BioAtla Reports Fourth Quarter and Full Year 2023 Financial Results and Highlights Recent Progress

March 26, 2024 at 4:01 PM EDT

- **CAB-CTLA-4 (BA3071) Phase 1 study cleared dose-limiting toxicity (DLT) observation period with 700 mg (10 mg/kg); initial Phase 2 monotherapy data readout anticipated in 2Q 2024 and in combination with pembrolizumab in 2H 2024**
- **CAB-ROR2 (BA3021) Phase 2 melanoma and squamous cell carcinoma of the head and neck (SCCHN) clinical trials fully enrolled; on track for data readouts in 2Q 2024**
- **CAB-AXL (BA3011) Phase 2 potentially registrational study in undifferentiated pleomorphic sarcoma (UPS) on track for enrollment completion of approximately 20 patients in April with anticipated FDA meeting for guidance on the remaining portion of the potentially registrational trial in 2H 2024**
- **CAB-EpCAM x CAB-CD3 (BA3182) Phase 1 dose-escalation study on track with full data readout anticipated in 2H 2024; potential initiation of Phase 2 study in 2H 2024**
- **Cash balance of $111.5 million at year-end 2023 is expected to fund operations into 2H 2025**
- **Management to host conference call and webcast today at 4:30 PM Eastern Time**

SAN DIEGO, March 26, 2024 (GLOBE NEWSWIRE) -- **BioAtla, Inc. (Nasdaq: BCAB)**, a global clinical-stage biotechnology company focused on the development of Conditionally Active Biologic (CAB) antibody therapeutics for the treatment of solid tumors, today announced its financial results for the fourth quarter and full year ended December 31, 2023, and provided highlights on its clinical programs.

“BioAtla continued to make considerable progress in 2023 across both of our CAB-ADC clinical trials targeting multiple tumor types, as well as advancing our CAB-CTLA-4 clinical asset, BA3071, with recent clearance of the DLT observation period at the 10 mg/kg dosing cohort,” said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. “We are excited to have several upcoming important milestones in the second quarter of this year including: initial data readouts from our Phase 2 BA3071 study; Phase 2 data for CAB-ROR2-ADC, BA3021, in both melanoma and head and neck cancer; and evaluation of clinical benefit in AXL-agnostic patients in our CAB-AXL-ADC, BA3011, Phase 2 NSCLC extension study. As we finalize these data sets in preparation for potentially registrational trials across our lead programs, we are engaging with potential pharmaceutical partners that are capable of accelerating development and maximizing the value of selected assets.”

Key Developments, Operational Updates and Upcoming Milestones

- **Phase 1/2 dose-escalation trial of Evalstotug, CAB-CTLA-4 (BA3071, NCT05180799) across multiple solid tumor types responsive to CTLA-4**
  - Phase 1 study
    - Cleared DLT observation period at 700 mg (10 mg/kg for 70 kg person)
    - Enrolling dose cohort of 1000 mg (14.2 mg/kg for 70 kg person); on track to clear DLT period in 2Q 2024
  - Initial Phase 2 data readout in approximately 20 patients with two scans in treatment-refractory solid tumors at 350 mg or 700 mg (5 or 10 mg/kg for 70 kg person) treated with monotherapy anticipated in 2Q 2024
  - Currently enrolling first-line melanoma and NSCLC patients at the 350 mg or 700 mg (5 or 10 mg/kg for 70 kg person); anticipated data readout of BA3071 combination with pembrolizumab in 2H 2024
- **Phase 2 Trials of Ozuriftamab Vedotin, CAB-ROR2-ADC, (BA3021) in treatment-refractory melanoma (NCT03504488) and treatment-refractory SCCHN (NCT05271604)**
  - Melanoma patients (n=28) dosed at the Q2W regimen; anticipate two plus scans in April
  - SCCHN patients dosed at Q2W or 2Q3W regimens (n=12 and 20, respectively); anticipate two plus scans in May
  - Data readouts for both indications anticipated in May
- **Phase 2 Trials of Mecbotamab Vedotin, CAB-AXL-ADC, (BA3011):**
  - **UPS (NCT03425279) ongoing potentially registrational trial**
    - On track to complete enrollment of approximately 20 patients in April
    - Anticipate FDA meeting for guidance on the remaining portion of the registration trial in 2H 2024
  - **Bone and soft tissue sarcomas (NCT03425279)**
    - Data presented as oral presentation at ESMO Sarcoma and Rare Cancers on March 14
      - Promising monotherapy disease control rate among 43% of patients with treatment-refractory sarcomas (n=87)
      - Osteosarcoma: two partial responses observed out of 11 efficacy-evaluable patients with observed PFS at 12 weeks of 45.5%
      - Manageable safety profile with no new safety signals reported, no Grade 3 peripheral neuropathy
  - **NSCLC (NCT04681131)**
    - Enrolled 33 target-agnostic patients at the 2Q3W regimen across squamous and non-squamous patients
    - Study is on track to evaluate initial clinical benefit in the target-agnostic non-squamous EGFR wild-type

patient population in 2Q 2024

- **Phase 1/2 dose-escalation for CAB-EpCAM x CAB-CD3 TCE (BA3182, NCT05808634)**
  - Anticipate completion of Phase 1 with data readout in 2H 2024
  - Potential initiation of Phase 2 study in 2H 2024
- **Anti-Nectin-4-ADC (BA3361)**
  - *In vitro* and *in vivo* characterization of a novel NextGen linker system yields differentiated anti-Nectin-4-ADC
  - Data to be presented at upcoming AACR Annual Meeting in April:
    - Complete tumor regression observed in several cell line derived xenograft models
    - Superior efficacy to an enfortumab vedotin analogue in a patient-derived xenograft pancreatic cancer model
    - Demonstrated influence of linker technology on specific cancer models and reduced toxicity through CAB selectivity
  - IND submission anticipated in 2Q 2024

Presentations

- Oral presentation titled "Results from a Phase 2 part 1 trial of mecbotamab vedotin (BA3011), a CAB-AXL-ADC, in patients with advanced refractory sarcoma" at ESMO Sarcoma and Rare Cancers Congress March 2024
- Trial in Progress poster titled "Phase 1 study of BA3182, a conditionally active bispecific anti-EpCAM x CD3 antibody, in patients with advanced adenocarcinoma" presented at SITC Spring Scientific Meeting March 2024
- Five preclinical abstracts accepted for poster presentations at the upcoming American Association for Cancer Research (AACR) 2024 Annual Meeting, titled:
  - "Using a novel NextGen linker system to generate a Conditionally Active Biologic (CAB) anti-Nectin4-ADC demonstrates improved efficacy in pancreatic PDX cancer models and improved tolerability and toxicity profile in non-human primates"
  - "Novel conditionally active tetravalent B7-H3 x CD3 T-cell engager targeting solid tumors"
  - "Novel Conditionally Active Biologic (CAB) tetravalent T-cell engagers targeting solid tumors"
  - "Targeting novel senescence markers by Conditionally Active Biologics eliminates senescence-associated secretory phenotype in *in vitro* and *in vivo* models"
  - "Development of a humanized anti-IL-22 antibody for cancer and inflammation therapy"
- Late-breaking abstract titled "Novel Conditionally Active Biologic (CAB) tetravalent T-cell engagers targeting solid tumors" accepted for presentation at the upcoming AACR Annual Meeting April 2024 and will be published online in *Proceedings of the AACR*
- Online article published in *mABs* March 2024 (https://doi.org/10.1080/19420862.2024.2322562), titled "A novel Conditional Active Biologic anti-EpCAM x anti-CD3 bispecific antibody with synergistic tumor selectivity for cancer immunotherapy"

Fourth Quarter and Full Year 2023 Financial Results

Research and development (R&D) expenses were $22.7 million for the quarter ended December 31, 2023 compared to $21.9 million for the same quarter in 2022. The increase of $0.8 million was due to clinical development expenses primarily related to the launch of our BA3011 UPS potentially registrational trial in 2023 and overall accelerated enrollment across our clinical trials in 2023, offset by a decrease in expense for our pre-clinical programs and selected clinical indications due to our program prioritization in 2023. We expect our R&D expenses to decrease overall in the 1H of 2024 due to recent completion of enrollment in clinical trials for data sets expected to enable potentially registrational trials for our ADC programs, BA3021 and BA3011.

General and administrative (G&A) expenses were $5.9 million for the quarter ended December 31, 2023 compared to $6.7 million for the same quarter in 2022. The $0.8 million decrease was primarily due to lower stock based compensation and D&O insurance premiums.

Net loss for the quarter ended December 31, 2023 was $26.9 million compared to a net loss of $27.6 million for the same quarter in 2022.

Net cash used in operating activities for the full year ended December 31, 2023 was $104.0 million compared to net cash used in operating activities of $90.4 million for the same period in 2022. Cash used for the quarter ended December 31, 2023 was $29.8 million.

Cash and cash equivalents as of December 31, 2023 were $111.5 million, compared to $215.5 million as of December 31, 2022. We expect our current cash and cash equivalents will be sufficient to fund operations into the second half of 2025.

Fourth Quarter and Full Year 2023 Conference Call and Webcast Details

The management of BioAtla, Inc. will host a conference call and webcast for the investment community today, March 26, 2024, at 4:30 pm Eastern Time. A live webcast may be accessed here:

https://viavid.webcasts.com/starthere.jsp?ei=1653291&tp_key=ca14db6fd2. The conference call can be accessed by dialing toll-free (877) 425-9470 or (201) 389-0878 (international). The passcode for the conference call is 13744024.

A replay of the webcast and slides with topline interim clinical data referenced on the call will be available through "Events & Presentations" in the Investors section of the company's website after the conclusion of the presentation and will be archived on the BioAtla website for one year.

About Mecbotamab Vedotin (BA3011)

Mecbotamab vedotin, CAB-AXL-ADC, is a conditionally and reversibly active antibody drug conjugate targeting the receptor tyrosine kinase AXL. This Phase 2 stage clinical asset is targeting multiple solid tumor indications, including the treatment of soft tissue and bone sarcoma and non-small cell lung cancer (NSCLC) patients who have previously progressed on PD-1/L1, EGFR or ALK inhibitor therapies. The Office of Orphan Products

Development (OOPD) at FDA granted Orphan Drug Designation to mecbotamab vedotin for the treatment of soft tissue sarcoma.

About Ozuriftamab Vedotin (BA3021)
Ozuriftamab vedotin, CAB-ROR2-ADC, is a conditionally and reversibly active antibody drug conjugate directed against ROR2, a receptor tyrosine kinase that is overexpressed across many different solid tumors including lung, head and neck and melanoma. This Phase 2 stage clinical asset is targeting multiple solid tumor indications, including the treatment of NSCLC patients who have previously progressed on PD-1/L1, EGFR or ALK inhibitor therapies, melanoma patients who have previously progressed on PD-1/L1 therapy and SCCHN patients who have previously progressed on PD-1/L1 therapies with or without platinum chemotherapy.

About Evalstotug (BA3071)
BA3071, is a CAB anti-CTLA-4 antibody that is being developed as an immuno-oncology agent with the goal of delivering efficacy at least comparable to the approved anti-CTLA-4 antibodies, but with lower toxicities due to the CAB's tumor microenvironment-restricted activity. This may enable safer anti-CTLA-4 antibody combination therapies, such as with anti-PD-1 antibody checkpoint inhibitors, and potentially broaden the patient population tolerant to combination therapy and deliver greater efficacy. Like our other CAB candidates, this Phase 2 clinical asset is designed to be conditionally and reversibly active in the tumor microenvironment. BA3071 is being developed as a potential therapeutic for multiple solid tumor indications that are known to be responsive to CTLA-4 treatment in combination with a PD-1 blocking agent.

About BA3182
BioAtla is developing BA3182 as a potential anticancer therapy for patients with advanced adenocarcinoma. BA3182 is a conditionally active biologic (CAB) EpCAM x (CAB) CD3 bispecific T cell engager antibody that contains two binding sites for EpCAM and two binding sites for CD3ε. The binding sites for EpCAM and CD3ε have been designed to bind their respective targets specifically and reversibly under the conditions found in the tumor microenvironment (TME) and to have reduced binding outside of the TME. The CAB selective binding to both the CAB EpCAM and CAB CD3ε arms are required to activate the T cell engagement against the tumor, thus enabling the combined selectivity of each CAB binding arm in the bispecific antibody. BioAtla continues to advance the ongoing Phase 1 study to evaluate the safety, pharmacokinetics, and efficacy of BA3182 in advanced adenocarcinoma patients.

About BA3361
BA3361, CAB-Nectin4-ADC, is a conditionally and reversibly active antibody drug conjugate directed against Nectin4, a cell-cell adhesion molecule overexpressed in multiple human malignancies. The Nectin4-binding domains of BA3361 have been optimized for binding under tumor microenvironment (TME) conditions and reduced binding under normal physiological conditions. BA3361 is the first molecule containing one of BioAtla's novel NextGen ADC linkers with highly improved stability and tumor specific payload release. BA3361 showed superior activity in patient-derived pancreatic cancer xenograft models.

About BioAtla®, Inc.
BioAtla is a global clinical-stage biotechnology company with operations in San Diego, California, and in Beijing, China through our contractual relationship with BioDuro-Sundia, a provider of preclinical development services. Utilizing its proprietary Conditionally Active Biologics (CAB) technology, BioAtla develops novel, reversibly active monoclonal and bispecific antibodies and other protein therapeutic product candidates. CAB product candidates are designed to have more selective targeting, greater efficacy with lower toxicity, and more cost-efficient and predictable manufacturing than traditional antibodies. BioAtla has extensive and worldwide patent coverage for its CAB technology and products with greater than 750 patents filed, more than 475 of which have been issued. Broad patent coverage in all major markets include methods of making, screening and manufacturing CAB product candidates in a wide range of formats and composition of matter coverage for specific products. BioAtla has two first-in-class CAB programs currently in Phase 2 clinical testing, mecbotamab vedotin, BA3011, a novel conditionally active AXL-targeted antibody-drug conjugate (CAB-AXL-ADC), and ozuriftamab vedotin, BA3021, a novel conditionally active ROR2-targeted antibody-drug conjugate (CAB-ROR2-ADC). The Phase 2 stage CAB-CTLA-4 antibody, BA3071, is a novel CTLA-4 inhibitor designed to reduce systemic toxicity and potentially enable safer combination therapies with checkpoint inhibitors such as anti-PD-1 antibody. The company's first bispecific T-cell engager antibody, BA3182, is currently in Phase 1 development. BA3182 targets EpCAM, which is highly and frequently expressed on many adenocarcinomas while engaging human CD3 expressing T cells. To learn more about BioAtla, Inc. visit www.bioatla.com.

Forward-looking statements
Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast" or other similar words. Examples of forward-looking statements include, among others, statements we make regarding our business plans and prospects and whether our clinical trials will support registration; achievement of milestones; results, conduct, progress and timing of our research and development programs and clinical trials; expectations with respect to enrollment and dosing in our clinical trials, plans and expectations regarding future data updates, clinical trials, regulatory meetings and regulatory submissions; plans to form strategic partnerships for selected assets; the potential regulatory approval path for our product candidates; expectations about the sufficiency of our cash and cash equivalents to fund operations; and expected R&D expenses. Forward-looking statements are based on BioAtla's current expectations and are subject to inherent uncertainties, risks and assumptions, many of which are beyond our control, difficult to predict and could cause actual results to differ materially from what we expect. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Factors that could cause actual results to differ include, among others: potential delays in clinical and pre-clinical trials; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, or regulatory approval dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; whether regulatory authorities will be satisfied with the design of and results from the clinical studies or take favorable regulatory actions based on results from the clinical studies; our dependence on the success of our CAB technology platform; our ability to enroll patients in our ongoing and future clinical trials; the successful selection and prioritization of assets to focus development on selected product candidates and indications; our ability to form collaborations and partnerships with third parties and the success of such collaborations and partnerships; our reliance on third parties for the manufacture and supply of our product candidates for clinical trials; our reliance on third parties to conduct our clinical trials and some aspects of our research and preclinical testing; potential adverse impacts due to any resurgence of COVID-19 and its variants; and those other risks and uncertainties described in the section titled "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 26, 2024 and our other reports as filed with the SEC. Forward-looking statements contained in this press release are made as of this date, and BioAtla undertakes no duty to update such information except as required under applicable law.

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BioAtla, Inc.
Unaudited Statements of Operations and Comprehensive Loss
(in thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development expense	$ 22,674	$ 21,874	$ 103,731	$ 79,347
General and administrative expense	5,862	6,686	25,956	28,793
Total operating expenses	28,536	28,560	129,687	(108,140)
Loss from operations	(28,536)	(28,560)	(129,687)	(108,140)
Other income:				
Interest income	1,638	1,047	6,312	1,648
Other income (expense)	(27)	(30)	(87)	10
Total other income	1,611	1,017	6,225	1,658
Net loss and comprehensive loss	$ (26,925)	$ (27,543)	$ (123,462)	$ (106,482)

BioAtla, Inc.
Balance Sheet Data
(in thousands)

	December 31, 2023	December 31, 2022
	(Unaudited)	
Cash and cash equivalents	$ 111,471	$ 215,507
Total assets	119,658	225,736
Total current liabilities	28,344	23,131
Total liabilities	48,986	45,397
Total stockholders' equity	70,672	180,339
Total liabilities and stockholders' equity	119,658	225,736