

**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 10, 2022

BOLT BIOTHERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39988
(Commission File Number)

47-2804636
(IRS Employer
Identification No.)

900 Chesapeake Drive
Redwood City, California
(Address of Principal Executive Offices)

94063
(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 10, 2022, Bolt Biotherapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2022. 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 are 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 10, 2022.
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 10, 2022

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



Bolt Biotherapeutics Reports Third Quarter 2022 Financial Results and Provides Business Update

- BDC-1001 dose-escalation clinical trial on track to complete recruitment by year-end 2022
- BDC-3042 on track to enter the clinic in 2023; new preclinical data at SITC 2022
- Cash balance of \$209.6 million anticipated to fund key milestones through 2025

REDWOOD CITY, Calif, Nov. 10, 2022 (GLOBENEWSWIRE) – Bolt Biotherapeutics, Inc. (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, 2022 and provided a business update.

“In the third quarter, our clinical development team advanced BDC-1001 for patients with HER2-expressing solid tumors through dose-escalation monotherapy and combination studies with Opdivo while exploring biweekly and weekly schedules. We look forward to announcing topline data and our recommended Phase 2 dose for the monotherapy and combination dose-expansion trials during the first quarter of 2023, with full data to be presented at an upcoming scientific conference,” said Randall C. Schatzman, Ph.D., Chief Executive Officer of Bolt Biotherapeutics. “We also continue to make strong progress in our proprietary BDC-3042 program, which is progressing through IND-enabling activities supporting initiation of clinical studies in 2023, and our collaboration programs. Our work with strategic partners on new ISAC pipeline programs positions Bolt to continuously innovate targeted immunotherapies with the potential to improve the treatment of cancer. Finally, I’d like to recognize how our talented research and development teams, have established our leadership position in ISACs, as they advance our promising next-generation immuno-oncology therapeutics.”

Recent Highlights and Anticipated Milestones

- **BDC-1001 – The monotherapy and combination dose-escalation trial is on track to complete enrollment by year-end.** Topline data, the recommended Phase 2 dose (RP2D), and Phase 2 dose-expansion study design are expected during the first quarter of 2023, with full data to follow later in 2023. Biweekly and weekly dosing regimens of BDC-1001, a HER2-targeting Boltbody™ immune-stimulating antibody conjugate (ISAC), are currently being evaluated in a Phase 1/2 multi-dose, multi-center study in monotherapy and combination studies with Bristol Myers Squibb’s PD-1 checkpoint inhibitor Opdivo® (nivolumab). To date, BDC-1001 has demonstrated a favorable safety profile, changes in plasma and tumor biomarkers consistent with its novel mechanism of action, and signs of durable clinical disease control.
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- **BDC-3042 on track to enter the clinic in 2023** – Investigational New Drug (IND)-enabling activities for BDC-3042, an agonist antibody that stimulates Dectin-2, are on track to support an IND filing and initiation of clinical development in 2023. Preclinical studies demonstrate that Dectin-2 agonist antibodies reprogram tumor-associated macrophages to drive anti-tumor immunity.
- **Cash, cash equivalents, and marketable securities were \$209.6 million as of September 30, 2022** – Cash on hand, coupled with growing collaboration revenues, is expected to fund multiple key milestones and operations through 2025.

Upcoming Events

- **BDC-3042 poster presentation highlighting new preclinical data will be presented at the 2022 Society for Immunotherapy of Cancer (SITC).** Bolt Biotherapeutics' Justin Kenkel, Ph.D., will present a poster entitled, "BDC-3042: A Dectin-2 agonistic antibody for tumor-associated macrophage-directed immunotherapy."

Authors: Justin Kenkel, Rishali Gadkari, Jess Nolin, Fang Xiao, Po Ho, Cindy Kreder, Laughing Bear Torrez, David Omstead, Katelynn McEachin, Jason Ptacek, Lu Xu, Duy Nguyen, Karla Henning, Steven Chapin, David Dornan, Michael Alonso, Shelley Ackerman

Poster Number: 1348

Presentation Date: Friday, Nov. 11, 2022, 9:00 a.m. – 8:30 p.m. EST, Poster Hall, Boston Convention and Exhibition Center

- **Stifel 2022 Healthcare Conference.** Management will be available for meetings with the investment community on Wednesday, November 16th, 2022, with a corporate presentation at 1:15 p.m. ET in New York, New York.

Third Quarter 2022 Financial Results

- **Collaboration Revenue** – Collaboration revenue was \$2.1 million for the third quarter ended September 30, 2022, compared to \$0.8 million for the same quarter in 2021. This represents 50% growth over the second quarter of 2022 as Bolt continues to ramp up activities supporting its collaborations. Revenue in 2022 was generated from the services performed under the R&D collaborations with Genmab A/S and Innovent Biologics, Inc.
 - **Research and Development (R&D) Expenses** – R&D expenses were \$19.0 million for the third quarter ended September 30, 2022, compared to \$19.3 million for the same quarter in 2021.
 - **General and Administrative (G&A) Expenses** – G&A expenses were \$5.5 million for the third quarter ended September 30, 2022, compared to \$4.9 million for the same quarter in 2021, primarily due to increases in personnel-related expenses relating to an increase in headcount.
 - **Loss from Operations** – Loss from operations was \$22.3 million for the third quarter ended September 30, 2022, compared to \$23.5 million for the same quarter in 2021.
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About the Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) Platform

Bolt Biotherapeutics' Boltbody ISAC platform unites the precision of antibodies with the power of the innate and adaptive immune system to reprogram the tumor microenvironment for 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 lowering 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 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-modulating antibody, and multiple Boltbody ISAC collaboration programs. Bolt Biotherapeutics is currently progressing BDC-1001 through a Phase 1/2 dose-escalation clinical trial, as a monotherapy and in combination with Bristol Myers Squibb's immune checkpoint inhibitor, Opdivo® (nivolumab), in a variety of HER2-expressing solid tumors. Bolt Biotherapeutics is advancing BDC-3042, an agonist antibody targeting Dectin-2, through IND-enabling studies. In preclinical development, BDC-3042 demonstrated the ability to convert tumor-supportive macrophages to tumor-destructive macrophages. Bolt Biotherapeutics is leveraging its ability to engineer and optimize novel applications of its Boltbody ISACs 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 our clinical trials, the timing of the completion of our monotherapy and combination dose escalation arms, the selection of a recommended Phase 2 dose for BDC-1001 for the treatment of patients with HER2-expressing solid tumors, our Phase 2 dose-expansion study design, the timing of our initiation of clinical development of BDC-3042, the resulting ISAC programs from our collaborations with Genmab A/S and Innovent Biologics, Inc., our ability to fund our clinical programs and the sufficiency of our cash, cash equivalents, and marketable securities, expectations for growing collaboration revenues, our future results of operations, financial condition, business strategy and plans and objectives of management for future operations, 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, 2021. 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.

Opdivo® is a trademark of Bristol-Myers Squibb Company.

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,	
	2022	2021	2022	2021
Collaboration revenue	\$ 2,112	\$ 752	\$ 4,318	\$ 752
Operating expenses:				
Research and development	18,973	19,337	56,278	53,171
General and administrative	5,485	4,941	17,321	13,294
Total operating expense	24,458	24,278	73,599	66,465
Loss from operations	(22,346)	(23,526)	(69,281)	(65,713)
Other income (expense), net				
Interest income, net	587	131	1,180	363
Change in fair value of preferred stock right liability	—	—	—	(6,084)
Total other income (expense), net	587	131	1,180	(5,721)
Net loss	(21,759)	(23,395)	(68,101)	(71,434)
Net unrealized gain (loss) on marketable securities	94	(15)	(1,388)	(38)
Comprehensive loss	\$ (21,665)	\$ (23,410)	\$ (69,489)	\$ (71,472)
Net loss per share, basic and diluted	\$ (0.58)	\$ (0.63)	\$ (1.83)	\$ (2.24)
Weighted-average shares outstanding, basic and diluted	37,454,340	37,206,793	37,293,121	31,824,180

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,617	\$ 27,383
Short-term investments	160,513	158,836
Prepaid expenses and other current assets	3,696	2,941
Total current assets	174,826	189,160
Property and equipment, net	6,905	6,158
Operating lease right-of-use assets	22,777	24,445
Restricted cash	1,565	1,565
Long-term investments	38,432	85,348
Other assets	1,000	1,042
Total assets	\$ 245,505	\$ 307,718
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,828	\$ 3,574
Accrued expenses and other current liabilities	14,793	12,384
Deferred revenue	3,169	2,869
Operating lease liabilities	2,384	2,501
Total current liabilities	24,174	21,328
Operating lease liabilities, net of current portion	20,857	21,854
Deferred revenue, non-current	11,828	14,207
Other long-term liabilities	200	210
Total liabilities	57,059	57,599
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	—	—
Additional paid-in capital	465,246	457,430
Accumulated other comprehensive loss	(1,709)	(321)
Accumulated deficit	(275,091)	(206,990)
Total stockholders' equity:	188,446	250,119
Total liabilities, convertible preferred stock, and stockholders' equity	\$ 245,505	\$ 307,718

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

	Nine Months Ended September 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (68,101)	\$ (71,434)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,204	832
Stock-based compensation expense	7,453	6,358
Accretion of premium/discount on marketable securities	655	1,833
Change in fair value of convertible preferred stock purchase rights liabilities	—	6,084
Non-cash lease expense	2,520	1,935
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(713)	(7,187)
Accounts payable and accrued expenses	2,481	7,225
Operating lease liabilities	(1,966)	(831)
Deferred revenue	(2,079)	15,911
Other long-term liabilities	(6)	2
Net cash used in operating activities	(58,552)	(39,272)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(1,769)	(1,776)
Purchases of marketable securities	(155,345)	(283,688)
Maturities of marketable securities	198,541	32,230
Net cash provided by (used in) investing activities	41,427	(253,234)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of preferred stock, net of issuance cost	—	51,902
Proceeds from initial public offering, net of issuance cost	—	244,316
Proceeds from issuance of common stock	359	757
Proceeds from issuance of common stock related to stock purchase agreement	—	13,638
Net cash provided by financing activities	359	310,613
Net (decrease) increase in cash	(16,766)	18,107
Cash, cash equivalents and restricted cash at beginning of year	28,948	7,107
Cash, cash equivalents and restricted cash at end of period	\$ 12,182	\$ 25,214
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 10,617	\$ 23,649
Restricted cash	1,565	1,565
Total cash, cash equivalents and restricted cash	\$ 12,182	\$ 25,214
Supplemental schedule of non-cash investing and financing activities:		
Vesting of early exercised options	\$ 4	\$ 114
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 182	\$ 591
Deferred offering costs in accounts payable and accrued liabilities	\$ 102	\$ —
Right of use assets obtained in exchange for operating lease obligations	\$ 852	\$ 14,884

Investor Relations and Media Contacts:

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