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): December 20, 2023

BARINTHUS BIOTHERAPEUTICS PLC

(Exact name of registrant as specified in its charter)

England and Wales	**001-40367**	**Not Applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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:

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
American Depositary Shares	BRNS	The Nasdaq Global Market
Ordinary shares, nominal value £0.000025 per share*		

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 1.01. Entry into a Material Definitive Agreement.

On December 20, 2023, Barinthus Biotherapeutics plc (the "Company"), the Chancellors, Masters and Scholars of the University of Oxford ("Oxford," together with the Company, the "Partners") and the Coalition for Epidemic Preparedness Innovations ("CEPI") entered into a Funding Agreement (the "Funding Agreement") pursuant to which CEPI will provide funding of up to $34.8 million to the Company to advance the development of VTP-500, the Company's vaccine candidate against Middle East Respiratory Syndrome ("MERS," and such development activities, the "Project"). In December 2023, VTP-500 received PRIME (PRIority MEdicines) designation by the European Medicines Agency. Under the Funding Agreement, the Partners have agreed to use reasonable endeavors to achieve the deliverables, milestones and timelines for the vaccine development activities under discrete "Work Packages" mutually agreed to by the parties from time to time.

Under the initial Work Package, the Company has agreed, subject to the achievement of certain milestones, including a successful Phase II clinical trial of VTP-500, that it will manufacture or have manufactured an investigational ready reserve of 100,000 doses of VTP-500 to be rapidly deployed for a clinical trial in the event of a substantial outbreak of MERS. During the Term (as defined below), the Company has also agreed to certain collaboration obligations in the event of a regional or national public health emergency or preparation need for an impending outbreak of MERS.

Pursuant to the Funding Agreement, the Company will retain ownership of its intellectual property owned or controlled throughout the term of the Funding Agreement, subject to the rights of CEPI under the Funding Agreement. The Company will also own any intellectual property invented by or on behalf of the Company in connection with the activities contemplated by the Funding Agreement, as well as all tangible materials and results made or developed by or on behalf of the Company in connection with the Funding Agreement.

Any amounts funded by CEPI to the Partners under the Funding Agreement in accordance with each Work Package will be paid in tranches covering six-month periods based on mutually agreed project-based budgets and subject to certain conditions as set forth in the Funding Agreement including the achievement of identified milestones.

Pursuant to the Funding Agreement, the Company has agreed to pay CEPI on a country-by-country basis increasing mid-single digit percentage royalties of net sales and net income with respect to future cash sales of VTP-500, less certain deductions, for a period starting on December 20, 2023 ("Effective Date") and ending the later of: (i) the expiration of the last valid patent claim included in intellectual property developed under the Project covering VTP-500 in such country, (ii) the expiration of Regulatory Exclusivity (as defined in the Funding Agreement) for VTP-500 in such country, and (iii) the tenth (10^{th}) anniversary of the first commercial sale of VTP-500 (the "Royalty Term"). The Company shall also pay CEPI a mid-double digit percentage of net revenue earned on VTP-500 until CEPI has received payments from the Company under the Funding Agreement equaling the total amount of funding paid by CEPI to the Company and a low double-digit percentage of such net revenue thereafter. Sales for the benefit of end users in specified low and middle income countries ("LMICs") and upper and middle income countries ("UMICs") are excluded from the calculations of net sales and net revenue. Sales of product for the benefit of end users in LMICs and UMICs are subject to tiered discounted pricing requirements under the Funding Agreement. The Company is further required to pay a mid-double digit percentage of any proceeds earned on any priority review voucher related to VTP-500 during the Royalty Period.

The Funding Agreement will commence on the Effective Date and will continue until the fifth (5^{th}) anniversary of the Effective Date, unless the parties agree to extend the Funding Agreement for a period of up to twenty-four (24) months unless all activities under the Funding Agreement have been completed ("Term"). Either Partner or CEPI can terminate the Funding Agreement following an insolvency event or material breach by the other party that is not cured within forty-five (45) business days, in the event of termination by a Partner, or thirty (30) business days, in the event of termination by CEPI. Pursuant to the Funding Agreement, CEPI also has certain discretionary termination rights, including if CEPI determines that the Company is involved in material safety, regulatory, scientific misconduct, or ethical issues or is no longer able to fulfill its obligations under the Funding Agreement.

Neither CEPI, the Company nor Oxford may assign its rights or obligations under the Funding Agreement without the other parties' consent; *provided* that CEPI may do so to an organization of equivalent charitable mission and technical capabilities.

The foregoing description of the material terms of the Funding Agreement does not purport to be complete and is qualified in its entirety by reference to such agreement, which will be filed with the Securities and Exchange Commission (the "SEC") as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Item 7.01. Regulation FD Disclosure.

On December 21, 2023, the Company issued a joint press release with Oxford and CEPI titled "New partnership aims to advance emergency vaccine against MERS coronavirus." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, dated December 21, 2023.
104	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: December 22, 2023

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

Exhibit 99.1

New partnership aims to advance vaccine against MERS coronavirus

Dec 21, 2023

- CEPI to invest funding of up to $34.8 million to Barinthus Bio in addition to funds previously committed to the University of Oxford to develop and stockpile a ready reserve of emergency MERS vaccine candidate, VTP-500.
- VTP-500 project with Barinthus Bio and University of Oxford uses tested ChAdOx1 platform.
- If successful in Phase II trials, this will progress VTP-500 significantly towards regulatory approval and doses could be rapidly deployed in a clinical trial setting in response to a substantial outbreak.

OXFORD, United Kingdom, Dec. 21, 2023 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS), formerly Vaccitech plc, today announced a project with the Coalition for Epidemic Preparedness Innovations (CEPI) and the University of Oxford, aiming to fast-track the development of a vaccine candidate known as VTP-500 for the prevention of Middle East Respiratory Syndrome (MERS), the often fatal disease caused by the MERS coronavirus. 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.

The project will see CEPI, Barinthus Bio, an Oxfordshire-based clinical-stage biopharmaceutical company, and the University of Oxford together take a MERS vaccine from early development through Phase II clinical trials and, if the Phase II clinical trials are successful, on into the development of an investigational ready reserve1 of 100,000 doses to be rapidly deployed in a clinical trial setting in the event of a substantial outbreak.

“Coronaviruses are one of the most urgent infectious disease threats the world faces, so it’s vital that we get on with developing medical defences against this particularly deadly one – MERS,” said Dr Richard Hatchett, CEPI’s Chief Executive Officer. “With this project, we will both advance scientific understanding of the coronavirus family as a whole, and at the same time bolster humanity’s ability to respond to an ever-present epidemic threat.”

“The COVID-19 pandemic showed us the critical importance of vaccines in saving millions of lives around the world,” said Professor Dame Sarah Gilbert, Pandemic Sciences Institute, University of Oxford. “We had a head-start in our development of the Oxford/AstraZeneca COVID-19 vaccine, thanks to the many years already spent researching a vaccine for another coronavirus, MERS. This new partnership will help ensure the world is better prepared with vaccines for future outbreaks.”

“We are thrilled to be working with the University of Oxford and CEPI on the development of this important vaccine candidate,” said Bill Enright, Barinthus Bio’s Chief Executive Officer. “There is an active need for a MERS vaccine for at-risk populations and travellers in the Middle East. As we observed during the COVID-19 pandemic, it is critical to ensure we have the necessary countermeasures in place to protect people around the world from deadly pathogens such as MERS which have the potential for future outbreaks.”

The three-way partnership, which awards up to $34.8 million to Barinthus Bio in addition to funds previously committed to the University of Oxford, builds on the early-stage development of VTP-500, which is based on the same viral vector platform technology as the licensed Oxford-AstraZeneca COVID-19 vaccine, Vaxzevria. VTP-500 has already completed Phase I clinical trials in Britain and Saudi Arabia, and the University of Oxford is now conducting a CEPI-funded extension to the Phase I trial in the UK to assess vaccination of older adults, the age group most in need of this vaccine. The VTP-500 programme was awarded PRIME designation earlier in December by the European Medicines Agency (EMA).

MERS is a severe respiratory infection caused by MERS-CoV, a coronavirus that was first identified in 2012 in Saudi Arabia. It has caused more than 2,600 human infections in at least 27 countries since it first emerged, and it has a case-fatality rate of more than 35 percent. There are as yet no licensed vaccines or treatments for MERS.

Enabling equitable access to VTP-500

CEPI, the University of Oxford and Barinthus Bio are committed to enabling equitable access to VTP-500 in line with CEPI’s Equitable Access Policy so the vaccine is first available to populations when and where it is needed to end an outbreak or curtail an epidemic, regardless of ability to pay. If the vaccine is successful in Phase II trials, CEPI will support production of an investigational ready reserve of 100,000 doses which can be rapidly deployed in a clinical trial setting in response to an outbreak of MERS. CEPI also has the ability to support technology transfer to an additional appropriate regional manufacturer to enable supply for low- and middle-income countries. The vaccine will be made available to low- and middle- income countries at a price no higher than the cost of manufacturing plus 10 percent.

[1] An investigational ready reserve is an agreed quantity of investigational doses for potential use in a clinical trial.

Notes to Editors

EMA PRIME Designation

Due to VTP-500's potential in significantly addressing the unmet need for MERS, the EMA has confirmed support for the program through the PRIME designation. PRIME enhances support for the development of medicines that target an unmet medical need, offering early and proactive support to medicine developers to optimise the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicines applications.

Emergency Use

The agreement refers to supply in Outbreaks defined as a Public Health Emergency of International Concern declared by WHO, or a public health emergency on a national or regional scale declared by one or more public health agencies.

About CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, launched at Davos in 2017. Its mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.

CEPI has supported the development of over 30 vaccine candidates against its priority pathogens—Chikungunya virus, Ebola Virus Disease, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever virus and SARS-CoV-2—and is a leading funder of research into broadly protective coronavirus vaccines, which could protect against future variants of COVID-19 as well as other coronaviruses with epidemic and pandemic potential. The organization has also invested in the development of rapid response platforms to develop vaccines against Disease X (the threat of an unknown virus).

CEPI has contributed to a number of scientific breakthroughs, including the first Phase 3 trial of a Chikungunya vaccine and the advancement of the first ever Nipah and Lassa vaccines into Phase I trials. The organization played a central role in the global response to COVID-19, supporting the development of one of the world's largest portfolios of vaccines against SARS-CoV-2, seven of which have been approved for domestic or global use. It also co-led COVAX, the global initiative to deliver fair and equitable access to COVID-19 vaccines, which has delivered approximately 2 billion doses of vaccine to 146 countries around the world.

CEPI's five-year plan for 2022-2026 aims to dramatically reduce or even eliminate the future risk of pandemics and epidemics. Central to the plan is CEPI's goal to compress the time taken to develop safe, effective, globally accessible vaccines against new threats to just 100 days. Achieving this '100 Days Mission', which has been embraced by the G7 and G20, would give the world a fighting chance of containing a future outbreak before it can spread to become a global pandemic.

Visit our news page for the latest updates. Follow us via @CEPIvaccines, @DrRHatchett, LinkedIn, and Facebook.

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; VTP-850, a second-generation immunotherapeutic candidate designed to treat recurrent prostate cancer; and VTP-1100, a preclinical cancer candidate designed to utilize the SNAP-Cancer Immunotherapy (CI) platform to treat patients with HPV-related 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.

Barinthus Bio 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 the Company's future expectations, plans and prospects, including the potential benefits of VTP-500 for the treatment of MERS. Any forward-looking statements in this press release are based on Barinthus Bio 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 Barinthus Bio's pipeline development activities and planned and ongoing clinical trials, Barinthus Bio's ability to execute on its strategy, regulatory developments, the risk that Barinthus Bio may not realize the benefits related to its rebranding and name change, Barinthus Bio's ability to fund its operations and access capital, 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 Barinthus Bio's filings with the Securities and Exchange Commission (the "SEC"), including its Annual Report on Form 10-K for the year ended December 31, 2022, its Quarterly Reports on Form 10-Q and subsequent filings with the SEC. Barinthus Bio cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Barinthus Bio 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.

About Pandemic Science Institute, University of Oxford

The Pandemic Sciences Institute at the University of Oxford is a research institute with a mission to discover, create and enable practical solutions to infectious disease threats worldwide. The Institute is hosted by the University's Nuffield Department of Medicine. Visit our website and Follow us on X (formerly Twitter).

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