

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 03, 2022

BIOATLA, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39787
(Commission File Number)

85-1922320
(IRS Employer
Identification No.)

11085 Torreyana Road
San Diego, California
(Address of Principal Executive Offices)

92121
(Zip Code)

Registrant's Telephone Number, Including Area Code: 858 558-0708

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	BCAB	NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2022, BioAtla, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2022 and provided clinical program updates for both mecbotamab vedotin (CAB-AXL-ADC, BA3011) and ozuriftamab vedotin (CAB-ROR2-ADC, BA3021) addressing multiple tumor types as well as updates on CAB-CTLA-4 (BA3071) and CAB-EpCAM x CAB-CD3 bispecific T-cell engager (BA3182). A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information set forth in Item 2.02 of this Current Report on Form 8-K (“Current Report”), including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of such section. The information set forth in Item 2.02 of this Current Report, including Exhibit 99.1 attached hereto, shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated November 3, 2022
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BioAtla, Inc.

Date: November 3, 2022

By: _____
/s/ Richard Waldron
Richard Waldron
Chief Financial Officer



BIOATLA REPORTS THIRD QUARTER 2022 FINANCIAL RESULTS AND HIGHLIGHTS RECENT PROGRESS

- Mecbotamab vedotin (BA3011) Phase 2 part 1 interim results in NSCLC continue to show antitumor activity with additional patients enrolled
- BA3011 Undifferentiated Pleomorphic Sarcoma (UPS) enrollment in Phase 2 part 2 of study anticipated to begin by year-end
- CAB-CTLA-4 (BA3071) Phase 1 study ongoing in tumor types responsive to CTLA-4 inhibition with first two cohorts completed without Dose Limiting Toxicities (DLTs) or Serious Adverse Events (SAEs) reported; third cohort (70mg) on-going with DLT observation period anticipated to conclude by year-end
 - BA3182, CAB-EpCAMx-CAB-CD3 bispecific T-cell engager (TCE) IND submission anticipated by year-end
 - Cash balance of \$178.1 million at quarter-end expected to provide funding into 2H24
 - Management to host conference call and webcast today at 4:30 PM Eastern Time

SAN DIEGO, November 3, 2022 – 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, 2022, and provided clinical program updates for both mecbotamab vedotin (BA3011) and ozurifamab vedotin (BA3021) addressing multiple tumor types as well as updates on CAB-CTLA-4 (BA3071) and CAB-EpCAM x CAB-CD3 bispecific T-cell engager (TCE) (BA3182).

“BioAtla continues an upward trajectory with our CAB-ADC programs, with encouraging data as evidenced by the multiple partial responses observed in our part 1 Phase 2 NSCLC study as patients continue to enroll. Also, we continue to observe encouraging antitumor activity in our Phase 2 BA3011 sarcoma study. Going forward, we anticipate several updates over the coming months as we continue to progress BA3021 in Phase 2 NSCLC, melanoma and head & neck cancer, as well as our Phase 1/2 CAB-CTLA-4 (BA3071) study,” said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc.

“We are excited with the compelling evidence of antitumor activity of BA3011, in both monotherapy and in combination with nivolumab, in treatment-refractory NSCLC patients in the ongoing part 1 of the phase 2 study. In addition, we are pleased with the written feedback received from the FDA regarding part 2 of the phase 2 study in UPS and are proceeding with enrollment in this part of the study, which we believe supports registration for this difficult to treat disease.” said Scott Smith, President of BioAtla. He continued, “We also remain encouraged with the continued execution of our other promising CAB assets, including BA3021, BA3071, and BA3182 in multiple cancer indications. We have a strong cash position with runway into the second half of 2024. BioAtla will continue to have strong focus and execution with the goal of pursuing indications of high unmet medical need that we feel will have significant impact for patients and our shareholders worldwide.”

Key Developments, Operational Updates and Upcoming Milestones

- **Phase 2 Trial of Mecbotamab Vedotin (BA3011, NCT03425279) in Patients with:**
 - **AXL-positive NSCLC**
 - Part 1 of the trial ongoing in patients who have previously experienced failure of PD-1/L1, EGFR, or ALK inhibitor therapy (average failure 3 lines of therapy)
 - 24 patients enrolled to date (as of October 2022)
 - 14 efficacy-evaluable patients (12 in the non-squamous adenocarcinoma group and 2 in the squamous cell carcinoma group)
 - In the non-squamous group, 8 of 12 had monotherapy and 4 of 12 had combination therapy
 - All CR / PRs observed were in the non-squamous group
 - 4 PRs were in monotherapy, (4 of 8, ORR 50%)
 - 1 CR in combination therapy, (1 of 4, ORR 25%)
 - Initiating preparations for discussions with the FDA regarding the potentially registrational part 2 of the study in AXL-positive NSCLC patients. FDA interactions anticipated to occur in 1H2023
 - Following BA3011 in both monotherapy and in combination with nivolumab in advanced NSCLC patients, the safety profile continues to be differentiated, with no new safety signals observed
 - Full interim data set of approximately 20 efficacy evaluable patients anticipated by year-end
 - **AXL-positive Soft Tissue and Primary Bone Sarcomas**
 - Part 2 of the Phase 2 study:
 - UPS; written feedback received from the FDA to the proposed part 2 of the Phase 2 (potentially registrational) study design, including primary endpoint and size of the study; we are initiating part 2 and anticipate study enrollment commencement by year-end
 - Osteosarcoma, synovial sarcoma, and liposarcoma cohorts met pre-defined Go criteria to advance into part 2 and we may pursue these indications (and any other indications that meet Go criteria) as part of a label expansion strategy post-UPS approval
 - In refractory sarcomas, BA3011 in both monotherapy and in combination with nivolumab is generally well-tolerated with no new safety signals observed
 - **Phase 2 Trial of Ozuriftamab Vedotin (BA3021, NCT03504488) in Patients with:**
 - **ROR2-positive NSCLC**
 - Trial enrolling in patients who have previously experienced failure of PD-1/L1, EGFR or ALK inhibitor therapy
 - Interim update anticipated in beginning of next year
 - **ROR2-positive Melanoma**
 - Trial ongoing in patients who have previously experienced failure of PD-1 therapy
 - Anticipate initiating screening of patients with validated liquid biopsy by year-end
 - **ROR2-positive SCCHN**
 - Trial ongoing in patients who have previously experienced failure of PD-1 therapy alone or in combination with platinum therapy
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- Actively screening patients; anticipate multiple patients dosed by year-end
- **Phase 1/2 Dose-Escalation Trial of CAB-CTLA-4 (BA3071) Across Multiple Solid Tumor Types responsive to CTLA-4**
 - Trial ongoing with first two cohorts completed without any DLTs or SAEs reported; third cohort (70mg) is on-going with DLT observation period anticipated to conclude by year end
- **On track for IND submission for CAB EpCAM x CAB-CD3 TCE (BA3182) by year end**
 - Received pre-IND written feedback from FDA with no major issues identified
 - Preclinical package deemed adequate to move forward to the clinic, with agreement on starting dose and study design
- **Anticipate potential IND submissions for pre-clinical next generation CAB candidates in 2023 and beyond**

Third Quarter Financial Results

Cash and cash equivalents as of September 30, 2022 were \$178.1 million, compared to \$245.0 million as of December 31, 2021. We expect current cash and cash equivalents will be sufficient to fund planned operations including all ongoing CAB product development programs into second half 2024.

Research and development (R&D) expenses were \$19.8 million for the quarter ended September 30, 2022 compared to \$16.6 million for the same quarter in 2021. The increase of \$3.2 million was primarily driven by our clinical product development efforts. We expect our R&D expenses to remain variable from quarter to quarter and generally increase as we continue to invest in R&D activities to advance our product candidates and our clinical programs.

General and administrative (G&A) expenses were \$6.3 million for the quarter ended September 30, 2022 compared to \$7.1 million for the same quarter in 2021. The \$0.8 million change was attributable to a decrease in stock-based compensation for the 2022 period. We expect our G&A expenses to moderately increase to support development of our product candidates, advance our intellectual property portfolio, support focused pre-commercialization activities for our product candidate mecbotamab vedotin (BA3011) and satisfy requirements as a public company.

Net loss for the quarter ended September 30, 2022 was \$25.8 million compared to a net loss of \$22.9 million for the same quarter in 2021.

Net cash used in operating activities for the nine months ended September 30, 2022 was \$66.1 million compared to net cash used in operating activities of \$41.3 million for the same period in 2021. The increase in net cash used in operating activities for the first nine months of 2022 is primarily due to an increase in research and development expense related to our program development efforts as compared to the first nine months of 2021.

Third Quarter 2022 Conference Call and Webcast Details

The management of BioAtla, Inc. will host a conference call and webcast for the investment community today, November 3, 2022, at 4:30 pm Eastern Time. A live webcast may be accessed here: https://viaavid.webcasts.com/starthere.jsp?ei=1572537&tp_key=6d10a8eb15. The conference call can be accessed by dialing toll-free (844) 826-3035. The passcode for the conference call is 10171336.

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. We are also supporting a multi-center investigator-initiated clinical trial in combination with a PD-1 inhibitor in patients with platinum-resistant ovarian cancer, with other potential indications in the future. 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 lung, head and neck and melanoma. We are advancing this Phase 2 stage clinical asset for 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 platinum chemotherapy or PD-1/L1 therapies. We are also supporting a multi-center investigator-initiated clinical trial in combination with a PD-1 inhibitor in patients with platinum-resistant ovarian cancer, with other potential indications in the future.

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 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 mecbotamab vedotin, ozuriftamab vedotin and our other CAB candidates, BA3071 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, including renal cell carcinoma, NSCLC, small cell lung cancer, hepatocellular carcinoma, melanoma, bladder cancer, gastric cancer and cervical cancer.

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 antibody 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 more than 600 patents, more than 350 of which are 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 in the United States, 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 1 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. 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, including whether our clinical trials will support registration; 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 regarding future data updates, clinical trials, regulatory meetings and regulatory submissions; the potential regulatory approval path for our product candidates; expectations about the sufficiency of our cash and cash equivalents; 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 due to the global COVID-19 pandemic; other potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; 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 success of our current and future collaborations with third parties; 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; 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 February 28, 2022 and in our Quarterly Reports on Form 10-Q filed with the SEC on May 5, 2022 and August 9, 2022 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 Consolidated Statements of Operations and Comprehensive Loss
(in thousands)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Collaboration and other revenue	\$ —	\$ —	\$ —	\$ 250
Operating expenses:				
Research and development expense	19,839	16,553	57,473	41,826
General and administrative expense	6,340	7,142	22,107	31,376
Total operating expenses	<u>26,179</u>	<u>23,695</u>	<u>79,580</u>	<u>73,202</u>
Loss from operations	(26,179)	(23,695)	(79,580)	(72,952)
Other income (expense):				
Interest income	370	76	601	254
Interest expense	—	—	—	(3)
Gain on extinguishment of long-term debt	—	690	—	690
Other income (expense)	30	(1)	40	(1)
Total other income (expense)	<u>400</u>	<u>765</u>	<u>641</u>	<u>940</u>
Consolidated net loss and comprehensive loss	<u>\$ (25,779)</u>	<u>\$ (22,930)</u>	<u>\$ (78,939)</u>	<u>\$ (72,012)</u>

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

	<u>September 30,</u>	<u>December 31,</u>
	<u>2022</u>	<u>2021</u>
	<u>(unaudited)</u>	
Cash and cash equivalents	\$ 178,120	\$ 244,979
Total assets	189,112	254,422
Total current liabilities	23,825	19,813
Total liabilities	46,478	43,601
Total stockholders' equity	142,634	210,821
Total liabilities and stockholders' equity	189,112	254,422

