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): August 8, 2024

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 2.02. Results of Operations and Financial Condition.

On August 8, 2024, Barinthus Biotherapeutics plc (the "Company") provided an overview of the Company's progress and announced its financial results for the second quarter of 2024. The full text of the press release issued in connection with the update is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) 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 in any 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release dated August 8, 2024.
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: August 8, 2024

By: /s/ William Enright

William Enright

Chief Executive Officer

Barinthus Bio Reports Second Quarter 2024 Update on Corporate Developments and Financial Results

OXFORD, United Kingdom, August 8, 2024 (GLOBE NEWSWIRE) – Barinthus Biotherapeutics plc (NASDAQ: BRNS), a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates, provided an overview of the Company's progress and announced its financial results for the second quarter of 2024.

"Following the positive VTP-300 Phase 2 data in hepatitis B virus (HBV) in the second quarter, we made the strategic decision to prioritize our HBV and celiac disease programs. These two programs have the greatest probability for success and value creation, and represent significant opportunities in therapeutic areas with substantial unmet patient need," said Bill Enright, Chief Executive Officer of Barinthus Bio. "We are very excited as we plan to initiate our first in human clinical trial of VTP-1000 in celiac disease in the third quarter, utilizing our novel SNAP-TI platform. Celiac disease is an increasingly common autoimmune disease with no FDA or EMA-approved treatments. Towards the end of the year we look forward to sharing updated data from our HBV program as our two Phase 2 trials utilizing VTP-300, which are evaluating a potential functional cure regimen, mature further."

Second Quarter 2024 and Recent Corporate Developments

Clinical developments: VTP-300 (HBV)

In June 2024, we announced updated data from two ongoing Phase 2 clinical trials in people with chronic hepatitis B (CHB) at the European Association for the Study of the Liver (EASL) Congress 2024. The presentations included updated interim data from the Phase 2b clinical trial (HBV003), as well as updated interim data from the Phase 2a clinical trial (IM-PROVE II, AB-729-202) in partnership with Arbutus Biopharma, both in people with CHB receiving ongoing standard of care nucleos(t)ide analogue (NUC) therapy.

Interim HBV003 data: VTP-300 and Low-dose Nivolumab

Interim data from the HBV003 trial showed;

- Nearly 20% of participants across the groups had undetectable HBsAg and this was maintained for ≥16 weeks in the two cases who had reached that time point.
- 76% of participants were eligible for NUC discontinuation.
- 71% of those who did discontinue remained off NUCs at time of data cutoff on April 15, 2024.
- 67% of participants across all groups assessed for NUC discontinuation had HBsAg <10 IU/mL at Week 24 or later.
- Robust T cell responses were observed to all VTP-300 encoded antigens.
- There were no Serious Adverse Events (SAEs), Grade 3 or 4 Adverse Events (AEs) related to treatment.

Interim IM-PROVE II data: imdusiran and VTP-300

Interim data from the IM-PROVE II clinical trial showed;

- 20% of participants had undetectable HBsAg at Week 72 in the VTP-300 treatment group, compared to none in the placebo group.
- 84% of participants in the VTP-300 treatment group were eligible for NUC discontinuation, compared to 52% in the placebo group.
- 88% of those who did discontinue remained off NUCs, compared to 80% in the placebo group remaining off NUCs at time of data cutoff on April 12, 2024.
- Robust reductions of HBsAg were observed during the imdusiran lead-in period with 95% of participants achieving HBsAg <100 IU/mL before undergoing dosing in the VTP-300 treatment or placebo groups at week 24. A statistically significant difference ($p<0.05$) in HBsAg levels between the VTP-300 treatment and placebo groups was recorded at Week 72.
- Treatment with imdusiran and VTP-300 was generally well-tolerated, with no SAEs or treatment discontinuations reported.

Corporate Updates

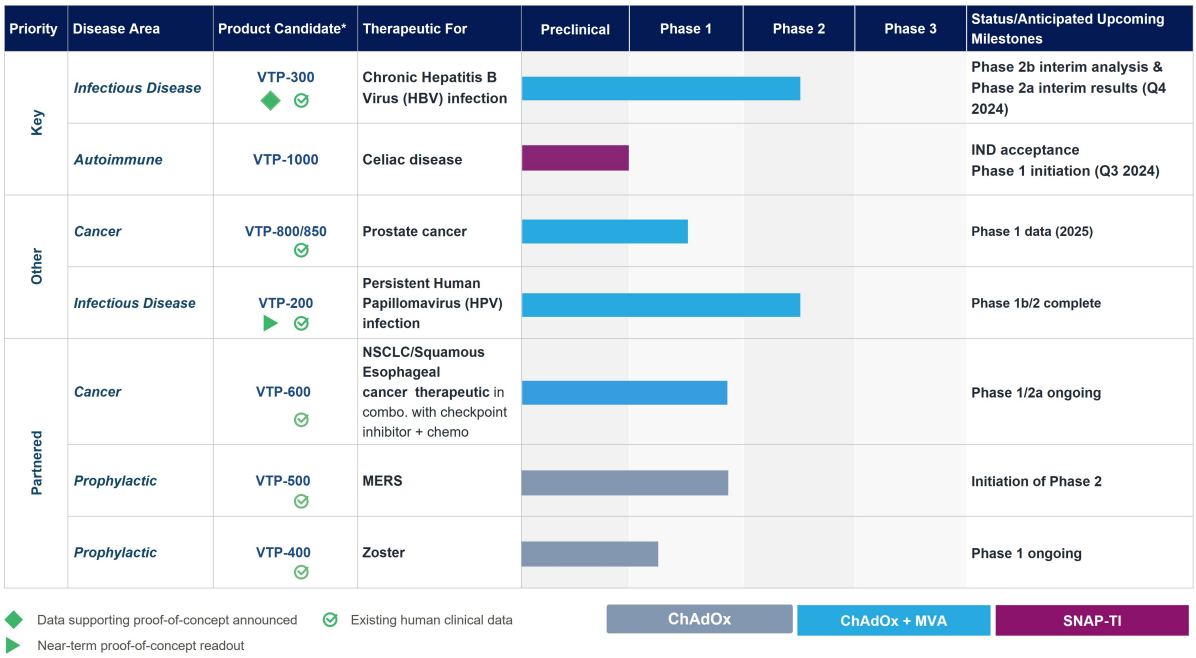
- On June 3, 2024, Dr. Leon Hooftman joined the Company as Chief Medical Officer. He brings significant drug development expertise across a broad array of therapeutic areas including immunology, autoimmunity, hematology, oncology and infectious diseases.

- In June 2024, we announced a strategic pipeline prioritization following the positive interim data from VTP-300 in CHB presented at EASL. This announcement included the prioritization of the development of VTP-300 in CHB and VTP-1000 in celiac disease, and consequently a reduction in workforce.

Upcoming Milestones

- In the third quarter of 2024, the Company expects to:
    - VTP-1000 (Celiac Disease):
        - Dose the first patient in GLU001, a randomized, placebo-controlled Phase 1 trial including a controlled gluten challenge to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of VTP-1000 in adults with celiac disease.
- In the fourth quarter of 2024, the Company expects to:
    - VTP-300 (HBV):
        - Announce updated interim data from HBV003, our Phase 2b trial evaluating additional dosing of VTP-300 and timing of PD-1 inhibition, in people with CHB on NUC therapy.
        - Announce updated interim data from the Phase 2a AB-729-202 clinical trial evaluating the combination of VTP-300 and Arbutus' imdusiran, in people with CHB on NUC therapy.

Pipeline



These are estimated timelines only and our pipeline may be subject to change.

Second Quarter 2024 Financial Highlights

- **Cash position:** As of June 30, 2024, cash, cash equivalents and restricted cash were $117.8 million, compared to $130.0 million as of March 31, 2024. The net cash used in operating activities was $12.0 million in the second quarter of 2024, primarily resulting from development of our pipeline and ongoing clinical trials offset by receipt of an R&D tax credit of $1.4 million. Based on current research and development plans, the Company expects its available resources to fund its operating expenses and capital expenditure requirements into the second quarter of 2026.

- **Research and development expenses:** Research and development expenses were $11.7 million in the second quarter of 2024 compared to $11.1 million in the first quarter of 2024, with the increase mainly attributable to the progression of VTP-300 (HBV) through the two ongoing Phase 2 trials, partially offset by a reduction in expense from VTP-200 (HPV) which completed in the first quarter of 2024 and for which data was presented in April 2024. The quarter-on-quarter R&D expense per program is outlined in the following table.

Period ended	Three months ended June 30, 2024	Three months ended March 31, 2024	Change
	$000	$000	$000
Direct research and development expenses by program:			
VTP-200 HPV	$ 383	$ 1,253	$ (870)
VTP-300 HBV	3,034	1,913	1,121
VTP-500 MERS[1]	304	172	132
VTP-600 NSCLC[2]	24	164	(140)
VTP-850 Prostate cancer	414	178	236
VTP-1000 Celiac	1,371	1,374	(3)
Other and earlier stage programs	908	784	124
Total direct research and development expenses	$ 6,438	$ 5,838	$ 600
Indirect research and development expenses:			
Personnel-related (including share-based compensation)	4,763	4,335	428
Facility related	342	390	(48)
Other indirect costs	119	562	(443)
Total indirect research and development expenses	5,224	5,287	(63)
Total research and development expense	$ 11,662	$ 11,125	$ 537

[1] *The development of VTP-500 is funded pursuant to an agreement with the Coalition for Epidemic Preparedness Innovations (CEPI).*

[2] *The VTP-600 NSCLC Phase 1/2a trial is sponsored by Cancer Research UK.*

- **General and administrative expenses:** General and administrative expenses were $7.2 million in the second quarter of 2024, compared to $6.0 million in the first quarter of 2024. The increase of $1.2 million relates primarily to a loss of $0.1 million on foreign exchange in the second quarter of 2024, compared to a gain of $1.2 million in the first quarter of 2024.

- **Net loss:** For the second quarter of 2024, the Company generated a net loss attributable to its shareholders of $16.9 million, or $(0.43) per share on both basic and fully diluted bases, compared to a net loss attributable to its shareholders of $15.5 million, or $(0.40) per share on both basic and fully diluted bases in the first quarter of 2024.

About Barinthus Bio

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 and autoimmunity. Helping people living with serious diseases and their families is the guiding principle at the heart of Barinthus Bio. With a focused pipeline built around our proprietary platform technologies, Barinthus Bio is advancing product candidates in infectious disease and autoimmunity, including: VTP-300, an immunotherapeutic candidate utilizing our ChAdOx/MVA platform designed as a potential component of a functional cure for chronic HBV infection and VTP-1000, an autoimmune candidate designed to utilize the SNAP-Tolerance Immunotherapy (TI) platform to treat patients with celiac disease. Barinthus Bio also has a Phase 1 clinical trial for 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 and autoimmunity 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," "expect," 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 future expectations, plans and prospects, including our product development activities and clinical trials, including timing for readouts of any preliminary, interim or final data for any of our programs, the timing for initiation of any clinical trials, including dosing of the first patient in GLU001 for VTP-1000, our anticipated regulatory filings and approvals, our cash runway, 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, including the risk that the timing for preliminary, interim or final data or initiation of our clinical trials may be delayed, the risk that interim or topline data may not reflect final data or results, our ability to execute on our strategy, regulatory developments, the risk that we may not achieve the anticipated benefits of our pipeline prioritization and corporate restructuring, our ability to fund our operations and access capital, our cash runway, including the risk that our estimate of our cash runway may be incorrect, global economic uncertainty, including disruptions in the banking industry, the conflicts in Ukraine, Israel and Gaza, and other risks identified in our filings with the Securities and Exchange Commission, 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.

BARINTHUS BIOTHERAPEUTICS PLC
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT NUMBER OF SHARES AND PER SHARE AMOUNTS)
(UNAUDITED)

	June 30, 2024	December 31, 2023
ASSETS		
Cash, cash equivalents and restricted cash	$ 117,774	$ 142,090
Research and development incentives receivable	4,523	4,908
Prepaid expenses and other current assets	9,582	9,907
Total current assets	131,879	156,905
Goodwill	12,209	12,209
Property and equipment, net	10,962	11,821
Intangible assets, net	23,527	25,108
Right of use assets, net	7,286	7,581
Other assets	886	882
Total assets	$ 186,749	$ 214,506
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	2,556	1,601
Accrued expenses and other current liabilities	10,278	9,212
Deferred income	839	—
Operating lease liability - current	1,916	1,785
Total current liabilities	15,589	12,598
Non-current liabilities:		
Operating lease liability - non-current	10,654	11,191
Contingent consideration	1,888	1,823
Other non-current liabilities	1,338	1,325
Deferred tax liability, net	490	574
Total liabilities	$ 29,959	$ 27,511
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Ordinary shares, £0.000025 nominal value; 39,184,338 shares authorized, issued and outstanding (December 31, 2023: authorized, issued and outstanding:38,643,540)	1	1
Deferred A shares, £1 nominal value; 63,443 shares authorized, issued and outstanding (December 31, 2023: authorized, issued and outstanding:63,443)	86	86
Additional paid-in capital	390,273	386,602
Accumulated deficit	(209,010)	(176,590)
Accumulated other comprehensive loss – foreign currency translation adjustments	(24,732)	(23,315)
Total stockholders' equity attributable to Barinthus Biotherapeutics plc shareholders	156,618	186,784
Noncontrolling interest	172	211
Total stockholders' equity	$ 156,790	$ 186,995
Total liabilities and stockholders' equity	$ 186,749	$ 214,506

BARINTHUS BIOTHERAPEUTICS PLC
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(IN THOUSANDS, EXCEPT NUMBER OF SHARES AND PER SHARE AMOUNTS)
(UNAUDITED)

	Three months ended		Six months ended	
	June 30, 2024	**June 30, 2023**	**June 30, 2024**	**June 30, 2023**
License revenue [1]	$ —	$ 334	$ —	$ 802
Total revenue	—	334	—	802
Operating expenses				
Research and development	11,662	13,543	22,787	23,357
General and administrative	7,201	13,128	13,195	25,266
Total operating expenses	18,863	26,671	35,982	48,623
Other operating income	577	—	782	—
Loss from operations	(18,286)	(26,337)	(35,200)	(47,821)
Other income/(expense):				
Interest income	635	522	1,410	2,110
Interest expense	(12)	(14)	(24)	(14)
Research and development incentives	693	559	1,287	1,716
Other income	20	310	20	310
Total other income, net	1,336	1,377	2,693	4,122
Loss before income tax	(16,950)	(24,960)	(32,507)	(43,699)
Tax benefit	7	1,136	44	1,652
Net loss	(16,943)	(23,824)	(32,463)	(42,047)
Net loss attributable to noncontrolling interest	12	22	43	65
Net loss attributable to Barinthus Biotherapeutics plc shareholders	(16,931)	(23,802)	(32,420)	(41,982)
Weighted-average ordinary shares outstanding, basic	39,041,111	38,407,672	38,907,296	38,211,625
Weighted-average ordinary shares outstanding, diluted	39,041,111	38,407,672	38,907,296	38,211,625
Net loss per share attributable to ordinary shareholders, basic	$ (0.43)	$ (0.62)	$ (0.83)	$ (1.10)
Net loss per share attributable to ordinary shareholders, diluted	$ (0.43)	$ (0.62)	$ (0.83)	$ (1.10)
Net loss	$ (16,943)	$ (23,824)	$ (32,463)	$ (42,047)
Other comprehensive gain/(loss) – foreign currency translation adjustments	164	5,604	(1,413)	10,184
Comprehensive loss	(16,779)	(18,220)	(33,876)	(31,863)
Comprehensive loss attributable to noncontrolling interest	11	15	39	52
Comprehensive loss attributable to Barinthus Biotherapeutics plc shareholders	$ (16,768)	$ (18,205)	$ (33,837)	$ (31,811)

[1] Includes license revenue from related parties for the three and six months ended June 30, 2024 of nil (three and six months ended June 30, 2023: $0.3 million and $0.8 million, respectively).

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