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

Nov 6, 2024

OXFORD, United Kingdom, Nov. 06, 2024 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS), a clinical-stage biopharmaceutical company developing novel immunotherapeutic candidates that guide T cells to control disease, provided an overview of business updates and announced financial results for the third quarter of 2024.

“We continue our strong execution on our clinical trials, completing enrollment in the HBV003 trial of VTP-300 in chronic hepatitis B, and advancing VTP-1000 in celiac disease into the clinic with the first in human study of the novel SNAP-TI platform,” said Dr. Leon Hooftman, Chief Medical Officer of Barinthus Bio. “We expect a data rich fourth quarter from the VTP-300 chronic hepatitis B program, with updated interim readouts from both the HBV003 and IM-PROVE II trials accepted as late-breaking abstracts at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2024. These updates will provide more mature data than previously disclosed as participants progress and move towards a potential functional cure.”

Third Quarter 2024 and Recent Corporate Developments

VTP-300 (Chronic hepatitis B)

In September 2024, enrollment was completed in the HBV003 trial of VTP-300 in 121 adult participants with chronic hepatitis B. The Phase 2b trial is designed to obtain critical dosing information for a potential functional cure regimen for chronic hepatitis B, with participants receiving VTP-300 and low-dose (LD) nivolumab.

Earlier this year, interim data from the HBV003 trial was presented at the European Association for the Study of the Liver (EASL) Congress and demonstrated that treatment with VTP-300 and LD nivolumab was generally well-tolerated and led to a sustained decline in Hepatitis B surface antigen (HBsAg) levels. Seventy-six percent of participants (n=16/21) assessed for nucleos(t)ide analogue (NUC) therapy discontinuation met the criteria. Sixty-seven percent of participants (n=14/21) assessed for NUC discontinuation had HBsAg <10 IU/mL at Week 24 or later. Nineteen percent of the eligible participants (n=4/21) reached undetectable levels of HBsAg, with 2 of these patients maintaining undetectable levels for over 16 weeks.

VTP-1000 (Celiac Disease)

In September 2024, we initiated the first-in-human Phase 1 AVALON trial of VTP-1000 in adults with celiac disease. The randomized, placebo-controlled clinical trial, which includes a controlled gluten challenge, will evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of VTP-1000.

VTP-850 (Prostate Cancer)

In October 2024, we announced that the PCA001 trial of VTP-850 in men with rising prostate-specific antigen (PSA) after definitive local therapy for prostate cancer (*i.e.*, biochemical recurrence) had completed patient enrollment of 22 participants. The Phase 1 trial is designed to evaluate safety and efficacy, as measured by PSA and T cell response. We expect to have data from the Phase 1 trial in the first half of 2025.

Financial Update

In October 2024, we were informed that an additional $15.0 million of revenue was due to the Company from Oxford University Innovation (OUI) in relation to the Company's share of royalties received by OUI, as a result of prior commercial sales of Vaxzevria® by AstraZeneca. We expect that this additional cash, when received, will enable us to fund our research and development plans further into the second quarter of 2026.

Upcoming Milestones

VTP-300 (Chronic hepatitis B)

In the fourth quarter of 2024, we expect to announce updated data from the VTP-300 program in ongoing clinical trials in chronic hepatitis B at AASLD – The Liver Meeting® 2024 scheduled from November 15-19, 2024 in San Diego, CA:

- Updated interim data from HBV003, the Phase 2b trial evaluating additional dosing of VTP-300 and timing of PD-1 inhibition, accepted as a late-breaking oral presentation.
- Updated interim data from the Phase 2a IM-PROVE II clinical trial evaluating the combination of VTP-300 and Arbutus Biopharma’s imdusiran, accepted as a late-breaking poster.

VTP-1000 (Celiac Disease)

In the first half of 2025, we expect to announce data from the single ascending dose part of the Phase 1 AVALON trial of VTP-1000 in adults with celiac disease.

VTP-850 (Prostate Cancer)

In the first half of 2025, we expect to announce results of the Phase 1 PCA001 trial of VTP-850 in men with rising PSA after definitive local therapy for prostate cancer (*i.e.*, biochemical recurrence).

Third Quarter 2024 Financial Highlights

- **Cash position:** As of September 30, 2024, cash, cash equivalents and restricted cash were $106.1 million, compared to

$117.8 million as of June 30, 2024. The net cash used in operating activities was $18.2 million in the third quarter of 2024, primarily resulting from the development of our pipeline and ongoing clinical trials, offset by $6.2 million due to the effect of foreign exchange rates on cash balances. Based on our current operating plans, we expect our available resources to fund operating expenses and capital expenditure requirements into the second quarter of 2026.

- **Revenue:** Revenue consisted of $15.0 million in the third quarter of 2024 compared to nil in the second quarter of 2024. Revenue was comprised of the Company's share of royalties received by OUI as a result of prior commercial sales of Vaxzevria® by AstraZeneca.There is no expectation of additional payments or that we will be notified of such payments in a timely manner.

- **Research and development expenses:** Research and development expenses were $11.1 million in the third quarter of 2024 compared to $11.7 million in the second quarter of 2024, with the decrease mainly attributable to a reduction in personnel-related costs as a result of the pipeline prioritization earlier in the year. The quarter-on-quarter R&D expense per program is outlined in the following table.

Period ended	Three months ended September 30, 2024	Three months ended June 30, 2024	Change
	$ 000	$ 000	$ 000
Direct research and development expenses by program:			
VTP-200 HPV	$ 246	$ 383	$ (137)
VTP-300 HBV	2,748	3,034	(286)
VTP-500 MERS[1]	40	304	(264)
VTP-600 NSCLC/ESCC[2]	108	24	84
VTP-850 Prostate cancer	914	414	500
VTP-1000 Celiac	1,751	1,371	380
Other and earlier stage programs	707	908	(201)
Total direct research and development expenses	$ 6,514	$ 6,438	$ 76
Indirect research and development expenses:			
Personnel-related (including share-based compensation)[3]	3,871	4,763	(892)
Facility related	214	342	(128)
Other indirect costs	540	119	421
Total indirect research and development expenses	4,625	5,224	(599)
Total research and development expense	$ 11,139	$ 11,662	$ (523)

[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/Esophageal Squamous-Cell Carcinoma (ESCC) Phase 1/2a trial is sponsored by Cancer Research UK.

[3] This includes $0.6 million of personnel-related indirect expenses relating to time spent progressing the VTP-500 MERS program funded by CEPI.

- **General and administrative expenses:** General and administrative expenses were $13.4 million in the third quarter of 2024, compared to $7.2 million in the second quarter of 2024. The increase of $6.2 million relates primarily to a loss of $7.7 million on foreign exchange in the third quarter of 2024, compared to a loss of $0.1 million in the second quarter of 2024.

- **Net loss:** For the third quarter of 2024, we generated a net loss attributable to shareholders of $8.1 million, or $(0.21) per share on both basic and fully diluted bases, compared to a net loss attributable to shareholders of $16.9 million, or $(0.43) per share on both basic and fully diluted bases in the second quarter of 2024.

About Barinthus Bio

Barinthus Bio is a clinical-stage biopharmaceutical company developing novel 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 immunotherapeutic product candidates in infectious diseases and autoimmunity, including: VTP-300, that utilizing our ChAdOx/MVA platform designed as a potential component of a functional cure for chronic HBV infection and VTP-1000, utilizing our SNAP-Tolerance Immunotherapy (SNAP-TI) platform and is designed to treat people with celiac disease. Barinthus Bio is also conducting a Phase 1 clinical trial for VTP-850, a second-generation immunotherapeutic candidate designed to treat recurrent prostate cancer. Barinthus Bio's differentiated technology platforms 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 chronic infectious diseases and autoimmunity. For more information, visit www.barinthusbio.com.

Barinthus Bio intends to use the Investors section of its website, its X (formerly known as Twitter) account at @Barinthusbio and its LinkedIn account at linkedin.com/company/barinthus-bio as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor Barinthus Bio's website, its X account and its LinkedIn account in addition to following Barinthus Bio's press releases, SEC filings, public conference calls, presentations, and webcasts.

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, our anticipated regulatory filings and approvals, our cash runway, the potential benefits of our product candidates, 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)

	September 30, 2024	December 31, 2023
ASSETS		
Cash, cash equivalents and restricted cash	$ 106,102	$ 142,090
Contract asset - related parties	14,969	—
Research and development incentives receivable	5,403	4,908
Prepaid expenses and other current assets	8,180	9,907
Total current assets	134,654	156,905
Goodwill	12,209	12,209
Property and equipment, net	10,719	11,821
Intangible assets, net	22,737	25,108
Right of use assets, net	7,444	7,581
Other assets	926	882
Total assets	$ 188,689	$ 214,506
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	3,076	1,601
Accrued expenses and other current liabilities	7,966	9,212
Deferred income	2,044	—
Operating lease liability - current	1,986	1,785
Total current liabilities	15,072	12,598
Non-current liabilities:		
Operating lease liability - non-current	10,683	11,191
Contingent consideration	1,610	1,823
Other non-current liabilities	1,406	1,325
Deferred tax liability, net	457	574
Total liabilities	$ 29,228	$ 27,511
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Ordinary shares, £0.000025 nominal value; 39,542,518 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	391,882	386,602
Accumulated deficit	(217,124)	(176,590)
Accumulated other comprehensive loss – foreign currency translation adjustments	(15,551)	(23,315)
Total stockholders' equity attributable to Barinthus Biotherapeutics plc shareholders	159,294	186,784
Noncontrolling interest	167	211
Total stockholders' equity	$ 159,461	$ 186,995
Total liabilities and stockholders' equity	$ 188,689	$ 214,506

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(IN THOUSANDS, EXCEPT NUMBER OF SHARES AND PER SHARE AMOUNTS)
(UNAUDITED)

	Three months ended		Nine months ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
License revenue [1]	$ 14,969	$ —	$ 14,969	$ 802
Total revenue	14,969	—	14,969	802
Operating expenses				
Research and development	11,139	15,144	33,926	38,501
General and administrative	13,420	961	26,615	26,227
Total operating expenses	24,559	16,105	60,541	64,728
Other operating income	210	—	992	—
Loss from operations	(9,380)	(16,105)	(44,580)	(63,926)
Other income/(expense):				
Interest income	631	196	2,041	2,306
Interest expense	(17)	(7)	(41)	(21)
Research and development incentives	608	1,205	1,895	2,921
Other income/(expense)	26	(2)	46	308
Total other income, net	1,248	1,392	3,941	5,514
Loss before income tax	(8,132)	(14,713)	(40,639)	(58,412)
Tax benefit	3	603	47	2,255
Net loss	(8,129)	(14,110)	(40,592)	(56,157)
Net loss attributable to noncontrolling interest	15	38	58	103
Net loss attributable to Barinthus Biotherapeutics plc shareholders	(8,114)	(14,072)	(40,534)	(56,054)
Weighted-average ordinary shares outstanding, basic	39,419,447	38,533,833	39,079,259	38,320,208
Weighted-average ordinary shares outstanding, diluted	39,419,447	38,533,833	39,079,259	38,320,208
Net loss per share attributable to ordinary shareholders, basic	$ (0.21)	$ (0.37)	$ (1.04)	$ (1.46)
Net loss per share attributable to ordinary shareholders, diluted	$ (0.21)	$ (0.37)	$ (1.04)	$ (1.46)
Net loss	$ (8,129)	$ (14,110)	$ (40,592)	$ (56,157)
Other comprehensive gain/(loss) – foreign currency translation adjustments	9,191	(7,820)	7,778	2,364
Comprehensive income/(loss)	1,062	(21,930)	(32,814)	(53,793)
Comprehensive loss attributable to noncontrolling interest	5	48	44	100
Comprehensive income/(loss) attributable to Barinthus Biotherapeutics plc shareholders	$ 1,067	$ (21,882)	$ (32,770)	$ (53,693)

[1] Includes license revenue from related parties for the three and nine months ended September 30, 2024 of $15.0 million (three and nine months ended September 30, 2023: nil and $0.8 million, respectively).

IR contacts:
Christopher M. Calabrese
Managing Director
LifeSci Advisors
+1 917-680-5608
ccalabrese@lifesciadvisors.com

Kevin Gardner
Managing Director
LifeSci Advisors
+1 617-283-2856
kgardner@lifesciadvisors.com

Media contact:
Audra Friis
Sam Brown, Inc.
+1 917-519-9577
audrafriis@sambrown.com

Company contact:
Jonothan Blackbourn
IR & PR Manager
Barinthus Bio
ir@barinthusbio.com