

**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): April 18, 2024

BARINTHUS BIOTHERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

**England and Wales
(State or other jurisdiction
of incorporation)**

**001-40367
(Commission
File Number)**

**Not Applicable
(I.R.S. Employer
Identification No.)**

**Barinthus Biotherapeutics plc
Unit 6-10, Zeus Building Rutherford Avenue,
Harwell, Didcot, OX11 0DF
United Kingdom**

(Address of principal executive offices, including zip code)

**+44 (0) 1865 818 808
(Registrant's telephone number, including area code)**

**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>Trade Symbol(s)</u>	<u>Name of each exchange on which registered</u>
American Depositary Shares Ordinary shares, nominal value £0.000025 per share*	BRNS	The Nasdaq Global 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.

* American Depositary Shares may be evidenced by American Depositary Receipts. Each American Depositary Share represents one (1) ordinary share. Not for trading, but only in connection with the listing of the American Depositary Shares on The Nasdaq Global Market. The American Depositary Shares represent the right to receive ordinary shares and are being registered under the Securities Act of 1933, as amended, pursuant to a separate Registration Statement on Form F-6. Accordingly, the American Depositary Shares are exempt from the operation of Section 12(a) of the Securities Exchange Act of 1934, as amended, pursuant to Rule 12a-8.

Item 8.01. Other Events.

On April 18, 2024, Barinthus Biotherapeutics plc (the “Company”) issued a press release titled “Barinthus Bio Announces Topline Data from Phase 1b/2 APOLLO Trial of VTP-200 in Persistent High-Risk Human Papillomavirus (HPV) Infections” announcing topline final data from APOLLO (also known as HPV001), a completed randomized, placebo-controlled Phase 1b/2 multi-center trial of 108 participants across the UK and EU evaluating the safety, tolerability and immunogenicity of VTP-200 in women aged 25-55 with persistent high-risk (hr) HPV infection and low-grade cervical lesions. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on form 8-K.

Study APOLLO: VTP-200

The primary objective of the trial was to evaluate the safety and tolerability of VTP-200. The trial was also designed to assess the effect of VTP-200 on clearance of hrHPV infection and cervical lesion(s), as well as select appropriate doses for further development. The study consisted of an open label, non-randomized, dose escalation lead-in phase (n=9), followed by a blinded, randomized main phase (n = 99; 67 randomized to VTP-200 and 32 to placebo). Participant groups were dosed sequentially with ChAdOx and MVA 28 days apart, as follows: Group 1, ChAdOx 2×10^9 viral particles (vp), MVA 1×10^7 plaque-forming units (pfu); Group 2, ChAdOx 2×10^{10} vp, MVA 1×10^7 pfu; Group 3, ChAdOx 2×10^8 vp, MVA 1×10^8 pfu; Group 4, ChAdOx 2×10^9 vp, MVA 1×10^8 pfu; Group 5, ChAdOx 2×10^{10} vp, MVA 1×10^8 pfu.

- The APOLLO study met its primary safety endpoint, demonstrating that VTP-200 was generally well-tolerated, and was administered with no treatment-related grade 3 or higher unsolicited adverse events (AEs) and no treatment-related serious AEs.
- The highest hrHPV clearance rate of 60% at Month 12 was observed in group 2, which included the highest dose of ChAdOx, compared to a 33% clearance rate in the placebo group. Groups 1, 3, 4 and 5 showed 12%, 11%, 33% and 36% hrHPV clearance rates, respectively.
- The study also evaluated cervical lesion clearance rates in participants with both reported lesions at screening and visualization of the cervical transformation zone at 12 months (n=57). The highest cervical lesion clearance rate of 67% was observed in group 2 and group 5, both received the highest dose of ChAdOx, compared to 39% in the placebo group. Groups 1, 3 and 4 showed 40%, 20% and 33% cervical lesion clearance rates, respectively.
- Pooled data from the five active dose groups showed no significant improvement in hrHPV clearance or cervical lesion clearance rates in comparison to the placebo group.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, which can generally be identified as such by use of the words “may,” “will,” “plan,” “forward,” “encouraging,” “believe,” “potential,” and similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements include, without limitation, express or implied statements regarding: the Company’s product development activities and clinical trials, including timing for readouts of any interim data or next steps for any of our programs, including VTP-200 and the APOLLO trial, the tolerability or potential benefits of VTP-200, and the Company’s ability to develop and advance its current and future product candidates and programs. Any forward-looking statements in this Current Report on Form 8-K are based on management’s current expectations and beliefs and are subject to numerous risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this Current Report on Form 8-K, including, without limitation, risks and uncertainties related to the success, cost and timing of the Company’s pipeline development activities and planned and ongoing clinical trials, the Company’s ability to execute on its strategy, regulatory developments, the Company’s ability to fund its operations and access capital, the risk that interim or topline data may not reflect final data or results, global economic uncertainty, including disruptions in the banking industry, the conflict in Ukraine, and the conflict in Israel and Gaza, and other risks identified in the Company’s filings with the Securities and Exchange Commission (the “SEC”), including its Annual Report on Form 10-K for the year ended December 31, 2023, its Quarterly Reports on Form 10Q and subsequent filings with the SEC. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company expressly disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#)

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[Press Release dated April 18, 2024.](#)

Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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.

Barinthus Biotherapeutics plc

Date: April 18, 2024

By: /s/ William Enright
William Enright
Chief Executive Officer



Barinthus Bio Announces Topline Data from Phase 1b/2 APOLLO Trial of VTP-200 in Persistent High-Risk Human Papillomavirus (HPV) Infections

- *Primary safety endpoint met; VTP-200 was generally well-tolerated, with no treatment-related grade 3 or higher adverse events (AEs) or serious AEs (SAEs).*
- *Positive trends in clearance rate for both high-risk (hr)HPV (60%, Group 2) and cervical lesions (67%, Groups 2 and 5), were observed in the groups receiving the highest ChAdOx dose.*
- *Pooled data from the five different active dose groups demonstrated no statistically significant improvement in either hrHPV or cervical lesion clearance in comparison to the placebo group.*

OXFORD, United Kingdom, April 18, 2024 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS), formerly Vaccitech plc, a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases, autoimmunity and cancer, today announced topline final data from the APOLLO trial (also known as HPV001), a completed randomized, placebo-controlled Phase 1b/2 dose-ranging trial of VTP-200 in women with low-grade cervical lesions associated with persistent hrHPV infection.

“This was our first in-human, dose-ranging trial of VTP-200 in women with hrHPV-associated low-grade cervical lesions, who currently don’t have any treatment option until progression to high-grade lesions,” said Bill Enright, Chief Executive Officer of Barinthus Bio. “While we didn’t observe a significant improvement from VTP-200 in the overall pooled results, we did observe positive trends in the highest dose cohorts.”

APOLLO (NCT04607850) was a randomized, placebo-controlled Phase 1b/2 multi-center trial of 108 participants across the UK and EU evaluating the safety, tolerability and immunogenicity of VTP-200 in women aged 25-55 with persistent hrHPV infection and low-grade cervical lesions. The primary objective was to evaluate the safety and tolerability of VTP-200. The trial was also designed to assess the effect of VTP-200 on clearance of hrHPV infection and cervical lesion(s), as well as select appropriate doses for further development.

The APOLLO study met its primary safety endpoint, demonstrating that VTP-200 was generally well-tolerated and was administered with no treatment-related grade 3 or higher unsolicited AEs and no treatment-related SAEs.

The highest hrHPV clearance rate of 60% at Month 12 was observed in group 2, which included the highest dose of ChAdOx, compared to a 33% clearance rate in the placebo group. Groups 1, 3, 4 and 5 showed 12%, 11%, 33% and 36% hrHPV clearance rates, respectively.

The study also evaluated cervical lesion clearance rates in participants with both reported lesions at screening and visualization of the cervical transformation zone at 12 months (n=57). The highest cervical lesion clearance rate of 67% was observed in group 2 and group 5, both received the highest dose of ChAdOx, compared to 39% in the placebo group. Groups 1, 3 and 4 showed 40%, 20% and 33% cervical lesion clearance rates, respectively.

Pooled data from the five active dose groups showed no significant improvement in hrHPV clearance or cervical lesion clearance rates in comparison to the placebo group. Future development options for the VTP-200 program are currently being evaluated with further analyses ongoing.

“We were pleased to see that VTP-200 was generally well-tolerated, meeting the primary safety endpoint in this study. The most promising hrHPV and cervical lesion clearance data were observed in the highest ChAdOx-HPV dosing groups which is informative for future development,” said Nadege Pelletier, Chief Scientific Officer of Barinthus Bio. “However, these differences compared to placebo were not statistically significant given that the trial was not powered for individual dose group comparisons. Further analyses are ongoing, mostly focusing on immunological responses and we plan to share the detailed results in due course.”

About the APOLLO trial

APOLLO (NCT04607850) was a randomized, placebo-controlled Phase 1b/2 multi-center trial of 108 participants across the UK and EU evaluating the safety, tolerability and immunogenicity of VTP-200 in women aged 25-55 with persistent high-risk (hr) HPV infection and low-grade cervical lesions. The primary objective was to evaluate the safety and tolerability of VTP-200. The trial was also designed to assess the effect of VTP-200 on clearance of hrHPV infection and cervical lesion(s), as well as select the appropriate doses for further development. The study consisted of an open label, non-randomized, dose escalation lead-in phase (n=9), followed by a blinded, randomized main phase (n=99; 67 randomized to VTP-200 and 32 to placebo). Participant groups were dosed sequentially with ChAdOx and MVA 28 days apart, as follows: Group 1, ChAdOx 2×10^9 viral particles (vp), MVA 1×10^7 plaque-forming units (pfu); Group 2, ChAdOx 2×10^{10} vp, MVA 1×10^7 pfu; Group 3, ChAdOx 2×10^8 vp, MVA 1×10^8 pfu; Group 4, ChAdOx 2×10^9 vp, MVA 1×10^8 pfu; Group 5, ChAdOx 2×10^{10} vp, MVA 1×10^8 pfu.

About VTP-200

VTP-200 is an investigational immunotherapeutic combination regimen consisting of an initial dose using the ChAdOx vector and a second dose using MVA vector, both encoding the same HPV antigens, designed to elicit an antigen-specific T cell immune response to HPV. VTP-200 is being developed as a potential non-invasive treatment for persistent high-risk HPV infections and associated pre-cancerous cervical lesions.

About HPV

It is estimated that approximately 291 million women worldwide are carriers of human papillomavirus DNA.² Persistent genital HPV infection is responsible for almost all cases of cervical pre-cancerous lesions, which can lead to cervical carcinoma.³ Over 95% of cervical cancers are caused by HPV infection.³ Cervical cancer was the fourth most common cancer in women in 2022, with approximately 660,000 cases and 350,000 deaths from the disease worldwide.³ The American Cancer Society predicted that in 2023, approximately 13,960 new cases of invasive cervical cancer would be diagnosed in the US with over 4,310 women dying from the disease.⁴

About Barinthus Biotherapeutics

Barinthus Bio is a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases, autoimmunity and cancer. Helping people living with serious diseases and their families is the guiding principle at the heart of Barinthus Bio. With a broad pipeline, built around three proprietary platform technologies: ChAdOx, MVA and SNAP, Barinthus Bio is advancing a pipeline of five product candidates across a diverse range of therapeutic areas, including: VTP-300, an immunotherapeutic candidate designed as a potential component of a functional cure for chronic HBV infection; VTP-200, a non-surgical product candidate for persistent high-risk human papillomavirus (HPV); VTP-1000, an autoimmune candidate designed to utilize the SNAP-Tolerance Immunotherapy (TI) platform to treat patients with celiac disease; and VTP-850, a second-generation immunotherapeutic candidate designed to treat recurrent prostate cancer. Barinthus Bio's proven scientific expertise, diverse portfolio and focus on pipeline development uniquely positions the company to navigate towards delivering treatments for people with infectious diseases, autoimmunity and cancers that have a significant impact on their everyday lives. For more information, visit www.barinthusbio.com.

Forward Looking Statements

This press release contains forward-looking statements regarding Barinthus Bio within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, which can generally be identified as such by use of the words “may,” “will,” “plan,” “forward,” “encouraging,” “believe,” “potential,” and similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements include, without limitation, express or implied statements regarding our product development activities and clinical trials, including timing for readouts of any interim data or next steps for any of our programs, including VTP-200 and the APOLLO trial, the tolerability or potential benefits of VTP-200, and our ability to develop and advance our current and future product candidates and programs. Any forward-looking statements in this press release are based on our management’s current expectations and beliefs and are subject to numerous risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to the success, cost and timing of our pipeline development activities and planned and ongoing clinical trials, our ability to execute on our strategy, regulatory developments, our ability to fund our operations and access capital, the risk that interim or topline data may not reflect final data or results, global economic uncertainty, including disruptions in the banking industry, the conflict in Ukraine, the conflict in Israel and Gaza, and other risks identified in our filings with the Securities and Exchange Commission (the “SEC”), including our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We expressly disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

References

1. Womens Health (Lond). 2021; 17: 17455065211020702. doi: 10.1177/17455065211020702
2. Lancet Infect Dis. 2007 Jul;7(7):453-9. doi: 10.1016/S1473-3099(07)70158-5
3. WHO, Cervical Cancer, 2024.
4. American Cancer Society, Key Statistics for Cervical Cancer, 2022.

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