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

August 7, 2023

- First patients dosed in the BDC-1001 Phase 2 program
- BDC-1001 Phase 1 data presented at ASCO 2023 demonstrated favorable safety profile and encouraging efficacy as a monotherapy and in combination with nivolumab in HER2-expressing tumors
- BDC-3042 received IND clearance; clinical trial expected to start before year-end
- Cash balance of $157.1 million anticipated to fund key milestones through 2025

REDWOOD CITY, Calif., Aug. 07, 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 second quarter ended June 30, 2023 and provided an update on the continued advancement of its clinical programs.

“We have extended our leadership position in immunotherapy as the first company to initiate a Phase 2 program for an ISAC,” said Randall Schatzman, Ph.D., Chief Executive Officer. “The FDA has also cleared the IND for BDC-3042, the first and only program targeting Dectin-2 with an agonist antibody. This is our second successful IND and we expect to begin this first-in-human clinical trial later this year. We presented positive data at ASCO and look forward to presenting more data at ESMO and other upcoming major medical meetings. Our team is highly motivated by all of this positive momentum and the opportunities for us to make a difference for cancer patients.”

“The data in the Phase 1 dose-escalation trial of BDC-1001 included durable objective clinical responses and a favorable safety profile. Importantly, these data provide clinical validation of our Boltbody™ ISAC approach, which has the potential to deliver a novel mechanism for the treatment of HER2-positive cancers and shows promise for patients who are resistant to current therapies on the market.”

Recent Highlights and Anticipated Milestones

- **Comprehensive safety and efficacy data from the BDC-1001 Phase 1 dose-escalation study presented at the American Society of Oncology (ASCO) Annual Meeting** in June 2023 by Bob T. Li, M.D., Ph.D., MPH, medical oncologist and principal investigator at Memorial Sloan Kettering Cancer Center (MSK). BDC-1001 achieved a 29% objective response rate in evaluable patients with HER2-positive tumors, both as monotherapy and in combination with nivolumab at the recommended Phase 2 dose (RP2D). The percentage of evaluable patients with HER2-positive tumors who experienced PRs or at least 24 weeks of disease control was 43% in the monotherapy arm and 57% in combination with nivolumab. These data supported the selection of 20 mg/kg dosed every other week (q2w) as the RP2D for the BDC-1001 Phase 2 clinical program.
- **First patients dosed in BDC-1001 Phase 2 dose-expansion study** in August 2023. This study is investigating BDC-1001 initially as single-agent monotherapy in three separate cohorts: HER2-positive colorectal, endometrial, and gastroesophageal cancer.

  A second Phase 2 study is evaluating BDC-1001 as monotherapy and in combination with pertuzumab for the treatment of patients with HER2-positive metastatic breast cancer whose disease has progressed following treatment with Enhertu®.

- **FDA clears IND for BDC-3042** in July 2023. BDC-3042 is a proprietary agonist antibody that targets Dectin-2, an immune-activating receptor expressed by tumor-associated macrophages (TAMs). The Company remains on track to initiate a Phase 1 clinical study of BDC-3042 in solid tumors later in 2023.
- **Additional BDC-1001 clinical and biomarker data will be presented in a mini-oral session at ESMO Congress 2023.** The presentation, “Recommended phase 2 dose (RP2D) selection and pharmacodynamic (PD) data of the first-in-human immune-stimulating antibody conjugate (ISAC) BDC-1001 in patients (pts) with advanced HER2-expressing solid tumors,” will be made by Bob T. Li, M.D., Ph.D., MPH, October 20-24 in Madrid, Spain.
- **Cash, cash equivalents, and marketable securities were $157.1 million as of June 30, 2023.** Cash on hand is expected to fund multiple milestones and operations through 2025.

Upcoming Events

- **Bolt Biotherapeutics will participate in upcoming conferences:**
  - BTIG Virtual Biotechnology Conference 2023, August 7-9
  - Morgan Stanley Annual Global Healthcare Conference, September 11-13 in New York, NY
  - H.C. Wainwright 25th Annual Global Investment Conference, September 11-13 in New York, NY

Second Quarter 2023 Financial Results

- **Collaboration Revenue –** Collaboration revenue was $1.4 million for each of the quarters ended June 30, 2023, and 2022. Revenue in the comparative periods were generated from the services performed under the R&D collaborations as we fulfill our performance obligations.
- **Research and Development (R&D) Expenses –** R&D expenses were $15.6 million for the quarter ended June 30, 2023, compared to $18.9 million for the same quarter in 2022. The decrease in R&D expenses was due to lower manufacturing expenses related to the timing of batch production of our product candidates and lower lab supplies and contract service expenses, offset by higher clinical expenses related to the ongoing BDC-1001 clinical trial.
- **General and Administrative (G&A) Expenses –** G&A expenses were $5.6 million for the quarter ended June 30, 2023, compared to $5.5 million for the same quarter in 2022.
- **Loss from Operations –** Loss from operations was $19.8 million for the quarter ended June 30, 2023, compared to $23.1 million for the same quarter in 2022. This is in part a reflection of proactive cost-containment measures taken in June 2022.

About the Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) Platform
Bolt Biotherapeutics' Boltbody ISAC platform harnesses the precision of antibodies with the power of the innate and adaptive immune system to reprogram the tumor microenvironment to generate a productive anti-cancer response. Each Boltbody ISAC candidate comprises a tumor-targeting antibody, a non-cleavable linker and a proprietary immune stimulant. The antibody is designed to target one or more markers on the surface of a tumor cell, and the immune stimulant is designed to recruit and activate myeloid cells. Activated myeloid cells initiate a positive feedback loop by releasing cytokines and chemokines, 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 is currently in Phase 2 clinical development following the successful completion of a Phase 1 dose-escalation trial that demonstrated tolerability and early clinical efficacy. BDC-3042, an agonist antibody targeting Dectin-2, is expected 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 also developing multiple Boltbody™ ISACs in 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 cohorts, the timing of our initiation of clinical development of BDC-3042, the success of our clinical collaborations, the ability of our clinical collaboration partners to supply nivolumab and pertuzumab, 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, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "on track," "plan," "potential," "predict," "project," "should," "will," or "would," or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements represent our current beliefs, estimates and assumptions only as of the date of this press release and information contained in this press release should not be relied upon as representing our estimates as of any subsequent date. These statements, and related risks, uncertainties, factors and assumptions, include, but are not limited to: the potential product candidates that we develop may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release; such product candidates may not be beneficial to patients or become commercialized; and our ability to maintain our current collaborations and establish further collaborations. These risks are not exhaustive. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. Further information on factors that could cause actual results to differ materially from the results anticipated by our forward-looking statements is included in the reports we have filed or will file with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2022. These filings, when available, are available on the investor relations section of our website at investors.boltbio.com and on the SEC's website at www.sec.gov.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 1,433	$ 1,393	$ 3,259	$ 2,206
Operating expenses:				
Research and development	15,644	18,920	30,269	37,305
General and administrative	5,621	5,532	11,237	11,836
Total operating expense	21,265	24,452	41,506	49,141
Loss from operations	(19,832)	(23,059)	(38,247)	(46,935)
Other income, net				
Interest income, net	1,775	395	3,210	593
Total other income, net	1,775	395	3,210	593
Net loss	(18,057)	(22,664)	(35,037)	(46,342)
Net unrealized gain (loss) on marketable securities	6	(407)	690	(1,482)
Comprehensive loss	$ (18,051)	$ (23,071)	$ (34,347)	$ (47,824)
Net loss per share, basic and diluted	$ (0.48)	$ (0.61)	$ (0.93)	$ (1.25)
Weighted-average shares outstanding, basic and diluted	37,750,393	37,293,557	37,717,391	37,211,174

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 13,451	$ 9,244
Short-term investments	112,415	159,644
Prepaid expenses and other current assets	4,802	3,858
Total current assets	130,668	172,746
Property and equipment, net	5,609	6,453
Operating lease right-of-use assets	20,622	22,072
Restricted cash	1,565	1,565
Long-term investments	31,220	23,943
Other assets	1,012	1,028
Total assets	$ 190,696	$ 227,807
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,436	$ 3,594
Accrued expenses and other current liabilities	9,916	15,140
Deferred revenue	1,685	1,993
Operating lease liabilities	2,581	2,391
Total current liabilities	17,618	23,118
Operating lease liabilities, net of current portion	18,891	20,220
Deferred revenue, non-current	12,012	12,921
Other long-term liabilities	43	42
Total liabilities	48,564	56,301
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	1	—
Additional paid-in capital	472,485	467,513
Accumulated other comprehensive loss	(229)	(919)
Accumulated deficit	(330,125)	(295,088)
Total stockholders' equity:	142,132	171,506
Total liabilities and stockholders' equity	$ 190,696	$ 227,807

BOLT BIOTHERAPEUTICS, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Six Months Ended June 30,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (35,037)	$ (46,342)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	925	765
Stock-based compensation expense	4,826	5,310
Accretion of premium/discount on marketable securities	(1,964)	693
Non-cash lease expense	1,450	1,838
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(928)	(1,941)
Accounts payable and accrued expenses	(5,428)	(3,087)
Operating lease liabilities	(1,139)	(1,461)
Deferred revenue	(1,217)	(870)
Other long-term liabilities	1	(6)
Net cash used in operating activities	(38,511)	(45,101)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(35)	(1,034)
Purchases of marketable securities	(96,524)	(107,433)
Maturities of marketable securities	139,130	148,444
Net cash provided by investing activities	42,571	39,977
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	147	359
Net cash provided by financing activities	147	359
Net increase (decrease) in cash	4,207	(4,765)
Cash, cash equivalents and restricted cash at beginning of year	10,809	28,948
Cash, cash equivalents and restricted cash at end of period	$ 15,016	$ 24,183
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 13,451	$ 22,618
Restricted cash	1,565	1,565
Total cash, cash equivalents and restricted cash	$ 15,016	$ 24,183
Supplemental schedule of non-cash investing and financing activities:		
Vesting of early exercised options	$ —	$ 4
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 46	$ 98
Deferred offering costs in accounts payable and accrued liabilities	$ 102	$ 102

Investor Relations and Media Contacts:

Paige Kelly
Stern Investor Relations, Inc.
212-698-8699
Paige.kelly@sternir.com

David Schull
Russo Partners, LLC
858-717-2310
david.schull@russopartnersllc.com