

**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): March 30, 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:

- 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 March 30, 2022, Bolt Biotherapeutics, Inc., issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2021. 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 March 30, 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: March 30, 2022

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



Bolt Biotherapeutics Reports Four Quarter and Full Year 2021 Financial Results and Provides Business Highlights

- *BDC-1001 for the treatment of patients with HER2-expressing solid tumors on track for recommended Phase 2 dose identification later in 2022; BDC-1001 combination study arm with OPDIVO® (nivolumab) progressing well*
- *Preclinical data on multiple pipeline programs will be presented at AACR 2022, including BDC-2034, BDC-3042, and a PD-L1 ISAC*
- *Cash balance of \$272 million expected to fund key milestones and operations into 2024*

REDWOOD CITY, CA, March 30, 2022 – Bolt Biotherapeutics, Inc. (NASDAQ: BOLT) a clinical-stage biotechnology company pioneering a new class of immuno-oncology agents that combine the targeting precision of antibodies with the power of both the innate and adaptive immune systems, today reported financial results for the fourth quarter and full year ended December 31, 2021, and provided an update on recent business highlights.

“In 2021, we demonstrated for the first time that our HER2-targeting Boltbody ISAC can increase myeloid cell infiltration and repolarize macrophages in the tumor microenvironment, and thereby, established proof of mechanism for our pioneering Boltbody ISAC platform. In our Phase 1/2 study, BDC-1001 was well tolerated at all dose levels tested with no dose-limiting toxicities. At the lower dose levels evaluated to date, we have seen stable disease in multiple different tumor types and a partial response that has now persisted for more than 60 weeks,” said Randall C. Schatzman, Ph.D., Chief Executive Officer of Bolt Biotherapeutics. “We continue to explore dose levels expected to achieve our targeted higher drug exposures, and look forward to determining the recommended Phase 2 dose for BDC-1001 as monotherapy and in combination with Opdivo.”

Recent Business Highlights

- **Initiation of BDC-1001 combination arm with Bristol Myers Squibb’s PD-1 checkpoint inhibitor OPDIVO® (nivolumab) in ongoing Phase 1/2 clinical trial for the treatment of patients with HER2-expressing solid tumors** – In December 2021, Bolt Biotherapeutics dosed the first patient in a new combination arm of the ongoing multi-center, multi-dose Phase 1/2 clinical trial of BDC-1001.
 - **Reported interim Phase 1/2 monotherapy data for BDC-1001 in HER2-expressing solid tumors at ESMO I-O 2021** – In December 2021, Bolt Biotherapeutics presented a poster at the European Society for Medical Oncology Immuno-Oncology (ESMO I-O) Congress 2021 detailing new safety, pharmacokinetic, and pharmacodynamic results from 57 subjects, 40 of whom were evaluable for efficacy, in the ongoing monotherapy dose-escalation portion of the Phase 1/2 trial. BDC-1001 demonstrated a favorable safety and tolerability profile. BDC-1001 also demonstrated early signs of clinical activity in the lower doses evaluable for efficacy with corresponding biomarker changes in the tumor microenvironment. The Company expects to determine the recommended Phase 2 dose for expansion trials in 2022.
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- **Advanced BDC-2034, a Boltbody ISAC targeting CEA, into IND-enabling studies with clinical development expected to begin in 2022** – Bolt Biotherapeutics is conducting IND-enabling studies with the goal of initiating clinical development in 2022. Data presented to date demonstrated tumor cell killing and innate immune activation in cellular and in vivo models of CEA-expressing cancers. Systemic administration in tumor-bearing animals was shown to result in dose-dependent anti-tumor activity.
- **Presented preclinical data demonstrating progress of three novel anti-cancer therapeutic candidates at SITC 2021** – In November 2021, Bolt Biotherapeutics presented three posters highlighting Bolt Biotherapeutics' pipeline including BDC-2034, a PD-L1 Boltbody ISAC, and BDC-3042, an agonist antibody targeting Dectin-2, a novel target for tumor macrophage reprogramming in cancer immunotherapy.
- **Expanded Bolt Biotherapeutics executive leadership team and board of directors with multiple appointments and promotions** – The Company added Nicole Onetto, M.D., Brian O'Callaghan, and Frank Lee to the board of directors, bringing deep industry experience in clinical development and commercial strategy within oncology drug development. Jim Healy, M.D., Ph.D., assumed the role of Lead Independent Director. Additionally, Bolt Biotherapeutics promoted Bruce Hug, M.D., Ph.D., to Senior Vice President, Clinical Development & Translational Medicine, Nathan Ihle, Ph.D., to Senior Vice President, Pharmaceutical Operations, and Brian Safina, Ph.D., to Senior Vice President, Discovery Research.
- **Cash, cash equivalents, and marketable securities were \$271.6 million as of December 31, 2021**, which is expected to fund operations and the advancement of the Company's oncology product pipeline to achieve multiple key milestones into 2024.

Upcoming Events

- **At the upcoming 2022 American Association for Cancer Research (AACR) Annual Meeting**, the Company will present three posters highlighting preclinical research, demonstrating anti-tumor activity and supporting future clinical development for these novel, early-stage pipeline programs.
 - o William G. Mallet, Ph.D., will present a poster entitled, "The CEA-targeted ISAC, BDC-2034, shows preclinical efficacy associated with innate immune activation, phagocytosis, and myeloid reprogramming" on Tuesday, April 12, 2022, from 9:00 a.m. - 12:30 p.m. CT.
 - o Shelley E. Ackerman, Ph.D., will present a poster entitled, "Dectin-2 agonist antibodies reprogram tumor-associated macrophages to drive anti-tumor immunity" on Tuesday, April 12, 2022, from 9:00 a.m. - 12:30 p.m. CT.
 - o Justin Kenkel, Ph.D., will present a poster entitled, "PD-L1-targeted ISAC combines myeloid cell activation, immune-checkpoint inhibition and ADCP to improve anti-tumor efficacy over anti-PD-L1 antibodies in preclinical models" on Wednesday, April 13, 2022, from 9:00 a.m. - 12:30 p.m. CT.
 - **At the 21st Annual Needham & Co Virtual Healthcare Conference**, management will be available for meetings with the investment community on Thursday, April 14, 2022, with a live virtual corporate presentation at 3:45 p.m. ET.
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Fourth Quarter and Full Year 2021 Financial Results

Cash Position – Cash, cash equivalents, and marketable securities were \$271.6 million as of December 31, 2021, compared to \$22.8 million as of December 31, 2020. Bolt Biotherapeutics expects its cash balance to fund operations into 2024.

Collaboration Revenue – Revenue was \$0.5 million for the quarter and \$1.3 million for the full year ended December 31, 2021, compared to zero and \$0.2 million for the same quarter and year in 2020. Revenue in 2021 was generated from services performed under the newly initiated R&D collaboration with Genmab A/S.

Research and Development Expenses – R&D expenses were \$22.5 million for the quarter and \$75.7 million for the full year ended December 31, 2021, compared to \$14.9 million and \$40.4 million for the same quarter and year in 2020, primarily due to increase in manufacturing and clinical trial expenses related to BDC-1001 and BDC-2034 and increase in personnel expenses relating to an increase in headcount.

General and Administrative Expenses – G&A expenses were \$5.1 million for the quarter and \$18.4 million for the full year ended December 31, 2021, compared to \$2.1 million and \$9.1 million for the same quarter and year in 2020, primarily due to increased expenses related to being a public company, including higher personnel expenses relating to increased headcount and an increase in professional services expenses.

Loss from Operations – Loss from operations was \$27.1 million for the quarter and \$92.8 million for the full year ended December 31, 2021, compared to \$16.9 million and \$49.2 million for the same quarter and year in 2020.

About the Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) Platform

ISACs are a new category of immunotherapy combining the precision of antibody targeting with the strength of the innate and adaptive immune systems. Boltbody ISACs comprise three primary components: a tumor-targeting antibody, a non-cleavable linker, and a proprietary immune stimulant to activate the patient's innate immune system. By initially targeting a single marker on the surface of a patient's tumor cells, an ISAC can create a new immune response by activating and recruiting myeloid cells. The activated myeloid cells start a feed-forward loop by releasing cytokines and chemokines, chemical signals that attract other immune cells and lower the activation threshold for an immune response. This reprograms the tumor microenvironment and invokes an adaptive immune response that targets the tumor, which can lead to the conversion of immunologically "cold" tumors to "hot" tumors with the goal of durable responses for patients with cancer.

About Bolt Biotherapeutics, Inc.

Bolt Biotherapeutics, Inc. is a clinical-stage biotechnology company pioneering a new class of immuno-oncology agents that combines the targeting precision of antibodies with the power of both the innate and adaptive immune systems. Bolt Biotherapeutics' proprietary Boltbody™ Immune-stimulating Antibody Conjugates (ISACs) are designed to target tumor cells for elimination by the immune system. BDC-1001 is a HER2-targeting Boltbody ISAC in an ongoing Phase 1/2 clinical trial enrolling patients with HER2-expressing solid tumors. Bolt is also advancing BDC-2034, a Boltbody ISAC targeting CEA, and BDC-3042, an agonist antibody targeting Dectin-2. BDC-3042 is the Company's first myeloid-modulating candidate outside of the Boltbody ISAC platform. In

addition, Bolt Biotherapeutics is developing new immuno-oncology Boltbody ISACs through strategic collaborations with leading biopharmaceutical companies.

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 enrollment for our Phase 1/2 trial for BDC-1001 for the treatment of patients with HER2-expressing solid tumors, the timing of our Phase 2 dose expansion part and the combination with an anti-PD-1 antibody part, the timing that Boltbody ISAC BDC-2034 will enter clinical trials, 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 for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “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. 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.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	For The Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Collaboration revenue	\$ 508	\$ —	\$ 1,260	\$ 231
Operating expenses:				
Research and development	22,484	14,864	75,655	40,357
General and administrative	5,099	2,058	18,393	9,056
Total operating expense	27,583	16,922	94,048	49,413
Loss from operations	(27,075)	(16,922)	(92,788)	(49,182)
Other income (expense), net				
Interest income	(82)	12	281	199
Change in fair value of convertible preferred stock purchase right liability	—	(14,125)	(6,084)	(11,745)
Total other expense, net	(82)	(14,113)	(5,803)	(11,546)
Net loss	(27,157)	(31,035)	(98,591)	(60,728)
Net unrealized loss on marketable securities	(283)	—	(321)	—
Comprehensive loss	\$ (27,440)	\$ (31,035)	\$ (98,912)	\$ (60,728)
Net loss per share, basic and diluted	\$ (0.73)	\$ (14.58)	\$ (2.97)	\$ (28.89)
Weighted-average shares outstanding, basic and diluted	37,269,511	2,129,133	33,196,712	2,102,328

BOLT BIOTHERAPEUTICS, INC.
BALANCE SHEETS
(in thousands)

	<i>December 31,</i>	
	<u>2021</u>	<u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 27,383	\$ 5,542
Short-term investments	158,836	17,296
Prepaid expenses and other current assets	2,941	2,523
Total current assets	189,160	25,361
Property and equipment, net	6,158	4,083
Operating lease right-of-use assets	24,445	12,267
Restricted cash	1,565	1,565
Deferred offering costs	—	2,357
Long-term investments	85,348	—
Other assets	1,042	909
Total assets	<u>\$ 307,718</u>	<u>\$ 46,542</u>
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 3,574	\$ 1,598
Accrued expenses and other current liabilities	12,384	6,663
Deferred revenue	2,869	1,502
Operating lease liabilities	2,501	1,501
Total current liabilities	21,328	11,264
Operating lease liabilities, net of current portion	21,854	9,376
Deferred revenue, non-current	14,207	—
Convertible preferred stock purchase right liability, non-current	—	25,224
Other long-term liabilities	210	329
Total liabilities	<u>57,599</u>	<u>46,193</u>
Commitments and contingencies		
Convertible preferred stock	—	105,296
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	—	—
Additional paid-in capital	457,430	3,452
Accumulated other comprehensive loss	(321)	—
Accumulated deficit	(206,990)	(108,399)
Total stockholders' equity (deficit):	<u>250,119</u>	<u>(104,947)</u>
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 307,718</u>	<u>\$ 46,542</u>

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

	Years Ended December 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (98,591)	\$ (60,728)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,193	611
Stock-based compensation expense	8,500	1,420
Accretion of premium/discount on short-term investments	2,975	34
Unrealized gain (loss) on marketable securities, net	(321)	—
Loss on disposal of property and equipment	108	—
Change in fair value of convertible preferred stock purchase right liability	6,084	11,745
Non-cash lease expense	2,479	1,893
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(568)	(1,878)
Accounts payable and accrued expenses	6,676	2,882
Operating lease liabilities	(1,179)	(3,389)
Deferred revenue	15,574	(69)
Other long-term liabilities	4	171
Net cash used in operating activities	(57,066)	(47,308)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(2,338)	(3,262)
Purchases of marketable securities	(313,375)	(33,229)
Maturities of marketable securities	83,512	15,899
Net cash used in investing activities	(232,201)	(20,592)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of preferred stock, net	51,902	41,270
Proceeds from initial public offering, net of issuance cost	244,316	—
Proceeds from issuance of common stock related to stock purchase agreement	13,638	—
Proceeds from issuance of common stock	1,252	294
Payment of deferred offering cost	—	(1,967)
Net cash provided by financing activities	311,108	39,597
NET INCREASE (DECREASE) IN CASH	21,841	(28,303)
Cash, cash equivalents and restricted cash at beginning of year	7,107	35,410
Cash, cash equivalents and restricted cash at end of period	\$ 28,948	\$ 7,107
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 27,383	\$ 5,542
Restricted cash	1,565	1,565
Total cash, cash equivalents and restricted cash	\$ 28,948	\$ 7,107
Supplemental schedule of non-cash investing and financing activities:		
Vesting of unvested issued common stock	\$ 123	\$ 49
Purchases of PPE included in accounts payable and accrued liabilities	\$ 1,021	\$ 28
Deferred offering costs in accounts payable and accrued liabilities	\$ —	\$ 390
Right of use assets obtained in exchange for operating lease obligations	\$ 14,657	\$ 4,081

Investor Relations and Media Contacts:

Karen L. Bergman

Vice President, Communications and Investor Relations

Bolt Biotherapeutics, Inc.

650-665-9295

kbergman@boltbio.com

Sarah McCabe

Stern Investor Relations, Inc.

212-362-1200

sarah.mccabe@sternir.com

Maggie Beller or David Schull

Russo Partners, LLC

646-942-5631

maggie.beller@russopartnersllc.com

david.schull@russopartnersllc.com
