

**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): August 09, 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 August 9, 2022, BioAtla, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2022 and provided an interim topline data update from its mecbotamab vedotin (CAB-AXL-ADC, BA3011) Phase 2 studies in NSCLC and sarcoma, clinical progress of ozuriftamab vedotin (CAB-ROR2-ADC, BA3021) Phase 2 studies in NSCLC and melanoma, and an operational update on additional ongoing clinical programs. 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

Exhibit Number	Description
99.1	Press Release dated August 9, 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 thereunto duly authorized.

BioAtla, Inc.

Date: August 9, 2022

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



BIOATLA REPORTS SECOND QUARTER 2022 FINANCIAL RESULTS AND HIGHLIGHTS RECENT PROGRESS

- **Mecbotamab vedotin (BA3011) Phase 2 preliminary observations in Non-Small Cell Lung Carcinoma (NSCLC) supports advancing to the registrational stage of the study; anticipate full interim data set in 4Q22**
- **Mecbotamab vedotin (BA3011) Undifferentiated Pleomorphic Sarcoma (UPS) and osteosarcoma Phase 2 part 2 enrollment anticipated to begin 4Q22 following requested written feedback from FDA; continuing to enroll additional cohorts**
- **Mecbotamab vedotin (BA3011) sarcoma Phase 2 top-line interim data support advancing with liposarcoma and synovial sarcoma; next steps under evaluation**
- **Ozuriftamab vedotin (BA3021) NSCLC and Squamous Cell Carcinoma of the Head and Neck (SCCHN) Phase 2 studies ongoing as planned; NSCLC preliminary cohort interim update on track for 2H22, SCCHN trial ongoing with first patient dosed now anticipated in 3Q22; melanoma enrollment ongoing with status update using new validated Circulating Tumor Cell (CTC) assay anticipated Q422**
- **CAB-CTLA-4 (BA3071) Phase 1 study ongoing with first patient dosed**
- **Cash balance of \$202.3 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, August 9, 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 second quarter ended June 30, 2022, and provided an interim topline data update from the mecbotamab vedotin (BA3011) Phase 2 study in NSCLC as well as an operational update on its ongoing clinical programs, including BA3011, ozuriftamab vedotin (BA3021) and CAB-CTLA-4 (BA3071) addressing multiple tumor types.

“BioAtla continues to progress our CAB-ADC programs, most recently with important signals observed this quarter in our Phase 2 BA3011 NSCLC study. In parallel, we continue to advance with our Phase 2 studies for BA3011 in multiple sarcoma subtypes, with positive signals identified in liposarcoma and synovial sarcoma and official enrollments into part 2 for UPS and osteosarcoma expected to begin this year. We also are progressing with our additional clinical assets, ozuriftamab vedotin (BA3021) in Phase 2 NSCLC, melanoma and head & neck cancer, as well as with our Phase 1/2 naked immuno-oncology antibody CAB-CTLA-4 (BA3071) across multiple tumor types, and anticipate several updates later this year,” said Jay M. Short, Ph.D., Chairman, Chief Executive Officer and co-founder of BioAtla, Inc.

“We are very encouraged by our Phase 2 NSCLC preliminary observations, which are consistent with results from our Phase 1 NSCLC and Phase 2 sarcoma studies. Collectively, these data further strengthen the potential opportunity of BA3011 as a best-in-class therapeutic across multiple solid tumor types,” said Scott Smith, President of BioAtla. He continued, “We are also very excited with the continued execution across all the other important programs in our pipeline, including BA3021, BA3071, and BA3182. BioAtla



has a strong cash position to support our robust clinical and preclinical programs into the second half of 2024, and we will remain acutely focused on prioritizing the indications we view have the highest probability of success to maximize value for patients and our shareholders.”

Key Developments, Operational Updates and Upcoming Milestones

- **Phase 2 Trial of Mechatamab Vedotin (BA3011, NCT03425279) in Patients with:**
 - o **AXL-positive NSCLC**
 - Trial ongoing in patients who have previously experienced failure of PD-1/L1, EGFR, or ALK inhibitor therapy (average failure 2.5 lines of therapy; 2 prior lines for non-squamous, 4 prior lines for squamous)
 - 15 patients enrolled to date, with 9 efficacy-evaluable patients
 - 4 patients currently on treatment did not yet have the opportunity to be followed for 3 months and 2 patients were not deemed efficacy-evaluable. Of the 9 evaluable patients (7 in the non-squamous adenocarcinoma group and 2 in the squamous cell carcinoma group), a total of 1 complete response (CR) and 2 partial responses (PRs) were observed for a combined objective response rate (ORR) of 33%
 - o In the non-squamous group, 4 of 7 had monotherapy and 3 of 7 had combination therapy
 - o All CR / PRs observed were in the non-squamous group, representing an ORR of 43%, or 3 out of 7 patients (2 PRs were in monotherapy, ORR 50%; and 1 CR in combination therapy, ORR 33%)
 - The observations in non-squamous cohort are consistent with the signal observed in the Phase 1 study
 - Initiating preparations for discussions with the FDA about part 2 of the registrational study in AXL-positive NSCLC patients
 - No clinical responses (ORR, PR) observed to date in the squamous cohort in either monotherapy (n=1) or combination therapy (n=1)
 - BA3011 is generally safe and well-tolerated in both monotherapy and combination with nivolumab in advanced NSCLC patients with no new safety signals observed
 - Full interim data set of approximately 20 patients anticipated this year
 - o **AXL-positive Soft Tissue and Primary Bone Sarcomas**
 - Interim Phase 2 analysis after a minimum of 3 months demonstrates antitumor activity following BA3011 treatment in:
 - UPS and osteosarcoma; advancing as separate cohorts into part 2 of the Phase 2 study; additional detail for part 2 will become available following FDA written feedback
 - Liposarcoma; PFS rate 60% (n=6); next steps under evaluation
 - Synovial sarcoma; PFS rate 50% (n=5); next steps under evaluation
 - Continuing to enroll across cohorts, awaiting data and will provide an update when available



- **Phase 2 Trial of Ozuriftamab Vedotin (BA3021, NCT03504488) in Patients with:**
 - o **ROR2-positive NSCLC**
 - Trial enrolling in patients who have previously experienced failure of PD-1/L1, EGFR or ALK inhibitor therapy
 - Interim update on track for second half of 2022
 - o **ROR2-positive Melanoma**
 - Trial ongoing in patients who have previously experienced failure of PD-1 therapy
 - Completed successful validation of non-invasive liquid biopsy; implementation as part of study protocol is underway
 - Enrollment ongoing and actively dosing; anticipate trial enrollment status update in Q422
 - o **ROR2-positive SCCHN**
 - Trial ongoing in patients who have previously experienced failure of PD-1 therapy alone or in combination with platinum therapy
 - Anticipate first patient dosed in third quarter of this year
- **Phase 1/2 Dose-Escalation Trial of CAB-CTLA-4 (BA3071) Across Multiple Solid Tumor Types**
 - o Trial ongoing with first patient dosed and actively screening additional patients across multiple centers with advanced solid tumors
- **On track for IND filing for CAB EpCAM x CAB-CD3 bispecific antibody (BA3182) in 4Q22**
- **Anticipate potential IND filings for a pre-clinical next generation CAB-ADC candidate and a second CAB bispecific in 2023**

Second Quarter Financial Results

Cash and cash equivalents as of June 30, 2022 were \$202.3 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 \$20.7 million for the quarter ended June 30, 2022 compared to \$14.9 million for the same quarter in 2021. The increase of \$5.8 million was primarily driven by expansion of our product development efforts including clinical development for CAB-CTLA-4 (BA3071) and pre-clinical development of additional CAB candidates. 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 \$8.3 million for the quarter ended June 30, 2022 compared to \$15.9 million for the same quarter in 2021. The \$7.6 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 June 30, 2022 was \$28.9 million compared to a net loss of \$30.4 million for the same quarter in 2021.

Net cash used in operating activities for the six months ended June 30, 2022 was \$42.1 million compared to net cash used in operating activities of \$28.5 million for the same period in 2021. The increase in net



cash used in operating activities for the first six 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 six months of 2021.

Second Quarter 2022 Conference Call and Webcast Details

The management of BioAtla, Inc. will host a conference call and webcast for the investment community today, August 9, 2022, at 4:30 pm Eastern Time. A live webcast may be accessed here: <https://edge.media-server.com/mmc/p/czrtgct>. The conference call can be accessed by dialing toll-free (844) 826-3035. The passcode for the conference call is 10169204.

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 (BA3011), 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. In the Phase 1 clinical study in sarcoma patients mecbotamab vedotin was generally well-tolerated, few patients discontinued due to an adverse event, and no clinically meaningful on-target toxicity to healthy AXL-expressing tissue was observed. Of the seven sarcoma patients who had an AXL tumor membrane percent score (TmPS) of greater than or equal to 70, four of these obtained a confirmed partial response, including patients with leiomyosarcoma, UPS, and Ewing sarcoma. Multiple subtypes of sarcoma present a significant unmet medical need. For example, UPS is one of the most aggressive sarcoma subtypes with the highest recurrence rate and has approximately 4,000 new cases annually in the U.S. There is no FDA approved treatment for UPS and current first and second line therapies are typically limited to doxorubicin, gemcitabine and docetaxel.

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, melanoma and breast. 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, SCCHN that have previously progressed on a PD-1 inhibitor and ovarian cancers that have previously progressed on platinum therapy.

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 antibody, ipilimumab, 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, ozuriftimab 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 potential selective licensing and collaborations, expectations about the sufficiency of our cash and cash equivalents, expected R&D and G&A expenses, the timing and expectations with respect to enrollment in our clinical trials, the timing and success of our clinical trials and related data, plans to advance development of several bispecific CAB candidates, including the timing of potential IND submissions and our market opportunity. 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; 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 4, 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 June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Collaboration and other revenue	\$ —	\$ 250	\$ —	\$ 250
Operating expenses:				
Research and development expense	20,711	14,850	37,634	25,273
General and administrative expense	8,344	15,860	15,767	24,234
Total operating expenses	<u>29,055</u>	<u>30,710</u>	<u>53,401</u>	<u>49,507</u>
Loss from operations	(29,055)	(30,460)	(53,401)	(49,257)
Other income (expense):				
Interest income	146	80	231	178
Interest expense	—	(1)	—	(3)
Other income	3	—	10	—
Total other income (expense)	<u>149</u>	<u>79</u>	<u>241</u>	<u>175</u>
Consolidated net loss and comprehensive loss	<u>\$ (28,906)</u>	<u>\$ (30,381)</u>	<u>\$ (53,160)</u>	<u>\$ (49,082)</u>

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

	<u>June 30,</u>	<u>December 31,</u>
	<u>2022</u>	<u>2021</u>
	<u>(unaudited)</u>	
Cash and cash equivalents	\$ 202,290	\$ 244,979
Total assets	213,496	254,422
Total current liabilities	25,507	19,813
Total liabilities	48,544	43,601
Total stockholders' equity	164,952	210,821
Total liabilities and stockholders' equity	213,496	254,422

