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 11, 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 May 11, 2023, Bolt Biotherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 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 May 11, 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: May 11, 2023

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

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

- Comprehensive BDC-1001 clinical safety and efficacy data as a single agent and in combination with nivolumab, including RP2D, to be presented at ASCO 2023
- BDC-1001 Phase 2 program expected to initiate in 2023 in HER2+ colorectal, endometrial, gastroesophageal, and breast cancer
- Cash balance of $171.0 million anticipated to fund key clinical milestones through 2025

REDWOOD CITY, Calif., May 11, 2023 (GLOBE NEWSWIRE) – Bolt Biotherapeutics, Inc. (Nasdaq: BOLT), a clinical-stage biopharmaceutical company developing novel immunotherapies for the treatment of cancer, today reported financial results for the first quarter ended March 31, 2023 and provided a business update.

“We are pleased to be advancing our lead Boltbody™ ISAC, BDC-1001, into a broader Phase 2 program in four different HER2-positive solid tumor types, following the recent positive topline results from our Phase 1 dose-escalation trial. We are looking forward to presenting a comprehensive dataset at ASCO from this first-in-human study, in which BDC-1001 achieved target drug exposure levels, was well tolerated from a safety perspective and demonstrated objective clinical responses and long-term durability both as a single agent and in combination with nivolumab,” said Randall Schatzman, Ph.D., Chief Executive Officer of Bolt Biotherapeutics. “As we prepare for Phase 2 studies in the U.S. and internationally, we look forward to investigating the benefits of BDC-1001 and our novel ISAC mechanism to aid HER2-positive cancer patients who are not benefitting from current therapeutic options. Additionally, the Bolt team is excited to be advancing our next program, BDC-3042, a proprietary Dectin-2 agonist antibody, into the clinic later this year.”

Recent Highlights and Anticipated Milestones

- **Topline BDC-1001 Phase 1 dose-escalation clinical data unveiled** from a multi-center, multi-dose clinical trial in more than 100 patients. The data demonstrated BDC-1001 was well-tolerated at all dose levels and schedules. BDC-1001 achieved objective clinical responses as a monotherapy and in combination with the PD-1 inhibitor nivolumab across a diverse range of solid tumor types. Target drug exposure levels were achieved at or near the recommended Phase 2 dose (RP2D) by more frequent administration including every other week (q2w) and weekly (q1w) administration schedules.

  Comprehensive first-in-human safety and efficacy data will be presented by Bob Li, M.D., Ph.D., MPH, medical oncologist, and principal investigator at Memorial Sloan Kettering Cancer Center (MSK) in a poster presentation at the upcoming 2023 American Society of Clinical Oncology Annual Meeting (ASCO 2023) on Saturday, June 3 in Chicago, Illinois.

- **Phase 2 BDC-1001 studies in four HER2+ solid tumor types are planned to initiate in 2023** with trials conducted at clinical sites in the U.S., Europe, and South Korea. Phase 2 dose expansions will investigate BDC-1001 as a monotherapy in three separate cohorts of patients with colorectal, endometrial, and gastroesophageal cancer. A separate combination arm with nivolumab is expected to initiate following demonstration of monotherapy anti-tumor activity in each of the three tumor types. An additional study, a randomized two-arm Phase 2 clinical trial, will investigate BDC-1001 as monotherapy and in combination with pertuzumab in patients with HER2-positive metastatic breast cancer whose disease has progressed following treatment with Enhertu®.

  Under a new supply agreement with Roche announced in the first quarter of 2023, Roche will provide pertuzumab for the Phase 2 breast cancer study. Under a previously announced agreement, BMS will provide nivolumab for the Phase 2 expansion studies.

- **New BDC-3042 data presented at the 2023 American Association of Cancer Research (AACR) Annual Meeting** in April 2023 in Orlando, Florida. BDC-3042 is an agonist antibody targeting Dectin-2, an immune-activating receptor expressed by tumor-associated macrophages (TAMs) in solid tumors. These preclinical data highlight recent findings on key characteristics of BDC-3042 in reprogramming Dectin-2-expressing TAMs, leading to the production of an array of pro-inflammatory cytokines and chemokines associated with anti-tumor immunity, and tumor growth inhibition in humanized mouse models of cancer, alone and in combination with a PD-1 checkpoint inhibitor.

  BDC-3042 to enter the clinic in 2023 following completion of Investigational New Drug (IND)-enabling activities, and clearance of a U.S. IND to initiate first-in-human studies later in 2023.

- **Boltbody™ ISAC collaborations with Genmab and Innovent to develop next-generation Boltbody ISACs continue to make progress.** These collaborations are exploring proprietary linker-payloads from the Boltbody ISAC platform in combination with Genmab's proprietary bispecific antibodies and with Innovent's proprietary antibodies, respectively.

- **Cash, cash equivalents, and marketable securities were $171.0 million** as of March 31, 2023**.** Cash on hand, coupled with collaboration revenues, is expected to fund clinical milestones and operations through 2025.

Upcoming Events

- **BDC-1001 poster presentation at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Ill.**

  Title: A phase 1/2 study of a first-in-human immune-stimulating antibody conjugate (ISAC) BDC-1001 in patients with advanced HER2-expressing solid tumors
  Abstract ID: 2538
  Abstract Category: Developmental Therapeutics—Immunotherapy

  Presenter: Dr. Bob Li, medical oncologist, and principal investigator at MSK
  Poster Session: Developmental Therapeutics—Immunotherapy
  Details: Saturday, June 3, 2023, 8:00 - 11:00 a.m. CDT
  Location: McCormick Place Convention Center, Chicago, Illinois

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First Quarter 2023 Financial Results

- **Collaboration Revenue –** Collaboration revenue was $1.8 million and $0.8 million for the quarter ended March 31, 2023, and 2022, respectively. The increase in revenue for the comparative periods was due to increased activity in our collaborations with Genmab and Innovent as we fulfill our performance obligations.

- **Research and Development (R&D) Expenses –** R&D expenses were $14.6 million for the quarter ended March 31, 2023, compared to $18.4 million for the same quarter in 2022. The decrease in R&D expenses was due to lower manufacturing expenses related to the timing of batch production of our product candidates and lower contract service expenses as well as our pipeline reprioritization in June of 2022, offset by higher clinical expenses related to the ongoing BDC-1001 clinical trial.

- **General and Administrative (G&A) Expenses –** G&A expenses were $5.6 million for the quarter ended March 31, 2023, compared to $6.3 million for the same quarter in 2022. The decrease in G&A expenses was due to lower consulting and professional services expenses.

- **Loss from Operations –** Loss from operations was $18.4 million for the quarter ended March 31, 2023, compared to $23.9 million for the same quarter in 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 that attract other immune cells and lower the activation threshold for an immune response. This process increases the number of activated immune 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 developing novel immunotherapies for the treatment of cancer. Bolt Biotherapeutics' pipeline candidates are built on the Company's deep expertise in myeloid biology and cancer drug development. The Company's pipeline includes BDC-1001, a HER2-targeting Boltbody Immune-Stimulating Antibody Conjugate (ISAC), BDC-3042, a myeloid cell-modulating antibody, and multiple Boltbody ISAC collaboration programs. BDC-1001 has completed a Phase 1 dose-escalation study demonstrating tolerability and early clinical efficacy, and the Company plans to initiate Phase 2 studies in 2023. Bolt Biotherapeutics is advancing BDC-3042, an agonist antibody targeting Dectin-2, through IND-enabling activities and expects to initiate a Phase 1 trial in the second half of 2023. In preclinical development, BDC-3042 demonstrated the ability to convert tumor-supportive macrophages to tumor-destructive macrophages. Bolt Biotherapeutics is pursuing novel applications of its technologies to develop multiple immuno-oncology candidates through 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 the poster presentation at ASCO 2023, the advancement and success of our clinical trials, the expansion of our clinical trials across Europe and South Korea, the success of our collaborations and the ability of our clinical collaboration partners to supply nivolumab and pertuzumab, our ability to fund our clinical programs, the sufficiency of our cash, cash equivalents, and marketable securities, and our future results of operations, financial condition, business strategy and plans 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.

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

	Three Months Ended March 31,	
	2023	2022
Collaboration revenue	$ 1,826	$ 813
Operating expenses:		
Research and development	14,625	18,385
General and administrative	5,616	6,304
Total operating expense	20,241	24,689
Loss from operations	(18,415)	(23,876)
Other income, net		
Interest income, net	1,435	198
Total other income, net	1,435	198
Net loss	(16,980)	(23,678)
Net unrealized gain (loss) on marketable securities	684	(1,075)
Comprehensive loss	$ (16,296)	$ (24,753)
Net loss per share, basic and diluted	$ (0.45)	$ (0.64)
Weighted-average shares outstanding, basic and diluted	37,684,023	37,127,876

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 14,836	$ 9,244
Short-term investments	111,543	159,644
Prepaid expenses and other current assets	5,230	3,858
Total current assets	131,609	172,746
Property and equipment, net	6,035	6,453
Operating lease right-of-use assets	21,353	22,072
Restricted cash	1,565	1,565
Long-term investments	44,586	23,943
Other assets	1,033	1,028
Total assets	$ 206,181	$ 227,807
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,835	$ 3,594
Accrued expenses and other current liabilities	10,334	15,140
Deferred revenue	1,600	1,993
Operating lease liabilities	2,484	2,391
Total current liabilities	16,253	23,118
Operating lease liabilities, net of current portion	19,568	20,220
Deferred revenue, non-current	12,631	12,921
Other long-term liabilities	43	42
Total liabilities	48,495	56,301
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	—	—
Additional paid-in capital	469,989	467,513
Accumulated other comprehensive loss	(235)	(919)
Accumulated deficit	(312,068)	(295,088)
Total stockholders' equity:	157,686	171,506
Total liabilities and stockholders' equity	$ 206,181	$ 227,807

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

	Three Months Ended March 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (16,980)	$ (23,678)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	467	357
Stock-based compensation expense	2,476	2,919
Accretion of premium/discount on marketable securities	(852)	466
Non-cash lease expense	719	1,171
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,377)	(2,120)
Accounts payable and accrued expenses	(6,611)	(2,392)
Operating lease liabilities	(559)	(982)
Deferred revenue	(683)	(51)
Other long-term liabilities	1	(4)
Net cash used in operating activities	(23,399)	(24,314)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(3)	(605)
Purchases of marketable securities	(42,883)	(76,084)
Maturities of marketable securities	71,877	117,534
Net cash provided by investing activities	28,991	40,845
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	—	107
Net cash provided by financing activities	—	107
Net increase in cash	5,592	16,638
Cash, cash equivalents and restricted cash at beginning of year	10,809	28,948
Cash, cash equivalents and restricted cash at end of period	$ 16,401	$ 45,586
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 14,836	$ 44,021
Restricted cash	1,565	1,565
Total cash, cash equivalents and restricted cash	$ 16,401	$ 45,586
Supplemental schedule of non-cash investing and financing activities:		
Vesting of early exercised options	$ —	$ 2
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 46	$ 231
Deferred offering costs in accounts payable and accrued liabilities	$ 102	$ 64

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