

**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 29, 2023

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 March 29, 2023, Bolt Biotherapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter ended December 31, 2022. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On March 29, 2023, the Company issued a press release announcing positive topline data from the Company’s recently completed dose-escalation study of BDC-1001 in HER2-expressing solid tumors that supports advancing into two Phase 2 studies. A copy of the press release is furnished herewith as Exhibit 99.2 and incorporated herein by reference.

The information contained herein and the accompanying exhibits 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 they 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 29, 2023.](#)

99.2 [Topline Press Release dated March 29, 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: March 29, 2023

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



Bolt Biotherapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

- Positive topline data from BDC-1001 dose-escalation clinical study validates the ability of the Boltbody™ ISAC platform to generate anti-tumor activity with acceptable safety
- BDC-1001 advances into a focused Phase 2 program commencing in 2023: a trial as monotherapy and in combination with nivolumab in colorectal, endometrial, and gastroesophageal cancers; and a second trial in breast cancer studying monotherapy and combination with pertuzumab (Perjeta®)
- BDC-3042 expected to enter clinic in 2023; upcoming presentation at AACR 2023
- Cash balance of \$192.8 million anticipated to fund key milestones through 2025

REDWOOD CITY, Calif., March 29, 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 fourth quarter and full year ended December 31, 2022, and provided a business update.

“We believe the BDC-1001 Phase 1 results validate our Boltbody™ ISAC approach. Our design decisions enable us to deliver potent immune-stimulating antibody conjugates that can achieve positive clinical responses with acceptable tolerability, thereby, decoupling anti-tumor activity from the systemic safety issues that others have encountered. We are advancing into a thoughtfully designed, focused Phase 2 program evaluating BDC-1001 in patients with four different types of HER2-positive solid tumors where there remains important unmet medical need,” said Randall Schatzman, Ph.D., Chief Executive Officer of Bolt Biotherapeutics.

“We are pleased to be entering into an agreement with Roche to supply pertuzumab in support of a new combination study with BDC-1001 and we look forward to investigating the impact of this combination in patients with HER2-positive metastatic breast cancer, while we continue to investigate BDC-1001 as monotherapy and work with our partner Bristol Myers Squibb to explore the combination with nivolumab. The progress in developing new immunotherapies in both our proprietary and partnered research programs demonstrates the potential of myeloid biology to provide important new treatment options to patients with cancer.”

Recent Highlights and Anticipated Milestones

- **Topline BDC-1001 Phase 1 dose-escalation results** – Topline data from a multi-center, multi-dose Phase 1 clinical trial evaluating BDC-1001 as a single agent and in combination with nivolumab supports selection of a recommended phase 2 dose (RP2D) and initiation of a Phase 2 clinical program including two studies in four tumor types.
- **Phase 2 BDC-1001 studies planned to initiate in 2023** – Clinical trials will include patients with HER2-positive breast, colorectal, endometrial, and gastroesophageal cancers at clinical sites in the U.S., multiple European countries, and South Korea evaluating BDC-1001 as monotherapy, in combination with pertuzumab, and separately, in combination with nivolumab.
- **BDC-3042 to enter the clinic in 2023** – Investigational New Drug (IND)-enabling activities for a Phase 1 trial for BDC-3042 are proceeding on track. BDC-3042 is an agonistic antibody targeting Dectin-2, an immune-activating receptor expressed by TAMs in solid tumors. Preclinical studies demonstrate the ability of Dectin-2 agonistic antibodies to reprogram tumor-associated macrophages and drive anti-tumor activity.
- **Continued progress with Boltbody™ ISAC collaborations** – Collaborations with Genmab and Innovent developing next-generation Boltbody ISACs continue to progress. Both collaborations are exploring proprietary linker-payloads from the Boltbody ISAC platform, combining with Genmab's proprietary bispecific antibodies in one collaboration and with Innovent's proprietary antibodies in the other.
- **Strengthened Bolt's Board of Directors with appointment of Laura Berner** – In December 2022, Laura Berner joined the Bolt Board of Directors. Ms. Berner brings extensive biopharmaceutical industry experience, having executed more than 50 transactions including research collaborations and product co-development and co-promotion partnerships. She currently serves as the Chief Operating Officer at TRexBio and has held multiple leadership positions spanning corporate strategy, business development, investor relations, and law.
- **Cash, cash equivalents, and marketable securities were \$192.8 million as of December 31, 2022** – Cash on hand, coupled with growing collaboration revenues, is expected to fund multiple key milestones and operations through 2025.

Upcoming Events

- **BDC-3042 abstract accepted for presentation at the American Association for Cancer Research (AACR) Annual Meeting 2023 in Orlando, Fla.**

Title: Targeting tumor-associated macrophages to enhance anti-tumor immunity with the Dectin-2 agonistic antibody

Poster Board Number: 11

Abstract Presentation Number: 2964

Presenter: Justin A. Kenkel, Ph.D.

Details: Monday, April 17, 2023, 1:30 p.m. – 5:00 p.m. EDT

Location: Orange County Convention Center, Section 24

Fourth Quarter and Full Year 2022 Financial Results

- **Collaboration Revenue** – Collaboration revenue was \$1.4 million for the quarter and \$5.7 million for the full year ended December 31, 2022, compared to \$0.5 million and \$1.3 million for the same quarter and year in 2021. The collaboration with Genmab exploring Boltbody ISACs using Genmab's proprietary bispecific antibodies accounted for \$4.2 million in revenue for 2022 and the collaboration with Innovent exploring Boltbody ISACs using Innovent's proprietary antibodies accounted for \$1.5 million in revenue for 2022.
- **Research and Development (R&D) Expenses** – R&D expenses were \$16.8 million for the quarter and \$73.1 million for the full year ended December 31, 2022, compared to \$22.5 million and \$75.7 million for the same quarter and year in 2021. The decrease in R&D expenses was due to lower manufacturing expenses related to the timing of batch production of our product candidates, offset by higher clinical expenses related to the ongoing BDC-1001 clinical trial due to increase in patient activities.
- **General and Administrative (G&A) Expenses** – G&A expenses were \$5.6 million for the quarter and \$22.9 million for the full year ended December 31, 2022, compared to \$5.1 million and \$18.4 million for the same quarter and year in 2021. The increase in G&A expenses was due to higher personnel-related expenses due to an increase in headcount and higher office and facility-related expenses, offset by lower consulting and professional services expenses.
- **Loss from Operations** – Loss from operations was \$21.0 million for the quarter and \$90.3 million for the full year ended December 31, 2022, compared to \$27.1 million and \$92.8 million for the same quarter and year in 2021.

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 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 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. 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 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., the success of our clinical collaborations and the ability of our clinical collaboration partners to supply nivolumab and pertuzumab (Perjeta®), 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, 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.

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

Perjeta® is a trademark of Roche

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

	For The Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Collaboration revenue	\$ 1,411	\$ 508	\$ 5,729	\$ 1,260
Operating expenses:				
Research and development	16,845	22,484	73,123	75,655
General and administrative	5,606	5,099	22,927	18,393
Total operating expense	22,451	27,583	96,050	94,048
Loss from operations	(21,040)	(27,075)	(90,321)	(92,788)
Other income (expense), net				
Interest income	1,043	(82)	2,223	281
Change in fair value of convertible preferred stock purchase right liability	—	—	—	(6,084)
Total other income (expense), net	1,043	(82)	2,223	(5,803)
Net loss	(19,997)	(27,157)	(88,098)	(98,591)
Net unrealized loss on marketable securities	790	(283)	(598)	(321)
Comprehensive loss	\$ (19,207)	\$ (27,440)	\$ (88,696)	\$ (98,912)
Net loss per share, basic and diluted	\$ (0.53)	\$ (0.73)	\$ (2.36)	\$ (2.97)
Weighted-average shares outstanding, basic and diluted	37,552,208	37,269,511	37,358,425	33,196,712

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,244	\$ 27,383
Short-term investments	159,644	158,836
Prepaid expenses and other current assets	3,858	2,941
Total current assets	172,746	189,160
Property and equipment, net	6,453	6,158
Operating lease right-of-use assets	22,072	24,445
Restricted cash	1,565	1,565
Long-term investments	23,943	85,348
Other assets	1,028	1,042
Total assets	\$ 227,807	\$ 307,718
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,594	\$ 3,574
Accrued expenses and other current liabilities	15,140	12,384
Deferred revenue	1,993	2,869
Operating lease liabilities	2,391	2,501
Total current liabilities	23,118	21,328
Operating lease liabilities, net of current portion	20,220	21,854
Deferred revenue, non-current	12,921	14,207
Other long-term liabilities	42	210
Total liabilities	56,301	57,599
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	—	—
Additional paid-in capital	467,513	457,430
Accumulated other comprehensive loss	(919)	(321)
Accumulated deficit	(295,088)	(206,990)
Total stockholders' equity	171,506	250,119
Total liabilities, convertible preferred stock, and stockholders' equity	\$ 227,807	\$ 307,718

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

	Years Ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (88,098)	\$ (98,591)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,666	1,193
Stock-based compensation expense	9,576	8,500
Accretion of premium/discount on short-term investments	184	2,654
Loss on disposal of property and equipment	—	108
Change in fair value of convertible preferred stock purchase right liability	—	6,084
Non-cash lease expense	3,225	2,479
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(903)	(568)
Accounts payable and accrued expenses	2,768	6,676
Operating lease liabilities	(2,596)	(1,179)
Deferred revenue	(2,162)	15,574
Other long-term liabilities	(164)	4
Net cash used in operating activities	(76,504)	(57,066)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(1,953)	(2,338)
Purchases of marketable securities	(180,704)	(313,375)
Maturities of marketable securities	240,519	83,512
Net cash provided by (used in) investing activities	57,862	(232,201)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of preferred stock, net	—	51,902
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	503	1,252
Payment of deferred offering cost	—	—
Net cash provided by financing activities	503	311,108
NET INCREASE (DECREASE) IN CASH	(18,139)	21,841
Cash, cash equivalents and restricted cash at beginning of year	28,948	7,107
Cash, cash equivalents and restricted cash at end of period	\$ 10,809	\$ 28,948
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 9,244	\$ 27,383
Restricted cash	1,565	1,565
Total cash, cash equivalents and restricted cash	\$ 10,809	\$ 28,948
Supplemental schedule of non-cash investing and financing activities:		
Vesting of unvested issued common stock	\$ 4	\$ 123
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 8	\$ 1,021
Deferred offering costs in accounts payable and accrued liabilities	\$ 102	\$ —
Right of use assets obtained in exchange for operating lease obligations	\$ 852	\$ 14,657

Investor Relations and Media Contacts:

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Bolt Biotherapeutics Announces Positive Topline Data from BDC-1001 Phase 1 Dose-Escalation Trial in HER2-Expressing Tumors, Supporting Advancement to Phase 2 Clinical Studies

BDC-1001 elicited objective clinical responses, including multiple PRs and long-term stable disease, across a diverse set of solid tumor types in monotherapy and in combination with nivolumab

Data support selection of a recommended Phase 2 dose and advancement into Phase 2 studies in breast, colorectal, endometrial, and gastroesophageal cancers

Entered into a new collaboration with Roche, as part of further BDC-1001 Phase 2 program expansion, supplying pertuzumab (Perjeta®) to evaluate in combination with BDC-1001

REDWOOD CITY, Calif., March 29, 2023 (GLOBE NEWSWIRE) - Bolt Biotherapeutics, Inc. (Nasdaq: BOLT), a clinical-stage biopharmaceutical company pioneering novel immuno-oncology therapeutics for the treatment of cancer, today reported positive topline data from the company's recently completed dose-escalation study of BDC-1001 in HER2-expressing solid tumors that support advancing into two Phase 2 studies. BDC-1001 is an investigational Immune-Stimulating Antibody Conjugate (ISAC) in development for the treatment of patients with HER2-expressing cancer. Data will be presented at an upcoming medical meeting.

Topline findings from this trial indicate that BDC-1001 was well tolerated at all dose levels and schedules evaluated, both as monotherapy and in combination with nivolumab. 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. Anti-tumor activity was observed in the form of multiple partial responses (PRs), tumor shrinkage, and long-term stable disease at or near the RP2D across multiple HER2-expressing solid tumor types in monotherapy and in combination with nivolumab. Moreover, biomarker data demonstrate that corresponding clinical and safety data are related to the ISAC mechanism. These data support the selection of a RP2D and advancement to Phase 2 studies.

"We are enthusiastic to be taking the next step in investigating the therapeutic promise of BDC-1001. In the study, we not only achieved target exposure levels for BDC-1001, but at those levels we saw promising signs of clinical activity as a single agent and in combination with nivolumab," said Edith A. Perez, M.D., Chief Medical Officer of Bolt Biotherapeutics. "We look forward to sharing full data at an upcoming major medical conference, and to initiating a focused Phase 2 program working with a diverse group of investigators in the U.S. and internationally. I'd like to express my gratitude to all the patients and investigators who are participating in our trial and to the incredible team at Bolt for their hard work and dedication."

“While we have made remarkable progress in developing new treatments for patients with HER2-expressing cancers, there remains an urgent need for innovation,” said Bob T. Li, M.D., Ph.D., MPH, medical oncologist, and principal investigator at Memorial Sloan Kettering Cancer Center (MSK). “In this international dose-escalation trial, BDC-1001 leveraged a novel mechanism of HER2-targeted immune stimulating antibody conjugate and demonstrated encouraging evidence of efficacy and manageable safety, providing hope of a potential new treatment option for patients with HER2-expressing tumors.”

Bolt Biotherapeutics’ Phase 1 dose-escalation trial enrolled more than 100 patients with 16 different HER2-expressing solid tumor types. At enrollment, all patients entered in the study had evidence of tumor progression following prior standard of care treatments, and a majority of the patients were heavily pre-treated.

New Agreement with Roche Supporting Phase 2 Study

Bolt Biotherapeutics also announced today that it has entered into a clinical supply agreement with Roche to evaluate pertuzumab (Perjeta®) in combination with BDC-1001. Through a supply agreement, Roche will provide pertuzumab in support of a Phase 2 metastatic breast cancer trial.

Preclinical research combining pertuzumab with a BDC-1001-surrogate demonstrated enhanced anti-tumor efficacy in multiple models and a compelling mechanistic rationale for conducting a clinical trial to evaluate a potential impact on patients. Pertuzumab, which binds a distinct HER2 epitope from the trastuzumab component of BDC-1001, may increase the amount of clustered Fc or “eat me signals” on the surface of the tumor. This appears to trigger enhanced antibody-dependent cellular phagocytosis, a key element of the BDC-1001 mechanism of action, resulting in further propagation of BDC-1001-driven immune activation and anti-tumor efficacy.

BDC-1001 Phase 2 Clinical Program

Bolt’s Phase 2 clinical plan includes two distinct studies, each using a Simon two-stage design. These studies will build upon Bolt’s existing clinical sites and clinical trial centers of excellence in the U.S. and South Korea, expanding into multiple countries in Europe, and include:

- Phase 2 dose expansions of the current Phase 1/2 trial will initially focus on investigating BDC-1001 as a monotherapy, given the positive single-agent clinical data seen in the Phase 1 trial, enrolling HER2-positive colorectal, endometrial, and gastroesophageal cancer patients. Combination arms with nivolumab are expected to initiate in each indication following demonstration of monotherapy anti-tumor activity. Bristol Myers Squibb, Bolt’s clinical collaborator for this study, will continue to supply nivolumab at no cost for such expansion cohorts.
 - Initiation of a two-cohort Phase 2 clinical trial exploring BDC-1001 as monotherapy and BDC-1001 in combination with pertuzumab in patients with HER2-positive metastatic breast cancer who have developed tumor progression following treatment with Enhertu.
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About the Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) Platform

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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.

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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 advancement and success of our clinical trials and the expansion of our clinical trials across Europe, the success of our collaborations and the ability of our clinical collaboration partners to supply nivolumab and pertuzumab (Perjeta®), and the application of our ISAC platform 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.

Perjeta® is a trademark of Roche

Dr. Li has provided uncompensated advisory board services to Bolt Biotherapeutics.

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