

**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): May 04, 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 May 4, 2022, BioAtla, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2022 and provided an interim topline data update from its mecbotamab vedotin (BA3011) Phase 2 study in sarcoma as well as an operational update on its 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 May 4, 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: May 4, 2022

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



BIOATLA REPORTS FIRST QUARTER 2022 FINANCIAL RESULTS AND HIGHLIGHTS RECENT PROGRESS

- **Mecbotamab vedotin (BA3011) sarcoma Phase 2 top-line interim data support advancing with UPS and osteosarcoma –**
- **Mecbotamab vedotin (BA3011) Phase 2 interim analysis in NSCLC anticipated in first half 2022; interim update projected on 2Q22 earnings call –**
- **Ozuriftamab vedotin (BA3021) NSCLC Phase 2 preliminary cohort enrollment completion and interim update anticipated in second half of 2022 –**
- **Ozuriftamab vedotin (BA3021) SCCHN Phase 2 and BA3071 Phase 1 studies anticipate first patients dosed in second quarter of 2022 –**
- **Cash balance of \$219.4 million at quarter-end expected to provide funding into the second half of 2024 –**
 - **Management to host conference call and webcast today at 4:30 PM Eastern Time –**

SAN DIEGO, May 4, 2022 -- BioAtla, Inc. (Nasdaq: BCAB), a global clinical-stage biotechnology company focused on the development of Conditionally Active Biologic (CAB) antibody therapeutics for treatment of solid tumors, today announced its financial results for the first quarter ended March 31, 2022, and provided an interim topline data update from the mecbotamab vedotin (BA3011) Phase 2 study in sarcoma 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 has achieved several important clinical milestones in our CAB-ADC programs, most recently with encouraging interim clinical data this quarter in our Phase 2 BA3011 sarcoma study that support a path forward for multiple sarcoma subtypes. In parallel, we continue to progress additional Phase 2 studies for BA3011 in Non-Small Cell Lung Cancer and with our second lead asset, ozuriftamab vedotin (BA3021) in multiple indications, 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 excited by the interim Phase 2 sarcoma data, which confirm our Phase 1 results. We achieved, and even exceeded, pre-defined criteria in UPS and osteosarcoma subtypes, and plan to begin enrolling patients in part 2 of the study following upcoming discussions with the FDA. Given the significant unmet medical need and commercial opportunity in sarcoma, we are thrilled to move one step closer towards a potential accelerated regulatory approval pathway of BA3011 in multiple sarcoma subtypes. As BioAtla continues to build our medical affairs and commercial capabilities, coupled with our already robust clinical and preclinical pipeline, we are hopeful to bring innovative and differentiated treatments to cancer patients worldwide, while creating long-term sustainable value for our shareholders,” said Scott Smith, President of BioAtla.

Key Developments, Operational Updates and Upcoming Milestones

- **Phase 2 Trial of Mecbotamab Vedotin (BA3011, NCT03425279) in Patients with:**
 - **AXL-positive Soft Tissue and Primary Bone Sarcomas**
 - Interim Phase 2 analysis at 3 months demonstrates antitumor activity following BA3011 treatment
 - In undifferentiated pleomorphic sarcoma (UPS), partial responses (PR) were observed in two of six patients (ORR 33%) – one of five in monotherapy and one of one in the combination cohort
 - Combining Phase 1 and Phase 2 data at 1.8 mg/kg, PRs were observed in four of eight UPS patients (ORR 50%)
 - In osteosarcoma, the PFS rate at 3 months was 67% (n = 6)
 - Combining Phase 1 and Phase 2 data at 1.8 mg/kg, the PFS rate at 3 months was 57% (n = 7)
 - Enrollment is ongoing in synovial sarcoma, liposarcoma, Ewing sarcoma and other bone cohorts as present sample size is not sufficient to determine advancement into Part 2
 - Leiomyosarcoma cohort did not achieve pre-defined criteria, with a PFS rate at 3 months of 27% (pending confirmation; n = 17); thus, this subtype was not selected to move forward into part two of the trial
 - Interim data in UPS and osteosarcoma cohorts meet or exceed pre-defined criteria (*i.e.*, one PR or complete response [CR], or PFS at 3 months \geq 40%), which support moving forward into the second part of our Phase 2 study and working towards a meeting with the FDA anticipated by July 2022, with enrollment into second part of Phase 2 study expected shortly thereafter.
 - With regards to safety, there were no treatment-related deaths, and few treatment-related serious adverse events (9%, n = 6). Treatment-related AEs were generally consistent with monomethyl auristatin E (MMAE) toxicity. Two patients out of 68 (3%) discontinued treatment due to treatment related AEs (both were grade 2 peripheral neuropathy).
 - **AXL-positive Non-Small Cell Lung Carcinoma (NSCLC)**
 - Trial ongoing in patients who have previously experienced failure of PD-1/L1, EGFR, or ALK inhibitor therapy
 - Anticipate preliminary cohort enrolled by end of second quarter 2022
 - Interim update anticipated on or around 2Q22 earnings call
 - **Phase 2 Trial of Ozuritamab Vedotin (BA3021, NCT03504488) in Patients with:**
 - **ROR2-positive NSCLC**
 - Trial ongoing in patients who have previously experienced failure of PD-1/L1, EGFR or ALK inhibitor therapy
 - Anticipate preliminary cohort enrolled and interim update in second half of 2022
 - **ROR2-positive Melanoma**
 - Trial ongoing in patients who have previously experienced failure of PD-1 therapy
 - Enrollment ongoing and actively dosing
 - Anticipate transitioning to a non-invasive liquid biopsy in second quarter of 2022
 - Anticipate full trial enrollment update on the 2Q22 earnings call
 - **ROR2-positive Squamous Cell Carcinoma of the Head and Neck (SCCHN)**
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- 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 second quarter of 2022
- **Phase 2 Investigator-Initiated Trial in Patients with Platinum-Resistant Ovarian Cancer (NCT04918186)**
 - **Mecbotamab vedotin (BA3011) or ozuriftamab vedotin (BA3021) in combination with a PD-1 inhibitor**
 - Initiated and currently screening patients in a multi-center, investigator-initiated Phase 2 clinical trial in Canada and in the US
- **Phase 1/2 Dose-Escalation Trial of CAB-CTLA-4 (BA3071) Across Multiple Solid Tumor Types**
 - Trial ongoing in patients with advanced solid tumors
 - Anticipate first patient dosed in second quarter of 2022
- **Anticipate IND filing for CAB EpCAM x CAB-CD3 bispecific antibody in 2022**
- **Anticipate IND filings for multiple pre-clinical CAB bispecific and next generation CAB-ADC candidates in 2023**
- **Entered into a clinical collaboration with Bristol Myers Squibb (NYSE: BMY) to investigate mecbotamab vedotin (BA3011) and ozuriftamab vedotin (BA3021), in combination with Bristol Myers Squibb's anti-PD-1 therapy Opdivo® (nivolumab).**

First Quarter Financial Results

Cash and cash equivalents as of March 31, 2022 were \$219.4 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 \$16.9 million for the quarter ended March 31, 2022 compared to \$10.4 million for the same quarter in 2021. The increase 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 increase as we continue to invest in R&D activities to advance our product candidates and our clinical programs, and to expand our product candidate pipeline.

General and administrative (G&A) expenses were \$7.4 million for the quarter ended March 31, 2022 compared to \$8.4 million for the same quarter in 2021. The change was primarily attributable to a decrease in stock-based compensation related to awards issued under our equity incentive plan. We expect our G&A expenses to increase to support development of our product candidates, expand our intellectual property portfolio, support pre-commercialization activities for our lead product candidate mecbotamab vedotin (BA3011) and meet all requirements as a public company.

Net loss for the quarter ended March 31, 2022 was \$24.3 million compared to a net loss of \$18.7 million for the same quarter in 2021.

Net cash used in operating activities for the three months ended March 31, 2022 was \$25.1 million compared to net cash used in operating activities of \$15.0 million for the same period in 2021.



First Quarter 2022 Conference Call and Webcast Details

The management of BioAtla, Inc. will host a conference call and webcast for the investment community today, May 4, 2022, at 4:30 pm Eastern Time. A live webcast may be accessed here: <https://edge.media-server.com/mmc/p/vhg5myi4>. The conference call can be accessed by dialing toll-free (844) 419-8639. The passcode for the conference call is 2695713.

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, as a potential therapeutic for multiple solid tumor types, including soft tissue and bone sarcoma, non-small cell lung cancer (NSCLC) and 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, undifferentiated pleomorphic sarcoma (UPS), and Ewing sarcoma. The several 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 developing ozuriftamab vedotin as a potential therapeutic for multiple solid tumor types, including NSCLC, melanoma, SCCHN and ovarian cancer. Based on encouraging Phase 1 data we believe ozuriftamab vedotin has broad potential as a cancer therapy for patients with advanced solid tumors that have previously progressed on a PD-1 inhibitor.



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. Like mecbotamab vedotin, ozuriftimab vedotin and our other CAB candidates, BA3071 is designed to be conditionally and reversibly active in the tumor microenvironment via the Protein-associated Chemical Switch™ or PaCS™ mechanism discovered by BioAtla scientists. This proprietary system is expected to enable reduction of systemic toxicity and potentially enable safer combination therapies, such as with anti-PD-1 antibody checkpoint inhibitors in the case of BA3071. 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, and plans to advance development of several bispecific CAB candidates, including the timing of potential IND submissions. 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 Report on Form 10-Q filed with the SEC on May 4, 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)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development expense	16,923	10,423
General and administrative expense	7,423	8,374
Total operating expenses	24,346	18,797
Loss from operations	(24,346)	(18,797)
Other income (expense):		
Interest income	85	98
Interest expense	—	(2)
Other income	7	
Total other income	92	96
Consolidated net loss and comprehensive loss	<u>\$ (24,254)</u>	<u>\$ (18,701)</u>

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

	March 31,	December 31,
	2022 (Unaudited)	2021
Cash and cash equivalents	\$ 219,428	\$ 244,979
Total assets	230,653	254,422
Total current liabilities	17,186	19,813
Total liabilities	40,600	43,601
Total stockholders' equity	190,053	210,821
Total liabilities and stockholders' equity	230,653	254,422

