# Barinthus Bio Reports First Quarter 2025 Financial Results and Updates on Corporate Developments

May 7, 2025

- *Highly differentiated immunotherapy for celiac disease (VTP-1000) in the clinic, with Phase 1 single ascending dose readout from AVALON expected in the third quarter of 2025;*
- *Initiation of VTP-1000 multiple ascending dose expected in the second half of 2025;*
- *Encouraging results from HBV003 and IM-PROVE II presented at EASL, supporting ongoing partnering efforts;*
- *Available resources expected to provide a cash runway into 2027.*

OXFORD, United Kingdom and GERMANTOWN, Md., May 07, 2025 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS) ("Barinthus Bio," or the "Company"), an immunology and inflammation ("I&I") company focused on developing therapies that promote immune tolerance with curative potential, today announced its financial results for the quarter ended March 31, 2025 and provided an overview of the Company's corporate developments.

"2025 has started with a strategic focus on immunological and inflammatory diseases, which includes directing our resources to our highly differentiated lead asset,VTP-1000, using the SNAP-TI platform, being tested in patients with celiac disease. Looking ahead, we remain on track to announce Phase 1 single ascending dose data for the celiac program using VTP-1000 in the third quarter of 2025, and will be initiating the multiple ascending dose part of the Phase 1 clinical trial in the second half of 2025, where we are incorporating a gluten challenge as part of our initial clinical evaluation of efficacy," said Bill Enright, Chief Executive Officer of Barinthus Bio. "Today, we announced multiple data milestones from our viral vector pipeline, including encouraging primary endpoint analyses from the two Phase 2 trials in chronic hepatitis B ("CHB") which we believe strengthen VTP-300's market positioning as a component of a potential functional cure for CHB."

**First Quarter 2025 and Recent Corporate Developments**

*Clinical Developments*
Data from two Phase 2 clinical trials of VTP-300 will be showcased in poster presentations at the European Association for the Study of the Liver ("EASL") Congress 2025, taking place May 7-10, 2025, in Amsterdam, the Netherlands. The presentations include the six-month primary analysis of the Phase 2b clinical trial (HBV003), as well as end-of-study 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.

*HBV003 data: VTP-300 and Low-dose Nivolumab*
The HBV003 study is evaluating the safety, immunogenicity and disease modifying activity of three different dosing regimens of VTP-300 in combination with low-dose nivolumab ("LDN"), an anti-PD-1 monoclonal antibody. The primary analysis showed;

- In CHB participants with hepatitis B surface antigen ("HBsAg") levels of ≤200 IU/mL, meaningful reductions in HBsAg (>1 log decline) occurred soon after dosing on Day 29 in all treatment groups and were maintained to Day 169.
- In the two best treatment arms HBsAg declines of ≥1 log at Day 169 were observed in 33% (15/45) of participants with HBsAg ≤200 IU/mL at baseline, and 22% (10/45) of participants achieved HBsAg loss at any timepoint.
- 71% (48/68) of participants met the criteria for discontinuation of NUC therapy at day 169; and although NUC discontinuation was optional; two participants who did discontinue NUCs achieved functional cure and one seroconverted to HBsAb positivity.
- Treatment with VTP-300 in combination with LDN was generally well-tolerated, with no serious adverse events reported.

The primary analysis confirms observations from previous interim data, which indicated that stronger responses occurred in participants treated with the combination of VTP-300 and LDN (Groups 1 and 2).

*IM-PROVE II data: imdusiran and VTP-300*
The IM-PROVE II study is evaluating the combination of imdusiran ("IDR"), Arbutus' RNAi therapeutic, followed by Barinthus Bio's T-cell stimulating immunotherapeutic, VTP-300, with or without LDN. The end of study data showed:

- 25% (2/8) of participants with starting baseline HBsAg levels less than 1000 IU/mL receiving the combination of IDR, VTP-300 and LDN achieved functional cure.
- 3 of 13 participants (23%) receiving IDR+VTP-300+LDN had undetectable HBsAg levels at week 48; all (3/3) of participants with HBsAg loss seroconverted.
- Treatment with IDR and VTP-300 was generally well-tolerated, with no serious adverse events or treatment discontinuations reported.

*Corporate Updates*

- In January 2025, Barinthus Bio announced a strategic business refocus and restructuring to prioritize immunology and inflammation indications, including antigen-specific immune tolerance. Barinthus Bio will not invest in VTP-300 for chronic hepatitis B beyond the completion of the ongoing Phase 2b HBV003 clinical trial and will seek potential partners to be able to take advantage of its differentiated ability to achieve sustained HBsAg loss and functional cure in patients with low levels of HBsAg. Partners are also being sought for the other assets that are based upon the viral vector platforms.

**Upcoming Milestones**

*Celiac Disease (VTP-1000):*

- Single ascending dose data from the Phase 1 AVALON clinical trial evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of VTP-1000 in adults with celiac disease expected in the third quarter of 2025.
- Initiation of the multiple ascending dose portion of the Phase 1 AVALON clinical trial is expected in the second half of 2025.

*Prostate Cancer (VTP-850):*

- Topline results from the Phase 1 PCA001 clinical trial evaluating safety and efficacy of VTP-850 in men with rising prostate-specific antigen after definitive local therapy for prostate cancer were received and analysis is ongoing. Data will be used to support partnering efforts for VTP-850.

**First Quarter 2025 Financial Highlights**

- **Cash:** As of March 31, 2025, cash, cash equivalents and restricted cash was $100.6 million, compared to $112.4 million as of December 31, 2024. The $11.8 million decrease is a result of the net cash used in operating activities of $14.9 million for the development of our pipeline and ongoing clinical trials, offset by a $3.1 million gain on foreign exchange on cash, cash equivalents and restricted cash. Based on current research and development plans, the Company expects its available resources to fund its operating expenses and capital expenditure requirements into 2027.

- **Research and Development Expenses:** Research and development expenses were $8.3 million for the three months ended March 31, 2025 compared to $11.1 million for the three months ended March 31, 2024, with the decrease attributable to the stage of clinical development of the pipeline assets, a reduction in preclinical activity and a reduction in workforce when compared to the prior year. The year-on-year research and development expenses per program are outlined in the following table. It is anticipated that research and development expenses related to the legacy programs in infectious disease and oncology will reduce going forward, as the ongoing clinical trials complete, and that research and development expenses related to autoimmune programs will continue or increase, as the clinical development continues.

| | Three months ended March 31, 2025 | Three months ended March 31, 2024 | Change |
|---|---|---|---|
| | $000 | $000 | $000 |
| Direct research and development expenses by program: | | | |
| VTP-1000 Celiac | $ 982 | $ 1,374 | $ (392) |
| VTP-300 HBV | 1,350 | 1,913 | (563) |
| Other clinical programs[1] | 741 | 1,767 | (1,026) |
| Other pre-clinical programs | 419 | 784 | (365) |
| Total direct research and development expenses | 3,492 | 5,838 | (2,346) |
| Indirect research and development expenses: | | | |
| Personnel-related (including share-based compensation)[2] | 3,944 | 4,335 | (391) |
| Facility related | 335 | 390 | (55) |
| Other indirect costs | 519 | 562 | (43) |
| Total indirect research and development expenses | 4,798 | 5,287 | (489) |
| Total research and development expense | $ 8,290 | $ 11,125 | $ (2,835) |

*[1] This includes expenses relating to the infectious disease and oncology programs; VTP-850 Prostate cancer, VTP-200 HPV, VTP-600 NSCLC (the Phase 1/2a trial is sponsored by Cancer Research UK) and VTP-500 MERS (funded pursuant to an agreement with the Coalition for Epidemic Preparedness Innovations ("CEPI"). Expenses relating to these programs were previously presented separately, but are now aggregated for the prior period comparative.*

*[2] This includes $0.07 million and $0.14 million for the three months ended March 31, 2025 and 2024, respectively, of personnel-related indirect expenses relating to time spent progressing the VTP-500 MERS program, which is funded by CEPI.*

- **General and Administrative Expenses:** General and administrative expenses were $12.6 million in the first quarter of 2025, compared to $6.0 million in 2024. The increase of $6.6 million relates primarily to a loss of $4.4 million on foreign exchange in 2025, compared to a gain of $1.2 million in 2024 due to fluctuations between the pound sterling and the US dollar during the year. The remaining increase is attributable to an increase in depreciation of U.K. assets as a result of the expected closure of the U.K. site, and an increase in personnel costs as a result of the workforce reduction.

- **Net Loss:** For the first quarter of 2025, the Company generated a net loss attributable to its shareholders of $19.6 million, or $(0.49) 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 for the first quarter of 2024.

**About Barinthus Bio**

Barinthus Biotherapeutics (NASDAQ: BRNS) is a clinical-stage biopharmaceutical company focused on developing novel immunotherapeutic candidates for treating autoimmune and inflammatory diseases. Our guiding principle at the heart of Barinthus Bio is to help patients and their families by developing truly transformational and highly disease-specific immunotherapies that are potentially curative. Barinthus Bio's pipeline for I&I

indications is enabled by our proprietary and highly differentiated platform for promoting immune tolerance, SNAP-TI, that is designed to guide a patient's T cells to a specific location to reduce inflammation and restore the natural state of immune non-responsiveness to healthy tissue. Our lead candidate, VTP-1000, is designed to restore immune non-responsiveness to gluten in patients with celiac disease and is currently in a Phase 1 clinical trial. Barinthus Bio's differentiated technology platform and therapeutic approach, coupled with deep scientific expertise and focus on clinical development, uniquely positions the company to navigate towards delivering treatments that improve the lives of people with autoimmune and inflammatory diseases. 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, our anticipated regulatory filings and approvals, our cash runway and cash burn, our ability to develop and advance our current and future product candidates and programs, our ability to establish and maintain collaborations or strategic relationships and the terms and timing of the restructuring and related activities. 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, tariffs imposed by the U.S. and other countries and other risks identified in our filings with the Securities and Exchange Commission (the "SEC"), including our most recent annual report on Form 10-K and subsequent filings we may make with the SEC. 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)**

| | March 31, 2025 | December 31, 2024 |
|---|---|---|
| **ASSETS** | | |
| Cash and cash equivalents | $ 99,118 | $ 110,662 |
| Restricted cash | 1,461 | 1,738 |
| Research and development incentives receivable | 2,997 | 7,139 |
| Prepaid expenses and other current assets | 6,306 | 6,203 |
| Total current assets | 109,882 | 125,742 |
| Property and equipment, net | 6,201 | 7,373 |
| Intangible assets, net | 21,156 | 21,947 |
| Right of use assets, net | 3,855 | 4,384 |
| Other assets | 902 | 881 |
| Total assets | $ 141,996 | $ 160,327 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | 1,357 | 2,474 |
| Accrued expenses and other current liabilities | 7,198 | 9,525 |
| Deferred income | 1,461 | 1,738 |
| Operating lease liability - current | 1,960 | 1,920 |
| Total current liabilities | 11,976 | 15,657 |
| Non-current liabilities: | | |
| Operating lease liability - non-current | 9,959 | 10,087 |
| Contingent consideration | 2,652 | 2,650 |
| Other non-current liabilities | 1,400 | 1,360 |
| Deferred tax liability, net | 416 | 438 |
| Total liabilities | $ 26,403 | $ 30,192 |
| Commitments and contingencies (Note 15) | | |
| Stockholders' equity: | | |
| Ordinary shares, £0.000025 nominal value; 40,339,395 shares authorized, issued and outstanding (December 31, 2024: authorized, issued and outstanding: 40,234,663) | 1 | 1 |
| Deferred A shares, £1 nominal value; 63,443 shares authorized, issued and outstanding (December 31, 2024: authorized, issued and outstanding: 63,443) | 86 | 86 |
| Additional paid-in capital | 393,944 | 393,474 |
| Accumulated deficit | (257,312) | (237,664) |
| Accumulated other comprehensive loss – foreign currency translation adjustments | (21,225) | (25,868) |
| Total stockholders' equity attributable to Barinthus Biotherapeutics plc shareholders | 115,494 | 130,029 |
| Noncontrolling interest | 99 | 106 |
| Total stockholders' equity | $ 115,593 | $ 130,135 |

| | | |
|---|---|---|
| Total liabilities and stockholders' equity | $ 141,996 | $ 160,327 |

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

| | Three months ended | |
|---|---|---|
| | **March 31, 2025** | **March 31, 2024** |
| Operating expenses | | |
| Research and development | $ 8,290 | $ 11,125 |
| General and administrative | 12,639 | 5,994 |
| Total operating expenses | 20,929 | 17,119 |
| Other operating income | 329 | 205 |
| Loss from operations | (20,600) | (16,914) |
| Other income/(expense): | | |
| Interest income | 556 | 775 |
| Interest expense | (13) | (12) |
| Research and development incentives | 302 | 594 |
| Other income | 75 | — |
| Total other income, net | 920 | 1,357 |
| Loss before income tax | (19,680) | (15,557) |
| Tax benefit | 22 | 37 |
| Net loss | (19,658) | (15,520) |
| Net loss attributable to noncontrolling interest | 10 | 31 |
| Net loss attributable to Barinthus Biotherapeutics plc shareholders | (19,648) | (15,489) |
| | | |
| Weighted-average ordinary shares outstanding, basic | 40,265,216 | 38,773,482 |
| Weighted-average ordinary shares outstanding, diluted | 40,265,216 | 38,773,482 |
| Net loss per share attributable to ordinary shareholders, basic | $ (0.49) | $ (0.40) |
| Net loss per share attributable to ordinary shareholders, diluted | $ (0.49) | $ (0.40) |
| | | |
| Net loss | $ (19,658) | $ (15,520) |
| Other comprehensive gain/(loss) – foreign currency translation adjustments | 4,646 | (1,577) |
| Comprehensive loss | (15,012) | (17,097) |
| Comprehensive loss attributable to noncontrolling interest | 7 | 28 |
| Comprehensive loss attributable to Barinthus Biotherapeutics plc shareholders | $ (15,005) | $ (17,069) |

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