## 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 9, 2021

### **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)

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

Not Applicable (Former Name or Former Address, if Changed Since Last Report)

Common Stock, par value \$0.00001 per share	"BOLT"	The Nasdaq Global Select Market
Title of Each Class:	Trading Symbol(s):	Name of Exchange on Which Registered:
curities registered pursuant to Section 12(b) of the Act:		
Pre-commencement communications pursuant to Rule 13	3e-4(c) under the Exchange Act (	17 CFR 240.13e-4(c))
Pre-commencement communications pursuant to Rule 14	4d-2(b) under the Exchange Act (	17 CFR 240.14d-2(b))
Soliciting material pursuant to Rule 14a-12 under the Ex	change Act (17 CFR 240.14a-12)	
Written communications pursuant to Rule 425 under the	Securities Act (17 CFR 230.425)	
neck the appropriate box below if the Form 8-K filing is inter llowing provisions (see General Instructions A.2. below):	naca to simulationesis sudisty the	. Thing conguton of the registrant under any of the

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, 2021, Bolt Biotherapeutics, Inc., issued a press release announcing its financial results for the third quarter ended September 30, 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

<u>Press Release dated November 9, 2021.</u>
Cover Page Interactive Data File (embedded within the Inline XBRL document) 104

#### **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 hereunto duly authorized.

**Bolt Biotherapeutics, Inc.** 

By: /s/ William P. Quinn

William P. Quinn Chief Financial Officer

Dated: November 9, 2021



#### Bolt Biotherapeutics Reports Third Quarter 2021 Financial Results and Provides Business Highlights

–BDC-1001 Phase 1/2 dose-escalation interim clinical trial update in HER2-expressing solid tumors to be presented at ESMO Immuno-Oncology Congress 2021

-Strong cash position of \$295.5 million expected to fund operations through the end of 2023

**REDWOOD CITY, CA, November 9, 2021** – 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 third quarter ended September 30, 2021 and provided an update on recent business highlights.

"This quarter was notable for the significant progress we made across our entire pipeline of novel ISACs and with successful partnering of Bolt's pioneering technology. We continued robust enrollment of the dose escalation portion of the BDC-1001 Phase 1/2 trial and we anticipate initiation of the combination dose escalation with Opdivo by year-end," said Randall C. Schatzman, Ph.D., Chief Executive Officer of Bolt Biotherapeutics. "We look forward to providing an update on our progress with BDC-1001 at the ESMO Immuno-Oncology Congress in December."

#### **Recent Business Highlights and Anticipated Milestones**

- Progress in the BDC-1001 Phase 1/2 trial in HER2-expressing solid tumors, with a monotherapy interim update in Q4 2021 Interim data from more than 50 patients treated at increasing exposure levels will be presented in December at the ESMO Immuno-Oncology Congress 2021. The presentation will provide further details of the continued favorable safety and tolerability profile along with insights from data on phamacokinetics, tumor and serum biomarkers and early signs of clinical activity. The positive data support continued investigation of an optimal dosing regimen and Phase 2 initiation in 2022.
- **R&D** collaboration with Innovent Biologics to develop up to three anti-cancer ISAC candidates In August 2021, Bolt Biotherapeutics announced an R&D collaboration to apply Innovent's proprietary therapeutic antibody portfolio and discovery capability and Bolt's ISAC platform technology and myeloid biology expertise with the goal of creating up to three new cancer treatments with the potential to provide significant benefit to patients. Bolt Biotherapeutics received an upfront payment of \$5.0 million in cash from Innovent at signing and a possible future equity investment of up to \$10.0 million, as well as milestones and royalties. Bolt Biotherapeutics retains the option to license global rights outside of Greater China for one program and North American rights for another program.
- Clinical collaboration and supply agreement with Bristol Myers Squibb to investigate BDC-1001 in combination with Opdivo® (nivolumab) In September 2021, Bolt Biotherapeutics announced a

clinical collaboration and supply agreement with Bristol Myers Squibb Company (BMS) to investigate BDC-1001 in combination with BMS' PD-1 checkpoint inhibitor Opdivo. BMS will provide Opdivo for the combination dose escalation and combination dose expansion portions of the Phase 1/2 clinical trial in patients with HER2-expressing solid tumors, including breast, gastroesophageal and colorectal. The combination portion of the trial is expected to start in the fourth quarter of 2021.

- **IND-enabling studies with BDC-2034 (CEA-targeting ISAC) remain on track.** GLP toxicology studies are expected to commence in first quarter of 2022 and IND filing in mid-2022.
- Cash, cash equivalents, and marketable securities of \$290.5 million as of September 30, 2021, plus the \$5.0 million upfront payment received in October 2021 for the R&D collaboration with Innovent Biologics, is expected to fund operations and the advancement of the company's product pipeline to achieve multiple key milestones through the end of 2023.

#### **Upcoming Events**

- At the 2021 Society for Immunotherapy of Cancer (SITC) Annual Meeting, company scientists will be presenting data on three proprietary, early-stage oncology pipeline programs, including two Boltbody™ ISAC candidates and a novel agonist antibody targeting Dectin-2 (previously known as TAM1). Information about these presentations can be found below and on the 2021 SITC Annual Meeting website. All poster presentations will take place from 7:00 a.m. − 8:30 p.m. ET on Saturday, November 13, 2021.
  - William G. Mallet, Ph.D., will present a poster entitled "BDC-2034: Discovery of a CEA-targeting Immune-Stimulating Antibody Conjugate (ISAC) for Solid Tumors."
  - Justin A. Kenkel, Ph.D., will present a poster entitled "Dectin-2, a novel target for tumor macrophage reprogramming in cancer immunotherapy."
  - Marcin Kowanetz, 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."
- At the Stifel 2021 Virtual Healthcare Conference, management will participate in a virtual fireside chat and be available for meetings with the investment community on Tuesday, November 16, 2021.
- At the ESMO Immuno-Oncology Congress 2021, interim results will be presented from the monotherapy dose-escalation portion of a Phase 1/2 study of BDC-1001 for the treatment of patients with advanced HER2-expressing solid tumors, including breast, gastroesophageal and colorectal cancer. ESMO I/O is being held in Geneva, Switzerland in person and virtually from December 8-11, 2021.
  - **Title:** Preliminary results from a phase 1/2 study of BDC-1001, a novel HER2 targeting TLR7/8 immune-stimulating antibody conjugate (ISAC), in patients (pts) with advanced HER2-expressing solid tumors
  - Presenter: Manish R. Sharma, M.D., Associate Director of Clinical Research, START Midwest
  - Presentation Number: 164P
  - **Details:** December 8-11, 2021, ePoster presentation

#### **Third Quarter 2021 Financial Results**

**Cash Position** – Cash, cash equivalents, and marketable securities were \$290.5 million as of September 30, 2021, compared to \$310.9 million as of June 30, 2021. Bolt Biotherapeutics expects this cash balance to fund operations through the end of 2023.

**Collaboration Revenue** – Revenue was \$0.8 million for the quarter ended September 30, 2021, compared to zero for the same quarter in 2020. Revenue in 2021 was generated from services performed under the R&D collaboration with Genmab.

**Research and Development Expenses** – R&D expenses were \$19.3 million for the quarter ended September 30, 2021, compared to \$9.5 million for the same quarter in 2020, with the largest two increases due to manufacturing expenses related to BDC-1001 and BDC-2034 and personnel expenses relating to an increase in headcount.

**General and Administrative (G&A) Expenses** – G&A expenses were \$4.9 million for the quarter ended September 30, 2021, compared to \$2.9 million for the same quarter in 2020, with the largest increase due to personnel expenses relating to an increase in headcount.

**Loss from Operations** – Loss from operations was \$23.5 million for the quarter ended September 30, 2021, compared to \$12.4 million for the same quarter in 2020.

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

#### About Bolt Biotherapeutics, Inc. (Bolt Bio)

Bolt Biotherapeutics, Inc. is 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 Bolt's proprietary Boltbody<sup>TM</sup> Immune-stimulating Antibody Conjugate (ISAC) approach uses immunostimulants to engage and activate myeloid cells that directly kill tumor cells. This leads to the conversion of immunologically "cold" tumors to "hot" tumors. Bolt's lead candidate, BDC-1001, is a Boltbody ISAC comprised of a HER2-targeting biosimilar of trastuzumab conjugated to one of Bolt's proprietary TLR7/8 agonists for the treatment of patients with HER2-expressing solid tumors. Bolt is also advancing additional Boltbody ISAC product candidates targeting CEA and PD-L1. For more information, visit <a href="https://www.boltbio.com/">https://www.boltbio.com/</a>.

#### **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, the success of our ongoing 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 for future operations, are forwardlooking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "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 forwardlooking 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, 2020. 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)  ${\bf r}$ 

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2021		2020		2021		2020
Collaboration revenue	\$	752	\$	_	\$	752	\$	231
Operating expenses:								
Research and development		19,337		9,540		53,171		25,493
General and administrative		4,941		2,865		13,294		6,998
Total operating expense		24,278		12,405		66,465		32,491
Loss from operations		(23,526)		(12,405)		(65,713)		(32,260)
Other income (expense), net								
Interest income, net		131		24		363		187
Change in fair value of preferred stock right liability				2,380		(6,084)		2,380
Total other income (expense), net		131		2,404		(5,721)		2,567
Net loss		(23,395)		(10,001)		(71,434)		(29,693)
Net unrealized gain (loss) on marketable securities		(15)		1		(38)		2
Comprehensive loss	\$	(23,410)	\$	(10,000)	\$	(71,472)	\$	(29,691)
Net loss per share, basic and diluted	\$	(0.63)	\$	(4.73)	\$	(2.24)	\$	(14.19)
Weighted-average shares outstanding, basic and diluted		37,206,793	_	2,112,499		31,824,180		2,092,977
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#### BOLT BIOTHERAPEUTICS, INC. CONDENSED BALANCE SHEETS (Unaudited, in thousands)

	September 30, 2021			December 31, 2020		
Assets						
Current assets:						
Cash and cash equivalents	\$	23,649	\$	5,542		
Short-term investments		189,244		17,296		
Prepaid expenses and other current assets		9,595		2,523		
Total current assets		222,488		25,361		
Property and equipment, net		5,631		4,083		
Operating lease right-of-use assets		25,216		12,267		
Finance lease right-of-use assets		21		34		
Restricted cash		1,565		1,565		
Deferred offering costs		_		2,357		
Long-term investments		77,639		_		
Other assets		990		875		
Total assets	\$	333,550	\$	46,542		
Liabilities, convertible preferred stock, and stockholders' equity (deficit)						
Current liabilities:						
Accounts payable	\$	5,155	\$	1,598		
Accrued expenses and other current liabilities		10,922		6,663		
Deferred revenue		5,207		1,502		
Operating lease liabilities		2,411		1,501		
Total current liabilities		23,695		11,264		
Operating lease liabilities, net of current portion		22,519		9,376		
Deferred revenue, non-current		12,206		_		
Convertible preferred stock purchase right liability, non-current		_		25,224		
Other long-term liabilities		217		329		
Total liabilities		58,637		46,193		
Commitments and contingencies						
Convertible preferred stock		_		105,296		
Stockholders' equity (deficit):						
Common stock		_		_		
Additional paid-in capital		454,784		3,452		
Accumulated other comprehensive loss		(38)		_		
Accumulated deficit		(179,833)		(108,399)		
Total stockholders' equity (deficit):		274,913		(104,947)		
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	\$	333,550	\$	46,542		

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

		Nine Months Ended September 30,		
CACVAEVA ON 10 ED ON A ODED ATTANCA A CENTURATE		2021		2020
CASH FLOWS FROM OPERATING ACTIVITIES:	ф	(54.45.4)	Φ.	(20,002)
Net loss	\$	(71,434)	\$	(29,693)
Adjustments to reconcile net loss to net cash used in operating activities:		022		200
Depreciation and amortization		832		390
Stock-based compensation expense		6,358		851
Accretion of premium/discount on marketable securities		1,871		(23)
Unrealized gain (loss) on marketable securities, net		(38)		2
Change in fair value of convertible preferred stock purchase rights liabilities		6,084		(2,380)
Non-cash lease expense		1,935		1,352
Changes in operating assets and liabilities:		(= 10=)		/1 <b>-</b> / 1
Prepaid expenses and other assets		(7,187)		(1,544)
Accounts payable and accrued expenses		7,225		(221)
Operating lease liabilities		(831)		(3,251)
Deferred revenue		15,911		(69)
Other long-term liabilities		2		168
Net cash used in operating activities		(39,272)		(34,418)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of property and equipment		(1,776)		(2,364)
Purchases of marketable securities		(283,688)		(33,229)
Maturities of marketable securities		32,230		13,297
Net cash used in investing activities		(253,234)		(22,296)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of preferred stock, net of issuance cost		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		757		216
Payment of deferred offering costs		_		(824)
Net cash provided by financing activities		310,613		40,662
Net increase (decrease) in cash		18,107		(16,052)
Cash, cash equivalents and restricted cash at beginning of year		7,107		35,410
Cash, cash equivalents and restricted cash at end of period	\$	25,214	\$	19,358
Reconciliation of cash, cash equivalents and restricted cash:		<u> </u>	_	<u> </u>
Cash and cash equivalents	\$	23,649	\$	17,793
Restricted cash	Ψ	1,565	Ψ	1,565
Total cash, cash equivalents and restricted cash	\$	25,214	\$	19,358
·	<u>Ψ</u>	25,214	Ψ	15,550
Supplemental schedule of non-cash investing and financing activities:	¢	11.4	¢	20
Vesting of early exercised options	\$	114	\$	
Purchases of property and equipment included in accounts payable and accrued liabilities	\$	591	\$	859
Deferred offering costs in accounts payable and accrued liabilities	\$		\$	1,456
Right of use assets obtained in exchange for operating lease obligations	\$	14,884	\$	4,081

#### **Investor Relations and Media Contacts:**

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