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 09, 2023

BOLT BIOTHERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39988**	**47-2804636**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

900 Chesapeake Drive Redwood City, California	**94063**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 665-9295

Not Applicable
(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 (see General Instruction A.2. below):

☐ 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, par value $0.00001 per share	BOLT	The Nasdaq Global Select 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 9, 2023, Bolt Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2023. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

The information contained herein and the accompanying exhibit is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, nor shall it be deemed incorporated by reference in any filing with the Securities and Exchange Commission made by us, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 9, 2023.
104	Cover Page Interactive Data File (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.

Bolt Biotherapeutics, Inc.

Date: November 9, 2023

By: /s/ William P. Quinn
William P. Quinn
Chief Financial Officer

Bolt Biotherapeutics Reports Third Quarter 2023 Financial Results and Provides Business Update

- BDC-1001 program advances in multiple Phase 2 clinical studies in patients with HER2-positive colorectal, gastric, endometrial, and metastatic breast cancer, with recent updated data at ESMO showing improved clinical efficacy and longer durability; FDA Orphan Drug Designation granted for the BDC-1001 in gastric cancers
- First patient administered BDC-3042 in a Phase 1/2 dose-escalation and expansion clinical study
- Cash balance of $141.4 million as of September 30, 2023 anticipated to fund key milestones through 2025

REDWOOD CITY, CA, Nov. 9, 2023 – Bolt Biotherapeutics (Nasdaq: BOLT), a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer, today reported financial results for the third quarter ended September 30, 2023, and provided an update on the continued advancement of its clinical programs.

“During the quarter, we continued to advance our proprietary clinical stage development programs, BDC-1001 and BDC-3042,” said Randall Schatzman, Ph.D., Chief Executive Officer. “Updated Phase 1 data on BDC-1001 presented at this year’s ESMO Congress demonstrated improved efficacy, including our first complete response, and longer durability. We also recently received Orphan Drug Designation from the FDA for BDC-1001 in gastric cancers, one of the four types of cancer we are exploring in our BDC-1001 Phase 2 program. We look forward to presenting initial data from these Phase 2 trials in 2024.”

“In addition, we administered BDC-3042 to the first patient in our first-in-human Phase 1/2 clinical study evaluating BDC-3042 in patients with six different types of solid tumors. As we approach the end of the year, we are encouraged by the continued progress in our research and clinical studies and look forward to generating breakthroughs for patients in need of new treatment options that work with the person’s body, not against it.”

Recent Highlights and Anticipated Milestones

- **Updated clinical data from Phase 1 dose-escalation trial of BDC-1001 in HER2-expressing solid tumors presented at the ESMO 2023 Congress** in October 2023. The presentation was given by Bob T. Li, M.D., Ph.D., MPH, medical oncologist and principal investigator at Memorial Sloan Kettering Cancer Center (MSK). Improvements in BDC-1001 efficacy were observed since the data presented at ASCO in June 2023, including one new complete response (CR) observed in the monotherapy arm. BDC-1001 achieved a 29% objective response rate (ORR) in evaluable patients with HER2-positive tumors as monotherapy as well as a 29% ORR in combination with nivolumab at the recommended Phase 2 dose (RP2D). BDC-1001 was extremely well tolerated, with no Grade 5 treatment-related treatment-emergent adverse events (TEAEs), 1 Grade 4 TEAE (1%), and 9 Grade 3 TEAEs (7%). The most common TEAE was Grade 1 or 2 infusion-related reactions, which were seen in 30% of patients in the study. BDC-1001 upregulated gene signatures of an innate and adaptive immune response in clinical responders, providing support for the immune mechanism of action of our ISAC technology. The data also provided support for the every-other week (q2w) dosing schedule by demonstrating that innate and adaptive immune gene signatures were increased in patients dosed q2w.
- **First patient administered BDC-3042 in Phase 1 study of patients with advanced cancers** in October 2023. BDC-3042 is a proprietary agonist antibody that targets Dectin-2, an immune-activating receptor expressed by tumor-associated macrophages (TAMs). This single-agent, dose-escalation Phase 1 clinical study will evaluate BDC-3042 in patients with metastatic or unresectable triple-negative breast cancer (TNBC), colorectal cancer, clear cell renal cell carcinoma, head and neck cancer, non-small cell lung cancer (NSCLC), or ovarian cancer.
- **Received Orphan Drug Designation for BDC-1001 for the treatment of gastric cancers** in September 2023. The Office of Orphan Products Development of FDA grants Orphan Drug Designation to drugs and biologics intended for the treatment, diagnosis, or prevention of rare diseases, or conditions affecting fewer than 200,000 people in the United States. The designation affords Bolt the potential for certain benefits, including up to seven years of post-approval market exclusivity, assistance in the drug development process, tax credits for clinical development, and exemptions from certain FDA fees.
- **Presented four posters at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting** in November 2023. In the presentations, we shared preclinical data illustrating the benefits of combining BDC-1001 with the anti-HER2 antibody pertuzumab, along with trial-in-progress updates for BDC-1001 and BDC-3042. We also debuted our Claudin 18.2 ISAC program for the first time, demonstrating anti-tumor activity in multiple preclinical models.
- **Announced issuance of U.S. patent covering Dectin-2-targeting agonist antibodies, including BDC-3042** in September 2023. This patent covers antibodies with a novel mechanism of action that leverages Dectin-2 agonism to repolarize tumor-associated macrophages into immunostimulatory, anti-tumor macrophages. The claims of the patent will be valid through May 2041, excluding any patent term adjustments or extensions which may provide additional protection.
- **Cash, cash equivalents, and marketable securities were $141.4 million as of September 30, 2023.** Cash on hand is expected to fund multiple milestones and operations through 2025.

Third Quarter 2023 Financial Results

- **Collaboration Revenue –** Collaboration revenue was $2.5 million for the quarter ended September 30, 2023, compared to $2.1 million for the same quarter in 2022. Revenue in the comparative periods were generated from the services performed under the R&D collaborations as we fulfill our performance obligations.

- **Research and Development (R&D) Expenses –** R&D expenses were $15.0 million for the quarter ended September 30, 2023, compared to $19.0 million for the same quarter in 2022. The decrease in R&D expenses was due to lower manufacturing expenses primarily related to the timing of batch production of our product candidates and lower clinical expenses due to lower site and patient costs, offset by higher contract service expenses and salary and related expenses.

- **General and Administrative (G&A) Expenses –** G&A expenses were $5.8 million for the quarter ended September 30, 2023, compared to $5.5 million for the same quarter in 2022.

- **Loss from Operations –** Loss from operations was $18.2 million for the quarter ended September 30, 2023, compared to $22.3 million for the same quarter in 2022. This is in part a reflection of proactive cost-containment measures taken in June 2022.

About the Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) Platform
Bolt Biotherapeutics' Boltbody ISAC platform harnesses the precision of antibodies with the power of the innate and adaptive immune system to reprogram the tumor microenvironment to generate a productive anti-cancer response. Each Boltbody ISAC candidate comprises a tumor-targeting antibody, a non-cleavable linker and a proprietary immune stimulant. The antibody is designed to target one or more markers on the surface of a tumor cell, and the immune stimulant is designed to recruit and activate myeloid cells. Activated myeloid cells initiate a positive feedback loop by releasing cytokines and chemokines, chemical signals that attract other immune cells and lower the activation threshold for an immune response. This increases the population of activated immune system cells in the tumor microenvironment and promotes a robust immune response with the goal of generating durable therapeutic responses for patients with cancer.

About Bolt Biotherapeutics, Inc.
Bolt Biotherapeutics is a clinical-stage biopharmaceutical company leveraging the immune system for a better way to treat cancer. The company is developing novel immunotherapies using an approach that teaches the immune system to recognize and kill cancer in a way that is immediately personalized to each patient. Its pipeline candidates are built on the Company's deep expertise in myeloid biology and cancer drug development and include BDC-1001, a HER2-targeting Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) being evaluated in a Phase 2 trial, and BDC-3042, a myeloid-modulating agonist antibody targeting Dectin-2, being evaluated in a Phase 1 trial. Bolt Biotherapeutics is also developing multiple Boltbody™ ISACs in strategic collaborations with leading biopharmaceutical companies. For more information, please visit https://www.boltbio.com/

Forward-Looking Statements

This press release contains forward-looking statements about us and our industry that involve substantial risks and uncertainties and are based on our beliefs and assumptions and on information currently available to us. All statements other than statements of historical facts contained in this press release, including statements regarding our clinical trials, the timing of our presentation of initial data from our BDC-1001 Phase 2 trials, the success of our clinical collaborations, our ability to fund our clinical programs and the sufficiency of our cash, cash equivalents, and marketable securities, our future results of operations, financial condition, business strategy and plans and objectives of management, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “on track,” “plan,” “potential,” “predict,” “project,” “should,” “will,” or “would,” or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements represent our current beliefs, estimates and assumptions only as of the date of this press release and information contained in this press release should not be relied upon as representing our estimates as of any subsequent date. These statements, and related risks, uncertainties, factors and assumptions, include, but are not limited to: the potential product candidates that we develop may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release; such product candidates may not be beneficial to patients or become commercialized; and our ability to maintain our current collaborations and establish further collaborations. These risks are not exhaustive. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. Further information on factors that could cause actual results to differ materially from the results anticipated by our forward-looking statements is included in the reports we have filed or will file with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2022. These filings, when available, are available on the investor relations section of our website at investors.boltbio.com and on the SEC’s website at www.sec.gov.

Investor Relations and Media Contacts:

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BOLT BIOTHERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 2,528	$ 2,112	$ 5,787	$ 4,318
Operating expenses:				
Research and development	14,951	18,973	45,220	56,278
General and administrative	5,760	5,485	16,997	17,321
Total operating expense	20,711	24,458	62,217	73,599
Loss from operations	(18,183)	(22,346)	(56,430)	(69,281)
Other income, net				
Interest income, net	1,926	587	5,136	1,180
Total other income, net	1,926	587	5,136	1,180
Net loss	(16,257)	(21,759)	(51,294)	(68,101)
Net unrealized gain (loss) on marketable securities	55	94	745	(1,388)
Comprehensive loss	$ (16,202)	$ (21,665)	$ (50,549)	$ (69,489)
Net loss per share, basic and diluted	$ (0.43)	$ (0.58)	$ (1.36)	$ (1.83)
Weighted-average shares outstanding, basic and diluted	37,868,480	37,454,340	37,768,308	37,293,121

BOLT BIOTHERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(Unaudited, in thousands)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 9,160	$ 9,244
Short-term investments	110,564	159,644
Prepaid expenses and other current assets	5,742	3,858
Total current assets	125,466	172,746
Property and equipment, net	5,266	6,453
Operating lease right-of-use assets	19,878	22,072
Restricted cash	1,765	1,565
Long-term investments	21,638	23,943
Other assets	1,342	1,028
Total assets	$ 175,355	$ 227,807
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,682	$ 3,594
Accrued expenses and other current liabilities	10,451	15,140
Deferred revenue	1,938	1,993
Operating lease liabilities	2,680	2,391
Total current liabilities	18,751	23,118
Operating lease liabilities, net of current portion	18,177	20,220
Deferred revenue, non-current	10,125	12,921
Other long-term liabilities	43	42
Total liabilities	47,096	56,301
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	1	—
Additional paid-in capital	474,814	467,513
Accumulated other comprehensive loss	(174)	(919)
Accumulated deficit	(346,382)	(295,088)
Total stockholders' equity:	128,259	171,506
Total liabilities and stockholders' equity	$ 175,355	$ 227,807

BOLT BIOTHERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Nine Months Ended September 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (51,294)	$ (68,101)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,387	1,204
Stock-based compensation expense	7,155	7,453
Accretion (amortization) of premium/discount on marketable securities	(3,299)	655
Non-cash lease expense	2,194	2,520
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,198)	(713)
Accounts payable and accrued expenses	(4,601)	2,481
Operating lease liabilities	(1,754)	(1,966)
Deferred revenue	(2,851)	(2,079)
Other long-term liabilities	1	(6)
Net cash used in operating activities	(55,260)	(58,552)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(200)	(1,769)
Purchases of marketable securities	(132,828)	(155,345)
Maturities of marketable securities	188,257	198,541
Net cash provided by investing activities	55,229	41,427
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	147	359
Net cash provided by financing activities	147	359
Net increase (decrease) in cash	116	(16,766)
Cash, cash equivalents and restricted cash at beginning of year	10,809	28,948
Cash, cash equivalents and restricted cash at end of period	$ 10,925	$ 12,182
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 9,160	$ 10,617
Restricted cash	1,765	1,565
Total cash, cash equivalents and restricted cash	$ 10,925	$ 12,182
Supplemental schedule of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ —	$ 182
Deferred offering costs in accounts payable and accrued liabilities	$ 102	$ 102
Right of use assets obtained in exchange for operating lease obligations	$ —	$ 852