Barinthus Bio Reports Full Year 2024 Financial Results and Updates on Corporate Developments

Mar 20, 2025

- *Strategic transformation ongoing, positioning the Company as a focused leader in immunology and inflammatory diseases*
- *Highly differentiated, potentially curative immunotherapy for celiac disease (VTP-1000) in the clinic, with first data expected in third quarter of 2025*
- *Proprietary SNAP-TI platform promoting antigen-specific immune tolerance is anticipated to drive multiple future pipeline and partnership opportunities*
- *Strategic prioritization of resources expected to provide a cash runway into 2027*

OXFORD, United Kingdom and GERMANTOWN, Md., March 20, 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 year ended December 31, 2024 and provided an overview of the Company's business updates.

"We've entered 2025 with a refreshed strategic focus on immunological and inflammatory diseases. Following our restructuring, we are strongly positioned to advance our highly differentiated lead asset,VTP-1000, (and the underlying SNAP-TI platform) in patients with celiac disease. Through design innovations enabling greater targeting of disease antigens, intramuscular administration and potentially improved tolerability, VTP-1000 has promise to be a leading therapy for the approximate 80 million people worldwide with celiac disease. We look forward to reporting single-ascending dose Phase 1 data for this program in the third quarter of this year." said Bill Enright, Chief Executive Officer of Barinthus Bio. "VTP-1000 is based on our innovative SNAP-TI platform, which is differentiated based on its capacity to promote antigen-specific immune tolerance that specifically guides a patient's T cells to suppress unwanted inflammation and restore the natural state of immune non-responsiveness to healthy tissue without affecting immunity against cancer or infections. Given this mild and potentially curative approach to restoring balance to the immune system, we believe SNAP-TI is poised to drive multiple future pipeline and partnership opportunities for the company particularly for autoimmune diseases where broadly immunosuppressive drugs are not optimal."

"Turning to our development candidates designated for partnering, we reported highly encouraging results from two Phase 2 trials in our chronic hepatitis B ("CHB") program demonstrating that VTP-300 contributed to the achievement of undetectable HBsAg levels in eight participants, with two participants meeting functional cure criteria. Further Phase 2 data are anticipated in the second quarter of 2025, which are expected to strengthen VTP-300's market positioning as a component of a functional cure for CHB."

2024 Corporate Milestones
Clinical developments

Celiac Disease (VTP-1000)

- In April 2024, Barinthus Bio received clearance from the U.S. Food and Drug Administration and Australian regulatory authorities on an Investigational New Drug application to progress VTP-1000 in a first in human clinical trial in celiac disease.
- In September 2024, Barinthus Bio initiated the first-in-human, Phase 1 AVALON trial for VTP-1000 in celiac disease. The AVALON trial aims to enroll 42 participants with celiac disease and will be conducted in two parts: the first part, a randomized double-blind placebo controlled single ascending dose, followed by the second part, a randomized double-blind placebo-controlled multiple ascending dose and incorporating a controlled gluten challenge to assess the impact of VTP-1000 administration on patients' exposure to gluten.

Chronic Hepatitis B (VTP-300)

- In June 2024, Barinthus Bio presented interim data from the two Phase 2 trials of VTP-300, which achieved 19% undetectable HBsAg levels across both studies, indicating potential rates of functional cure. The majority of patients who were assessed reached very low levels of HBsAg and eligibility for nucleos(t)ide discontinuation.
- In October 2024, the Company completed enrollment of the Phase 2b HBV003 clinical trial for VTP-300 in CHB.
- In November 2024
    - Barinthus Bio reported positive updated interim data from the Phase 2b HBV003 clinical trial for VTP-300 showing that as of the data cut off, eight participants achieved complete HBsAg loss (defined as HBsAg levels below the lower limit of quantitation [<LLOQ, 0.05 IU/mL]) and two participants met the criteria for functional cure. Uniquely, two of the eight participants with HBsAg loss, including one of those who met functional cure criteria, developed anti-hepatitis B antibodies that they did not have before. The data were presented as an oral presentation at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2024.
    - Barinthus Bio announced interim data from the Phase 2a IM-PROVE II clinical trial in collaboration with Arbutus Biopharma Corporation ("Arbutus"). Participants received imdusiran followed by VTP-300 and low-dose nivolumab. Results indicated that Group C participants receiving nivolumab experienced increased rates of HBsAg loss at Week 48 (3/13) compared to Group A and B participants who received imdusiran and VTP-300 or placebo. These data were presented in a poster at AASLD.

Prostate Cancer (VTP-850)

- In October 2024, Barinthus Bio completed enrollment of 22 participants in the Phase 1 PCA001 clinical trial of VTP-850 for prostate cancer.

High-Risk Human Papillomavirus (VTP-200)

- In April 2024, Barinthus Bio announced topline results from the Phase 1b/2 APOLLO dose-ranging trial (also known as HPV001) of VTP-200 in women aged 25-55 with low-grade cervical lesions associated with persistent high-risk human papillomavirus (HPV) infection.

Corporate Updates

- In May 2024, Barinthus Bio appointed physician, Leon Hooftman, M.D., as Chief Medical Officer, effective as of June 3, 2024.
- In November 2024, Geoffrey Lynn, M.D., Ph.D. was promoted to Chief Scientific Officer following the departure of Nadège Pelletier, Ph.D.
- In January 2025, Barinthus Bio announced a strategic business refocus and restructuring to prioritize immunology and inflammation indications, including antigen-specific immune tolerance. As part of the restructuring, two executive leadership team members based in the U.K., the Chief Operating Officer, Graham Griffiths, and Chief Financial Officer, Gemma Brown, will leave the Company following a greater strategic focus on U.S. operations.
- 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 able to take advantage of its differentiated ability to achieve sustained HBsAg loss and functional cure in patients with low levels of HBsAg.

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.

Chronic Hepatitis B (VTP-300):

- Topline results from the Phase 2b HBV003 clinical trial evaluating additional dosing of VTP-300 and low-dose nivolumab timing in people with chronic hepatitis B infection are expected in the second quarter of 2025.
- Topline results from the Phase 2a IM-PROVE II clinical trial evaluating VTP-300, low-dose nivolumab and Arbutus' imdusiran in people with chronic hepatitis B infection are expected in the second quarter 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 (i.e., biochemical recurrence) are expected in the second quarter of 2025.

2024 Financial Highlights

- **Cash:** As of December 31, 2024, cash, cash equivalents and restricted cash was $112.4 million, compared to $142.1 million as of December 31, 2023. The net cash used in operating activities was $28.9 million, primarily resulting from development of our pipeline and ongoing clinical trials, offset by revenue of $15.0 million. Based on current research and development plans, the Company expects its available resources to fund its operating expenses and capital expenditure requirements into 2027.

- **Revenue:** Revenue was $15.0 million in 2024 compared to $0.8 million in 2023 and was comprised of the Company's share of royalties received by Oxford University Innovation as a result of commercial sales of Vaxzevria® by AstraZeneca. There is no expectation of additional payments.

- **Research and Development Expenses:** Research and development expenses were $42.2 million in 2024 compared to $44.9 million in 2023, with the decrease mainly attributable to a reduction in expenses from VTP-200 (HPV) which completed in the first quarter of 2024 and VTP-850 (prostate cancer) which completed enrollment in the third quarter of 2024, partially offset by an increase in spending on earlier stage programs in tolerance indications. The year-on-year R&D expense per program is outlined in the following table. It is anticipated that research and development expenses related to legacy programs in infectious disease and oncology will reduce going forward, as the ongoing trials complete.

Period ended	Twelve months ended December 31, 2024	Twelve months ended December 31, 2023	Change
	$ 000	$ 000	$ 000

Direct research and development expenses by program:			
VTP-1000 Celiac[1]	$ 5,486	$ 8,420	$ (2,934)
VTP-300 HBV	10,474	11,276	(802)
VTP-850 Prostate cancer	1,429	2,726	(1,297)
VTP-200 HPV	2,009	4,950	(2,941)
VTP-600 NSCLC[2]	473	597	(124)
VTP-500 MERS[3]	610	—	610
Other and earlier stage programs[4]	3,228	1,787	1,441
Total direct research and development expenses	$ 23,709	$ 29,756	$ (6,047)
Indirect research and development expenses:			
Personnel-related (including share-based compensation)	15,867	12,702	3,165
Facility related	1,249	1,339	(90)
Other indirect costs	1,411	1,077	334
Total indirect research and development expenses	18,527	15,118	3,409
Total research and development expense	$ 42,236	$ 44,874	$ (2,638)

[1] Research and development expenses related to VTP-1100 HPV Cancer were presented together with VTP-1000 Celiac in the prior period comparative, because our SNAP product candidates were both preclinical. Expenses related to VTP-1100 HPV Cancer are now included in "Other and earlier stage programs," because we are deferring the planned IND application for VTP-1100 in HPV cancer and we have initiated the clinical trial for VTP-1000 Celiac.

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

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

[4] This includes $0.9 million 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 $29.7 million in 2024, compared to $39.8 million in 2023. The decrease of $10.1 million relates primarily to a gain of $2.4 million on foreign exchange in 2024, compared to a loss of $7.8 million in 2023 due to fluctuations between the pound sterling and the US dollar during the year.

- **Goodwill Impairment Expense:** For the years ended December 31, 2024 and 2023, goodwill impairment expense was $12.2 million and nil, respectively, with the increase pertaining to the impairment assessment performed in the fourth quarter of 2024 based on the expected utilization of Company assets and external market conditions.

- **Net Loss:** For the financial year 2024, the Company generated a net loss attributable to its shareholders of $61.1 million, or $(1.55) per share on both basic and fully diluted bases, compared to a net loss attributable to its shareholders of $73.3 million, or $(1.91) per share on both basic and fully diluted bases for 2023.

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, our ability to develop and advance our current and future product candidates and programs, 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, 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)

	December 31, 2024	December 31, 2023
ASSETS		
Cash and cash equivalents	$ 110,662	$ 142,090
Restricted cash	1,738	—
Research and development incentives receivable	7,139	4,908
Prepaid expenses and other current assets	6,203	9,907
Total current assets	125,742	156,905
Goodwill	—	12,209
Property and equipment, net	7,373	11,821
Intangible assets, net	21,947	25,108
Right of use assets, net	4,384	7,581
Other assets	881	882
Total assets	$ 160,327	$ 214,506
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	2,474	1,601
Accrued expenses and other current liabilities	9,525	9,212
Deferred income	1,738	—
Operating lease liability - current	1,920	1,785
Total current liabilities	15,657	12,598
Non-current liabilities:		
Operating lease liability - non-current	10,087	11,191
Contingent consideration	2,650	1,823
Other non-current liabilities	1,360	1,325
Deferred tax liability, net	438	574
Total liabilities	$ 30,192	$ 27,511
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Ordinary shares, £0.000025 nominal value; 40,234,663 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	393,474	386,602
Accumulated deficit	(237,664)	(176,590)
Accumulated other comprehensive loss – foreign currency translation adjustments	(25,868)	(23,315)
Total stockholders' equity attributable to Barinthus Biotherapeutics plc shareholders	130,029	186,784
Noncontrolling interest	106	211
Total stockholders' equity	$ 130,135	$ 186,995
Total liabilities and stockholders' equity	$ 160,327	$ 214,506

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

	Twelve months ended	
	December 31, 2024	December 31, 2023
License revenue [1]	$ 14,969	$ 802
Total revenue	14,969	802
Operating expenses		
Research and development	42,236	44,874
General and administrative	29,670	39,842
Goodwill impairment	12,209	—
Total operating expenses	84,115	84,716
Other operating income	1,176	—
Loss from operations	(67,970)	(83,914)
Other income/(expense):		
Interest income	2,678	2,877
Interest expense	(53)	(28)

Research and development incentives	3,983	3,461
Other income	135	1,082
Total other income, net	6,743	7,392
Loss before income tax	(61,227)	(76,522)
Tax benefit	44	3,075
Net loss	(61,183)	(73,447)
Net loss attributable to noncontrolling interest	109	100
Net loss attributable to Barinthus Biotherapeutics plc shareholders	(61,074)	(73,347)
Weighted-average ordinary shares outstanding, basic	39,348,240	38,386,491
Weighted-average ordinary shares outstanding, diluted	39,348,240	38,386,491
Net loss per share attributable to ordinary shareholders, basic	$ (1.55)	$ (1.91)
Net loss per share attributable to ordinary shareholders, diluted	$ (1.55)	$ (1.91)
Net loss	$ (61,183)	$ (73,447)
Other comprehensive (loss)/gain – foreign currency translation adjustments	(2,549)	10,151
Comprehensive loss	(63,732)	(63,296)
Comprehensive loss attributable to noncontrolling interest	105	94
Comprehensive loss attributable to Barinthus Biotherapeutics plc shareholders	$ (63,627)	$ (63,202)

[1] All license revenue is from related parties and is generated in the United Kingdom for the years ended December 31, 2024 and 2023.

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