Bolt Biotherapeutics Reports Third Quarter 2024 Financial Results and Provides Business Update

November 12, 2024

- Advanced to the highest dose level in the Phase 1 dose-escalation clinical study of BDC-3042 in patients with advanced cancers
- Presented updated preclinical activity of BDC-4182 and key learnings from Phase 1 dose-escalation trial of BDC-1001 at the SITC 39th Annual Meeting
- BDC-4182 on track to start clinical trial in second quarter 2025
- Cash balance of $84.4 million as of September 30, 2024 anticipated to fund key milestones through mid-2026

REDWOOD CITY, Calif., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Bolt Biotherapeutics (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, 2024, and provided a business update.

“During the third quarter, we continued to make progress with our two proprietary programs, BDC-3042 and BDC-4182,” said Willie Quinn, Chief Executive Officer. “We have now completed the sixth dose level in the first-in-human clinical trial of BDC-3042, have opened the final cohort which will study a dose level of 10 mg/kg, and expect to provide a data update in the first half of 2025. We are particularly excited about our next-generation ISAC BDC-4182, which builds on the lessons we learned from our clinical experience with BDC-1001. We believe that BDC-4182’s dramatic increase in potency and activity will potentially enable the treatment of patients whose tumors have lower claudin 18.2 expression and may provide even better anti-tumor activity than conventional ADCs. We presented some of the data that underlies this excitement at SITC, and the team is hard at work preparing for a clinical trial initiation of BDC-4182 in the second quarter next year.”

Recent Highlights and Anticipated Milestones

- **Presented updated clinical activity of BDC-4182 at the 39th Annual Meeting of the Society for Immunotherapy of Cancer (SITC).** BDC-4182 is a next-generation Boltbody^{TM} ISAC clinical candidate targeting claudin 18.2, a novel, clinically validated target in oncology with expression in gastric/gastroesophageal junction cancer, pancreatic cancer, and other tumor types. BDC-4182 has advanced into IND-enabling activities, supported by *in vitro* and *in vivo* experiments demonstrating potent anti-tumor activity in multiple preclinical models, with clinical trial initiation expected in 2025. BDC-4182 was well tolerated in non-human primates at the highest dose tested (12mg/kg) with an acceptable safety profile. BDC-4182 outperformed cytotoxic claudin 18.2 ADCs in syngeneic models and BDC-4182’s favorable toxicology profile enables a variety of potential future combinations.
- **Presented key learnings from Phase 1 dose-escalation trial of BDC-1001 at SITC.** First-generation ISAC BDC-1001 demonstrated immunological activity in this first-in-human trial, particularly in patients with high HER2 antigen expression. Greater immune activation appeared to be associated with clinical benefit. Pharmacodynamic changes were observed in patients whose tumors had higher levels of HER2 and were statistically significant in patients with HER2 IHC 3+ tumors. Data supports the hypothesis that an ISAC with enhanced immune activation could offer greater efficacy, warranting further testing in next-generation ISACs.
- **Advanced to cohort 7 (10 mg/kg) in the Phase 1 study of BDC-3042 in patients with advanced cancers.** BDC-3042 is a proprietary agonist antibody that targets Dectin-2, an immune-activating receptor expressed by tumor-associated macrophages (TAMs). This single-agent, dose-escalation Phase 1 clinical study is evaluating BDC-3042 in patients with metastatic or unresectable triple-negative breast cancer (TNBC), colorectal cancer, clear cell renal cell carcinoma, head and neck cancer, non-small cell lung cancer (NSCLC), ovarian cancer, or melanoma.
- **Collaborations with Genmab and Toray continue to progress.** The Company continues to work with its collaborators to discover and develop ISACs for the treatment of cancer. Genmab and the Company have selected a product to advance into development for the collaboration’s first program. The Genmab collaboration also continues research and development on additional programs.

- **Cash, cash equivalents, and marketable securities were $84.4 million as of September 30, 2024.** Cash on hand is expected to fund multiple milestones and operations through mid-2026.

Third Quarter 2024 Financial Results

- **Collaboration Revenue –** Collaboration revenue was $1.1 million for the quarter ended September 30, 2024, compared to $2.5 million for the same quarter in 2023. Revenue in the comparative periods was generated from services performed under the R&D collaborations as we fulfill our performance obligations.

- **Research and Development (R&D) Expenses –** R&D expenses were $13.8 million for the quarter ended September 30, 2024, compared to $15.0 million for the same quarter in 2023. The decrease between the comparable periods was mainly due to a decrease in salary and related expenses primarily as a result of the May 2024 restructuring, partially offset by an increase in contract manufacturing expenses.

- **General and Administrative (G&A) Expenses –** G&A expenses were $3.8 million for the quarter ended September 30, 2024, compared to $5.8 million for the same quarter in 2023. The decrease between the comparable periods was mainly due to a decrease in salary and related expenses primarily as a result of the May 2024 restructuring.

- **Loss from Operations –** Loss from operations was $16.4 million for the quarter ended September 30, 2024, compared to $18.2 million for the same quarter in 2023.

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 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-3042, a first-in-class agonist antibody that activates macrophages by targeting Dectin-2, and BDC-4182, a next-generation Boltbody™ Immune-Stimulating Antibody Conjugate (ISAC) clinical candidate targeting claudin 18.2. BDC-3042 is currently in a Phase 1 dose escalation trial that includes patients with any of seven different solid tumor types. BDC-4182 is supported by strong in vitro and in vivo data demonstrating potent anti-tumor activity, and activities are underway to support the initiation of clinical trials in 2025. Bolt Biotherapeutics is also developing additional 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 the advancement and success of our BDC-3042 clinical trial, the potential initiation of clinical trials for BDC-4182, the anti-tumor potency, safety and tolerability, and characteristics of our product candidates, the initiation of future clinical trials, the potential value of collaborations, and the expected duration of our cash runway, 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, 2023. 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.

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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,	
	2024	2023	2024	2023
Collaboration revenue	$ 1,141	$ 2,528	$ 7,690	$ 5,787
Operating expenses:				
Research and development	13,785	14,951	45,747	45,220
General and administrative	3,799	5,760	14,510	16,997
Restructuring charges	—	—	3,565	—
Total operating expense	17,584	20,711	63,822	62,217
Loss from operations	(16,443)	(18,183)	(56,132)	(56,430)
Other income, net				
Interest income, net	1,267	1,926	4,275	5,136
Other income	—	—	4,675	—
Total other income, net	1,267	1,926	8,950	5,136
Net loss	(15,176)	(16,257)	(47,182)	(51,294)
Net unrealized gain on marketable securities	249	55	168	745
Comprehensive loss	$ (14,927)	$ (16,202)	$ (47,014)	$ (50,549)
Net loss per share, basic and diluted	$ (0.40)	$ (0.43)	$ (1.24)	$ (1.36)
Weighted-average shares outstanding, basic and diluted	38,250,982	37,868,480	38,149,830	37,768,308

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 9,366	$ 10,810
Short-term investments	44,432	91,379
Restricted cash	792	—
Prepaid expenses and other current assets	2,557	3,519
Total current assets	57,147	105,708
Property and equipment, net	3,565	4,957
Operating lease right-of-use assets	16,756	19,120
Restricted cash, non-current	981	1,765
Long-term investments	30,598	26,413
Other assets	287	1,821
Total assets	$ 109,334	$ 159,784
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,482	$ 2,987
Accrued expenses and other current liabilities	11,806	12,486
Deferred revenue	1,971	2,201
Operating lease liabilities	2,824	2,782
Total current liabilities	18,083	20,456
Operating lease liabilities, net of current portion	15,353	17,437
Deferred revenue, non-current	3,867	9,107
Other long-term liabilities	-	43
Total liabilities	37,303	47,043
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	1	1
Additional paid-in capital	483,292	476,988

Accumulated other comprehensive gain	205	37
Accumulated deficit	(411,467)	(364,285)
Total stockholders' equity:	72,031	112,741
Total liabilities and stockholders' equity	$ 109,334	$ 159,784

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

	Nine Months Ended September 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (47,182)	$ (51,294)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,355	1,387
Stock-based compensation expense	6,225	7,155
Accretion of discount on marketable securities	(2,307)	(3,299)
Gain on sale of fixed assets	(70)	—
Non-cash lease expense	2,364	2,194
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,496	(2,198)
Accounts payable and accrued expenses	(2,185)	(4,601)
Operating lease liabilities	(2,042)	(1,754)
Deferred revenue	(5,470)	(2,851)
Other long-term liabilities	(43)	1
Net cash used in operating activities	(46,859)	(55,260)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(41)	(200)
Proceeds from sales of property and equipment	148	—
Purchases of marketable securities	(75,602)	(132,828)
Maturities of marketable securities	120,839	188,257
Net cash provided by investing activities	45,344	55,229
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	79	147
Net cash provided by financing activities	79	147
Net (decrease) increase in cash	(1,436)	116
Cash, cash equivalents and restricted cash at beginning of year	12,575	10,809
Cash, cash equivalents and restricted cash at end of period	$ 11,139	$ 10,925
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 9,366	$ 9,160
Restricted cash	1,773	1,765
Total cash, cash equivalents and restricted cash	$ 11,139	$ 10,925