BioAtla Reports Third Quarter 2023 Financial Results and Highlights Recent Progress

November 7, 2023 at 4:02 PM EST

- **Observed additional clinical responses and FDA feedback supports path forward for CAB-AXL-ADC (BA3011) non-small cell lung cancer (NSCLC) registrational study; detailed interim Phase 2 data to be presented at upcoming IASLC conference in early December and discussed at KOL event on December 4, 2023**
- **Observed new PRs with CAB-ROR2-ADC (BA3021) Q2W dosing regimen in the Phase 2 melanoma study and a new PR with BA3021 2Q3W in the Phase 2 head and neck study**
- **Initiated Phase 2 CAB-CTLA-4 (BA3071) study; First Patient In (FPI) completed; Phase 1 data to be presented at upcoming R&D Day on December 13, 2023**
- **Phase 1 study for CAB-EpCAM x CAB-CD3 bispecific T-cell engager (TCE), BA3182, ongoing; data readout remains on track in 2024**
- **Cash balance of $141.3 million now expected to fund operations into 2H 2025**
- **Management to host conference call and webcast today at 4:30 PM Eastern Time**

SAN DIEGO, Nov. 07, 2023 (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 third quarter ended September 30, 2023, and provided an update on its clinical programs.

“At BioAtla, our highest priority is to deliver innovative, life-changing therapies to cancer patients with significant unmet medical needs. We have consistently observed multiple clinical responses in treatment-refractory NSCLC populations with CAB-AXL-ADC, BA3011. In addition, we recently have observed new PRs with CAB-ROR2-ADC, BA3021 in melanoma and head and neck cancer as we continue to dose patients, further underscoring our promising CAB-ADC opportunities,” said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc. “We are also advancing our CAB-CTLA-4, BA3071, and now have initiated the Phase 2 study and will provide an update at our upcoming R&D day in December. As we have obtained data to support several value inflection points across our CAB portfolio, we believe that forming one or more strategic collaborations with major pharmaceutical partners can accelerate development of selected assets and maximize their market opportunities.”

CAB-ADC Clinical-Stage Programs

- **Phase 2 Trial of Mecbotamab Vedotin, BA3011:**
  - **NSCLC**
    - In treatment-refractory patients (median 3 prior lines of therapy) receiving BA3011 Q2W monotherapy who previously experienced PD-1 treatment failure and were evaluable for efficacy at 12 weeks, the observed objective response rate was 27.8%
    - In treatment-refractory patients with epidermal growth factor receptor (EGFR) wild-type, non-squamous NSCLC who previously experienced PD-1 treatment failure, 33.3% had a partial response (PR) to BA3011 monotherapy
    - Continue to observe clinical benefit in patients, including multiple PRs at a TmPS score of 1% and exploring the potential clinical benefits in AXL TmPS negative patients
    - Based upon our meeting with the FDA in October, we believe the FDA is supportive of our registrational path forward; details forthcoming at IASLC conference and KOL event in early December
  - **Undifferentiated Pleomorphic Sarcoma (UPS)**
    - Phase 2 potentially registrational study ongoing
  - **Bone and soft tissue sarcomas**
    - All cohorts completed with additional subtypes achieving the predefined efficacy and safety criteria
    - Planned submission of data to medical meeting in 2024
- **Phase 2 Trials of Ozuriftamab Vedotin, BA3021:**
  - All dosing to be completed before year-end 2023
  - **Melanoma**
    - Completed enrollment Q2W targeted cohort who previously progressed on PD-1/L1 therapy
    - To date, eight melanoma monotherapy patients are evaluable with reported first scan data across Phase 1 and Phase 2. Among these, we observed four responses, two stable disease and two progressive disease with at least one response observed in a ROR2 TmPS negative patient. The remainder of patients in the targeted cohort will have had the opportunity to have first scan by year end.
    - Continue to collect data in ongoing study
  - **Squamous Cell Carcinoma of Head and Neck (SCCHN)**
    - On track to complete all dosing regimens enrollment by year-end 2023; new PR observed in the first Phase

2 patient scanned at 2Q3W (ROR2 TmPS negative)
- Continue to collect data in ongoing study

- **NSCLC**
  - Clinical benefit observed and tumor volume reduction in Q2W dosing regimen but did not meet our internal criteria for advancing at this dose; currently no plans to internally explore additional dosing regimens

- **Phase 2 Investigator-initiated Trial of platinum-resistant ovarian cancer**
  - Interim analysis of n=10 patients in each BA3011 and BA3021 Q2W cohorts demonstrated modest disease control, but did not meet our internal criteria for advancing at this dose; currently no plans to internally explore additional dosing regimens
  - Data disclosure planned for future medical meeting at investigator's discretion

CAB-CTLA-4 I/O Clinical-Stage Program

- **Phase 1/2 dose-escalation trial of CAB-CTLA-4, BA3071 basket trial:**
  - Phase 1 data readout and path forward at upcoming R&D Day on December 13
  - Initiated Phase 2; FPI completed

CAB-T-Cell Engager Clinical-Stage Program

- **Phase 1/2 dose-escalation for CAB-EpCAM x CAB-CD3 TCE, BA3182:**
  - Progressing Phase 1 study for the treatment of advanced adenocarcinoma
  - Anticipated completion of Phase 1 and data readout remains on track in 2024

Presentations

- Upcoming poster presentation at the IASLC North America Conference on Lung Cancer (NACLC), titled "Phase 2 Trial of Mecbotamab Vedotin (BA3011), a CAB-AXL-ADC, Alone or in Combination With Nivolumab in Patients With Non-Squamous NSCLC", in early December
- KOL event planned for December 4 following conclusion of the IASCL conference, to discuss detailed interim Phase 2 data on CAB-AXL-ADC, BA3011, in NSCLC
- R&D Day planned for December 13 to discuss CAB-CTLA-4 (BA3071) Phase 1/2 basket trial

Third Quarter 2023 Financial Results
Cash and cash equivalents as of September 30, 2023 were $141.3 million, compared to $215.5 million as of December 31, 2022. We expect current cash and cash equivalents will be sufficient to fund planned operations including prioritized CAB programs into second half of 2025.

Research and development (R&D) expenses were $28.4 million for the quarter ended September 30, 2023 compared to $19.8 million for the same quarter in 2022. The increase of $8.6 million was primarily driven by a $6.3 million increase in our clinical product development expenses primarily related to the launch of our AXL UPS potentially registrational trial, and a $1.8 million increase in preclinical product development expenses primarily related to our CAB B7H3 x CD3 bispecific T-cell engager. We expect our R&D expenses to remain variable from quarter to quarter as we continue to advance our clinical programs, then decreasing after we complete enrollment and focus development on selected high potential indications.

General and administrative (G&A) expenses were $6.6 million for the quarter ended September 30, 2023 compared to $6.3 million for the same quarter in 2022. The $0.3 million change was attributable to an increase in professional services and consulting expenses for the 2023 period. We expect our G&A expenses to remain flat to moderately increasing to support development of our prioritized CAB programs.

Net loss for the third quarter ended September 30, 2023 was $33.3 million compared to a net loss of $25.8 million for the same quarter in 2022.

Net cash used in operating activities for the nine months ended September 30, 2023 was $74.1 million compared to net cash used in operating activities of $66.1 million for the same period in 2022. The increase in net cash used in operating activities for the first nine months of 2023 is primarily due to an increase in research and development expenses related to our program development efforts as compared to the first nine months of 2022.

Third Quarter 2023 Conference Call and Webcast Details
The management of BioAtla, Inc. will host a conference call and webcast for the investment community today, November 7, 2023, at 4:30 pm Eastern Time. A live webcast may be accessed here:

https://viavid.webcasts.com/starthere.jsp?ei=1635568&tp_key=63f5901bb0. The conference call can be accessed by dialing toll-free (888) 886-7786 or (416) 764-8658 (international). The passcode for the conference call is 05202391.

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 types, including soft tissue and bone sarcoma and non-small cell lung cancer (NSCLC) that have previously progressed on PD-1/L1, EGFR or ALK inhibitor therapies. The Office of Orphan Drug Products (OODP) 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 breast, lung, head and neck and melanoma. This Phase 2 stage clinical asset is targeting multiple solid tumor types, including NSCLC that have previously progressed on PD-1/L1, EGFR or ALK inhibitor therapies, melanoma that have previously progressed on PD-1/L1 therapy and SCCHN that have previously progressed on PD-1/L1 therapies with or without platinum chemotherapy.

About 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/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 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 EpCAM
EpCAM is involved in the maintenance of epithelial integrity, and its expression is associated with proliferation during morphogenesis, tissue regeneration, and stem cell maintenance. Expression levels of EpCAM vary amongst different organs and cell types, with epithelia of colon, small intestine, lung, pancreas, liver and gall bladder expressing the highest levels of EpCAM protein. Given the functions and properties of EpCAM protein, high levels of EpCAM expression have been found in many carcinomas. EpCAM is highly and frequently expressed in the vast majority of carcinomas and their metastases and has been considered as a potential prognostic and therapeutic marker for many carcinomas.

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 700 patents filed, more than 400 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 collaborations or other 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 planned operations, which includes plans to not explore additional dosing regimens, delaying certain pre-clinical development programs and to prioritize and focus development on selected assets and indications; and expected R&D and G&A 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 23, 2023, in our Quarterly Report on Form 10-Q filed with the SEC on May 11, 2023, August 1, 2023 and November 7, 2023 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 Condensed Statements of Operations and Comprehensive Loss
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development expense	$ 28,400	$ 19,839	$ 81,057	$ 57,473
General and administrative expense	6,620	6,340	20,094	22,107
Total operating expenses	35,020	26,179	101,151	79,580
Loss from operations	(35,020)	(26,179)	(101,151)	(79,580)
Other income (expense):				
Interest income	1,734	370	4,674	601
Other income (expense)	(39)	30	(60)	40
Total other income (expense)	1,695	400	4,614	641
Net loss and comprehensive loss	$ (33,325)	$ (25,779)	$ (96,537)	$ (78,939)

BioAtla, Inc.
Condensed Consolidated Balance Sheets Data
(in thousands)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 141,282	$ 215,507
Total assets	151,362	225,736
Total current liabilities	35,602	23,131
Total liabilities	56,659	45,397
Total stockholders' equity	94,703	180,339
Total liabilities and stockholders' equity	151,362	225,736