavir ® . Aviragen recently announced plans to merge with Vaxart, Inc., a privately-held clinical-stage company focused on developing oral recombinant vaccines from its proprietary delivery platform . For additional information, please visit www.aviragentherapeutics.com.



**Forward-Looking Statements**

This communication contains forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended) concerning Aviragen, Vaxart, the Merger and other matters. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Aviragen, as well as assumptions made by, and information currently available to, management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the timing of the availability of top-line data from the Phase 2 CT4 trial of teslexivir; the potential of teslexivir to both enhance clearance rates and reduce condyloma recurrence rates compared with currently approved treatments; the risk that the conditions to the closing of the Merger are not satisfied, including the failure to timely or at all obtain stockholder approval for the Merger; uncertainties as to the timing of the consummation of the Merger and the ability of each of Aviragen and Vaxart to consummate the Merger; risks related to Aviragen's ability to correctly estimate its operating expenses and its expenses associated with the Merger; risks related to the market price of Aviragen's common stock relative to the exchange ratio; the ability of Aviragen or Vaxart to protect their respective intellectual property rights; competitive responses to the Merger; unexpected costs, charges or expenses resulting from the Merger; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the Merger; provisions in certificate of incorporation, bylaws and laws of Delaware containing provisions that could delay or discourage a change in control of the Company; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Aviragen's most recent Annual Report on Form 10-K, and Aviragen's recent Quarterly Report on Form 10-Q and Current Reports on Form 8-K filed with the SEC. Aviragen can give no assurance that the conditions to the Merger will be satisfied. Except as required by applicable law, Aviragen undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

**No Offer or Solicitation**

This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the Merger or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the United States Securities Act of 1933, as amended. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

**Important Additional Information Will b e F iled with the SEC**

In connection with the proposed transaction between Aviragen and Vaxart, Aviragen intends to file relevant materials with the SEC, including a registration statement that will contain a proxy statement and prospectus. AVIRAGEN URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT AVIRAGEN, THE MERGER AND RELATED MATTERS. Investors and shareholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Aviragen with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In addition, investors and shareholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Aviragen with the SEC by contacting Aviragen Therapeutics, Inc., 2500 Northwinds Parkway, Suite 100, Alpharetta, Georgia 30009, Attention: Corporate Secretary or delivered via e-mail to investors@aviragentherapeutics.com. Investors and stockholders are urged to read the proxy statement, prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the Merger.

**Participants in the Solicitation**

Aviragen and Vaxart, and each of their respective directors and executive officers and certain of their other members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the Merger. Information about Aviragen ’s directors and executive officers is included in Aviragen’s Annual Report on Form 10-K for the year ended June 30, 2017, filed with the SEC on September 1, 2017, and the Form 10-K/A filed with the SEC on October 20, 2017. Additional information regarding these persons and their interests in the Merger will be included in the proxy statement relating to the Merger when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

**Contacts**

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