



Barinthus Bio Reports Full Year 2023 Financial Results and Update on Corporate Developments

Mar 20, 2024

OXFORD, United Kingdom, March 20, 2024 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS), formerly Vaccitech plc, announced its financial results for the year ended December 31, 2023, and an overview of the Company's progress. 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.

"2023 was a productive year for Barinthus Bio, with data presented in our HBV and HPV programs, the first patient visit in our next generation prostate cancer program and up to \$35 million of future funding committed from the Coalition for Epidemic Preparedness Innovations (CEPI) secured for our MERS program," said Bill Enright, Chief Executive Officer of Barinthus Bio. "We expect another data rich year in 2024, with anticipated final results from our Phase 1b/2 HPV APOLLO trial of VTP-200, and additional data from our two ongoing Phase 2 trials of VTP-300 in chronic HBV infection. In addition, our SNAP-TI platform is heading into the clinic for the first time as we expect to initiate a Phase 1 clinical trial of VTP-1000 in celiac disease, our lead program in autoimmunity."

2023 Corporate Milestones

Clinical Developments

HBV (VTP-300):

- In March 2023, we announced positive topline final data from the HBV002 Phase 2 clinical trial for VTP-300 in Chronic Hepatitis B (CHB). The data showed meaningful, durable reductions of Hepatitis B Surface Antigen (HBsAg) in all participants with a $>0.5 \log_{10}$ reduction in HBsAg who received VTP-300 alone or in combination with a single administration of low-dose PD-1 inhibitor, nivolumab. Two of five patients with baseline HBsAg below 100 IU/mL in Group 3, developed a non-detectable HBsAg level, which continued eight months after last dose. We presented the final data in June 2023 at the European Association for the Study of the Liver Congress 2023 – The International Liver Congress™.
- In November 2023, we presented interim data from the HBV003 Phase 2b clinical trial for VTP-300 in CHB showing that VTP-300 in combination with nivolumab continued to show sustained HBsAg reductions, particularly in patients with HBsAg levels below or equal to 200 IU/mL at screening. We presented this data during an oral presentation at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2023.
- Also in November 2023, interim data from the Phase 2a AB-729-202 clinical trial in collaboration with Arbutus Biopharma Corporation (Arbutus) in CHB patients were presented at AASLD, showing that imdusiran in combination with VTP-300 demonstrated meaningful and sustained declines in HBsAg levels.

HPV (VTP-200):

- In March 2023, we announced favorable topline interim data from the HPV001 Phase 1b/2 clinical trial of VTP-200 in high-risk HPV (hrHPV) infection.
- In April, we presented interim data from the VTP-200 APOLLO (HPV001) Phase 1b/2 clinical trial in hrHPV infection at the 35th Annual International Papillomavirus Conference. Immunological results showed VTP-200 induced high T cell responses to HPV antigens, and was generally well-tolerated with no product-related grade 3 unsolicited events and no product-related SAEs.

Celiac Disease (VTP-1000):

- In December 2023, we submitted an Australian ethics submission and regulatory notification to the Alfred Research Review Committee for the Phase 1 GLU001 study in Celiac disease.

Prostate Cancer (VTP-850):

- In June 2023, we announced the dosing of the first patient in the PCA001 Phase 1/2 clinical trial for VTP-850 in prostate cancer.

MERS (VTP-500):

- In December 2023, we announced an agreement with the Coalition for Epidemic Preparedness Innovations (CEPI) and the University of Oxford, aiming to fast-track the development of our vaccine candidate, VTP-500, for the prevention of Middle East Respiratory Syndrome. This agreement includes CEPI investing funding of up to \$35 million to Barinthus Bio in addition to funds previously committed to the University of Oxford to develop and stockpile a ready reserve of VTP-500.

Key Operational Updates

- In January 2023, we announced the appointment of Nadège Pelletier, Ph.D., as Chief Scientific Officer.

- In June 2023, we completed the move of our U.S. facility to Germantown, Maryland, which houses a state-of-the art wet laboratory and office space.
- In November 2023, we announced the company's renaming as Barinthus Biotherapeutics plc to represent the evolution and expansion of its focus beyond vaccines. As part of the renaming, the Company changed its Nasdaq ticker to "BRNS", which became effective on Nasdaq on November 7, 2023.

Upcoming Milestones

In 2024, the Company expects to:

- Q2 2024:
 - HBV:
 - Announce 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 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.
 - HPV:
 - Announce final results from participants receiving VTP-200 in the Phase 1b/2 APOLLO (HPV001) trial evaluating the safety, immunogenicity and efficacy of VTP-200 in persistent HPV infection and low-grade cervical lesions.
 - Celiac disease:
 - Initiate a Phase 1 clinical trial of VTP-1000.
- Q4 2024:
 - HBV:
 - Announce more mature 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 more mature 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.

2023 Financial Highlights

- **Cash position:** As of December 31, 2023, cash was \$142.1 million, compared to \$194.4 million as of December 31, 2022. The cash used in operating activities was \$50.9 million, primarily resulting from our net loss of \$73.4 million, adjusted by foreign exchange loss on translation of \$7.5 million, share-based compensation of \$5.1 million, depreciation and amortization of \$5.4 million, deferred tax movements of \$3.1 million and changes in our operating assets and liabilities, net of \$6.2 million primarily related to a \$5.8 million decrease in accounts receivable, a \$2.2 million decrease in prepaid expenses and other current assets, \$3.4 million decrease in accounts payable and \$2.0 million increase in accrued expenses.
- **Revenue:** Revenue was \$0.8 million in 2023 compared to \$44.7 million in 2022 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, sales of which reduced significantly in 2023 when compared to 2022.
- **Research and development expenses:** Research and development expenses were \$44.9 million in 2023 compared to \$42.4 million in 2022, demonstrating the progression of our pipeline through the clinic. Direct research and development expenses reduced \$0.6 million, comprising of a \$3.3 million increase in expense on the SNAP platform candidates, namely VTP-1000, offset by a reduction in expense of \$2.4 million due to the phasing of VTP-300 in two ongoing Phase 2 clinical trials, and a \$2.3 million reduction as a result of VTP-850 getting into the clinic in a Phase 1/2 clinical trial in prostate cancer. Indirect research and development expenses increased \$3.1 million as a result of an increase in headcount attributing to an increase in personnel costs of \$2.3 million and an increase in facility costs due to moving the U.S. office to a 19,700 square foot, state-of-the-art wet laboratory and office facility in Germantown, Maryland, in June 2023. The year-on-year R&D expense per program is outlined in the following table.

Year ended	December 31, 2023	December 31, 2022	Change
	\$ 000	\$ 000	\$ 000
Direct research and development expenses by program:			
VTP-200 HPV	\$ 4,950	\$ 4,050	\$ 900
VTP-300 HBV	11,276	13,700	(2,424)
VTP-600 NSCLC ¹	597	532	65
VTP-850 Prostate cancer	2,726	5,011	(2,285)
VTP-1000/VTP-1100 Celiac/HPV Cancer	8,420	5,118	3,302
Other and earlier stage programs	1,787	1,916	(129)
Total direct research and development expenses	\$ 29,756	\$ 30,327	\$ (571)
Indirect research and development expenses:			
Personnel-related (including share-based compensation)	12,702	10,424	2,278
Facility-related	1,339	1,308	31
Other internal costs	1,077	291	786

Total indirect research and development expenses	15,118	12,023	3,095
Total research and development expense	<u>\$ 44,874</u>	<u>\$ 42,350</u>	<u>\$ 2,524</u>

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

- **General and administrative expenses:** General and administrative expenses were \$39.8 million in 2023, compared to \$6.4 million in 2022. The increase is primarily attributable to a \$7.6 million loss on foreign exchange in 2023 compared to a \$26.4 million gain on foreign exchange in 2022 as a result of movements in the USD:GBP exchange rate during the respective periods.
- **Net loss:** For the financial year 2023, the Company generated a net loss attributable to its shareholders of \$73.3 million, or \$1.91 per fully diluted share and per basic share, compared to a net income attributable to shareholders of \$5.3 million, or \$0.14 per fully diluted share and per basic share, for 2022.

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, 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 four 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 HPV infection; 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 future expectations, plans and prospects, including our product development activities and clinical trials, including timing for readouts of any interim data for any of our programs, our anticipated regulatory filings and approvals, our preliminary estimated cash and cash equivalents, 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, our ability to execute on our strategy, regulatory developments, the risk that we may not realize the benefits related to our rebranding and name change, our ability to fund our operations and access capital, our preliminary estimates of our cash and cash equivalents and cash runway, including the risk that final financial results may differ materially from our preliminary estimates, 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.

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

	December 31, 2023	December 31, 2022
ASSETS		
Cash and cash equivalents	\$ 142,090	\$ 194,385
Accounts receivable	—	323
Accounts receivable – related parties	—	5,524
Research and development incentives receivable	4,908	4,541
Prepaid expenses and other current assets	9,907	8,268
Total current assets	156,905	213,041
Goodwill	12,209	12,209
Property and equipment, net	11,821	7,957
Intangible assets, net	25,108	28,269
Right of use assets, net	7,581	7,753
Other assets	882	976
Total assets	<u>\$ 214,506</u>	<u>\$ 270,205</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,601	3,748

Accrued expenses and other current liabilities	9,212	8,061
Deferred revenue	—	—
Operating lease liability - current	\$ 1,785	\$ 433
Total current liabilities	12,598	12,242
Non-Current liabilities:		
Operating lease liability - non-current	11,191	8,340
Contingent consideration	1,823	1,711
Other non-current liabilities	1,325	965
Deferred tax liability, net	574	3,746
Total liabilities	\$ 27,511	\$ 27,004
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Ordinary shares, £0.000025 nominal value; 38,643,540 shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 37,683,531)	1	1
Deferred A shares, £1 nominal value; 63,443 shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 63,443)	86	86
Deferred B shares, £0.01 nominal value; nil shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 570,987)	—	8
Deferred C shares, £0.000007 nominal value, nil shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 27,828,231)	—	0
Additional paid-in capital	386,602	379,504
Accumulated deficit	(176,590)	(103,243)
Accumulated other comprehensive loss – foreign currency translation adjustments	(23,315)	(33,460)
Total stockholders' equity attributable to Barinthus Biotherapeutics plc shareholders	186,784	242,896
Noncontrolling interest	211	305
Total stockholders' equity	\$ 186,995	\$ 243,201
Total liabilities and stockholders' equity	\$ 214,506	\$ 270,205

¹ indicates amount less than thousand.

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

	December 31, 2023	December 31, 2022
License revenue ¹	\$ 802	\$ 44,694
Research grants and contracts	—	9
Total revenue	802	44,703
Operating expenses		
Research and development	44,874	42,350
General and administrative	39,842	6,394
Total operating expenses	84,716	48,744
Loss from operations	(83,914)	(4,041)
Other income /(expense):		
Interest income	2,877	3,103
Interest expense	(28)	(19)
Research and development incentives	3,461	1,240
Other income, net	1,082	567
Total other income, net	7,392	4,891
(Loss)/profit before income tax	(76,522)	850
Tax benefit	3,075	4,471
Net (loss)/income	(73,447)	5,321
Net loss attributable to noncontrolling interest	100	21
Net (loss)/income attributable to Barinthus Biotherapeutics plc shareholders	(73,347)	5,342
Weighted-average ordinary shares outstanding, basic	38,386,491	37,248,126
Weighted-average ordinary shares outstanding, diluted	38,386,491	38,169,307
Net (loss)/income per share attributable to ordinary shareholders, basic	\$ (1.91)	\$ 0.14
Net (loss)/income per share attributable to ordinary shareholders, diluted	\$ (1.91)	\$ 0.14
Net (loss)/income	\$ (73,447)	\$ 5,321
Other comprehensive gain/(loss) – foreign currency translation adjustments	10,151	(25,083)
Comprehensive loss	(63,296)	(19,762)

Comprehensive loss attributable to noncontrolling interest	94	132
Comprehensive loss attributable to Barinthus Biotherapeutics plc shareholders	<u>\$ (63,202)</u>	<u>\$ (19,630)</u>

¹ Includes license revenue from related parties for the year ended December 31, 2023 of \$0.8 million (December 31, 2022: \$44.7 million).

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