Boundless Bio Provides Business Updates Focused on Key Value Drivers and Reports Second Quarter 2024 Financial Results

August 12, 2024

BBI-355 POTENTIATE clinical trial ongoing with initiatives implemented to expedite enrollment in combination cohorts; initial proof-of-concept data now expected in the second half of 2025

BBI-825 STARMAP clinical trial ongoing with initial proof-of-concept data expected in the second half of 2025

ECHO ecDNA diagnostic analytically validated and IRB-approved for use as a clinical trial assay in BBI-355 POTENTIATE trial

Streamlined operations expected to extend operating runway into the fourth quarter of 2026

SAN DIEGO, Aug. 12, 2024 (GLOBE NEWSWIRE) -- Boundless Bio (Nasdaq: BOLD), a clinical-stage oncology company interrogating extrachromosomal DNA (ecDNA) biology to deliver transformative therapies to patients with previously intractable oncogene amplified cancers, today provided business updates for the company's top strategic priorities and reported financial results for the second quarter of 2024.

"At Boundless, we're on a bold mission to pioneer a new category of cancer treatment for patients with oncogene amplified cancer who are in dire need of new therapeutic options," said Zachary Hornby, President and Chief Executive Officer of Boundless Bio. "In the second quarter of 2024, we continued to advance our first clinical-stage ecDTx, BBI-355, began dosing patients with our second ecDTx, BBI-825, and completed the analytical validation and received IRB approval of our novel ecDNA diagnostic, ECHO, for deployment as a clinical trial assay in our BBI-355 POTENTIATE trial. Though we have made progress toward our goals, the number of patients enrolled thus far in the combination cohorts of the BBI-355 POTENTIATE trial is lower than originally projected. While we implement measures to accelerate enrollment, we have chosen to scale back our early discovery efforts and streamline our operations to extend our runway and help ensure we have the necessary capital for our core ecDTx programs. Moving forward, we believe we are well-positioned to move our lead programs through initial clinical proof-of-concept data readouts and remain steadfast in advancing this innovative approach for patients with high unmet need."

Strategic Priorities for Core Programs

Boundless Bio has outlined its core portfolio priorities to support the achievement of potential near-term catalysts and long-term patient impact. Through 2025, the company's core strategic priorities remain:

- Executing the ongoing Phase 1/2 POTENTIATE (Precision Oncology Trial Evaluating Novel Therapeutic Interrupting Amplifications Tied to ecDNA) clinical trial of its lead ecDNA directed therapeutic candidate (ecDTx), BBI-355, a novel, oral CHK1 inhibitor, to generate initial proof-of-concept in solid tumor cancer patients with driver oncogene amplifications;
- Executing the ongoing Phase 1/2 STARMAP (Study Targeting Acquired Resistance: MAPK Amplifications) clinical trial of its second ecDTx, BBI-825, a novel, oral RNR inhibitor, to generate initial proof-of-concept in colorectal cancer patients with $BRAF^{V600E}$ or $KRAS^{G12C}$ mutations and resistance oncogene amplifications;
- Advancing the company's third ecDTx program, directed to a novel, previously undrugged kinesin target essential for ecDNA segregation, into IND-enabling studies; and
- Deploying its proprietary ecDNA diagnostic in the clinic to identify ecDNA+ patients who are most likely to benefit from its ecDTx therapeutics.

In alignment with its strategic priorities, Boundless Bio has narrowed its discovery research work and, as a result, modestly reduced its workforce. The company believes the combination of these operational efficiencies and its cash, cash equivalents, and short-term investments of $179.3 million as of June 30, 2024, provides an operating runway into the fourth quarter of 2026.

BBI-355, a novel, oral, potent, selective CHK1 inhibitor targeting replication stress for cancer patients with driver oncogene amplifications

- The company presented preclinical and clinical pharmacodynamic data on BBI-355 at the American Association for Cancer Research (AACR) Annual Meeting in April 2024.
- Enrollment is progressing in the Phase 1/2 POTENTIATE clinical trial evaluating BBI-355 as a single agent and in combination with targeted therapies in patients with locally advanced or metastatic solid tumors with oncogene amplifications.
- To date, no new safety signals have been observed, and there has been no evidence of combinatorial toxicity in the dose escalation cohorts evaluating BBI-355 in combination with either the EGFR inhibitor erlotinib or the FGFR inhibitor futibatinib.
- The initial pace of enrollment in the combination cohorts has been slower than anticipated. The company has recently implemented multiple initiatives to help accelerate enrollment, including engaging with next-generation sequencing vendors to identify patients, adding new clinical sites in the US, and preparing for the initiation of ex-US sites.
- Based on its current projections, the company now anticipates reporting initial clinical proof-of-concept data from POTENTIATE in the second half of 2025.

BBI-825, a novel, oral, potent, selective RNR inhibitor targeting ecDNA assembly and repair for cancer patients with resistance oncogene amplifications

- In April 2024, the company announced the first patient had been dosed with BBI-825 in the Phase 1/2 STARMAP clinical

trial.
- Multiple dose levels have been completed in the single-agent, dose-escalation portion of the STARMAP clinical trial and, to date, BBI-825 has demonstrated oral bioavailability and has been generally well-tolerated. Initial clinical proof-of-concept data from the trial are expected in the second half of 2025.

ecDTx 3, a novel kinesin program involved in ecDNA segregation

- The company's third ecDTx program, directed to a previously undrugged kinesin target essential for ecDNA segregation whose inhibition is synthetic lethal to ecDNA-enabled cancer cells, is currently advancing through lead optimization.

ECHO, a proprietary diagnostic for detection of ecDNA amplified oncogenes

- The company's proprietary ecDNA diagnostic, referred to as ECHO (ecDNA Harboring Oncogenes), is designed to detect ecDNA in patient tumor specimens. ECHO was previously determined by the FDA to be a non-significant risk device for use as a clinical trial assay (CTA) in the BBI-355 POTENTIATE trial.
- ECHO has now been analytically validated and institutional review board (IRB)-approved for use as a CTA in the BBI-355 POTENTIATE trial.

Second Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $179.3 million as of June 30, 2024.
- **R&D Expenses:** Research and development (R&D) expenses were $14.7 million for the second quarter of 2024 compared to $11.1 million for the same period in 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $4.7 million for the second quarter of 2024 compared to $2.9 million for the same period in 2023.
- **Net Loss:** Net loss totaled $17.0 million for the second quarter of 2024 compared to $12.4 million for the same period in 2023.

About BBI-355

Boundless Bio's lead ecDTx, BBI-355, is a novel, oral, selective small molecule inhibitor of checkpoint kinase 1 (CHK1) being studied in the ongoing, first-in-human, Phase 1/2 POTENTIATE clinical trial (NCT05827614) in cancer patients with oncogene amplifications. CHK1 is a master regulator of cells' response to replication stress (RS). RS is elevated in cancer cells with oncogene amplification, including on ecDNA, and, because of this, represents a key vulnerability of those cells. BBI-355 was designed to exploit the elevated RS in ecDNA-enabled oncogene amplified cancer cells by disrupting proper CHK1 function in regulating RS and thereby facilitating catastrophic RS to preferentially kill cancer cells relative to healthy cells.

About BBI-825

Boundless Bio's second ecDTx, BBI-825, is a novel, oral, selective small molecule inhibitor of ribonucleotide reductase (RNR) being studied in the ongoing, first-in-human, Phase 1/2 STARMAP clinical trial (NCT06299761) in colorectal cancer patients with $BRAF^{V600E}$ or $KRAS^{G12C}$ mutations and resistance gene amplifications. In preclinical studies, BBI-825 demonstrated low double digit nanomolar RNR inhibition and tumor growth inhibition, including regressions, in both the prevention and treatment of amplification-mediated resistance in mitogen-activated protein kinase (MAPK) pathway-activated tumors. RNR is the rate-limiting enzyme responsible for cellular *de novo* synthesis of deoxynucleotide triphosphates (dNTPs), the building blocks of DNA, and is essential to the assembly and repair of ecDNA. BBI-825 was shown to dysregulate ecDNA-reliant cancer cell dNTP pools, deplete ecDNA, and was synthetic lethal in multiple oncogene amplified preclinical cancer models.

About Boundless Bio

Boundless Bio is a clinical-stage oncology company dedicated to unlocking a new paradigm in cancer therapeutics to address the significant unmet need of patients with oncogene amplified tumors by targeting extrachromosomal DNA (ecDNA), a root cause of oncogene amplification observed in more than 14% of cancer patients. Boundless Bio is developing the first ecDNA-directed therapeutic candidates (ecDTx), BBI-355, which is an oral inhibitor of checkpoint kinase 1 (CHK1) being evaluated in a Phase 1/2 clinical trial in cancer patients with oncogene amplifications. Boundless Bio's second ecDTx, BBI-825, is an oral inhibitor of ribonucleotide reductase (RNR) being evaluated in a Phase 1/2 clinical trial in colorectal cancer patients with $BRAF^{V600E}$ or $KRAS^{G12C}$ mutations and resistance gene amplifications. Leveraging its Spyglass platform, Boundless Bio has an additional program (ecDTx 3) advancing through preclinical development and discovery. Boundless Bio is headquartered in San Diego, CA.

For more information, visit www.boundlessbio.com. Follow us on LinkedIn and X.

Forward-Looking Statements

Boundless Bio cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include but are not limited to: the potential to achieve catalysts and long-term patient impact; the potential to expedite enrollment in the POTENTIATE trial; the timing of expected data readouts; the impact on our cash runway of our streamlining efforts and the sufficiency of our cash position and such efforts to fund operations and initial clinical proof-of-concept data readouts; and the potential safety and therapeutic benefits of our ecDTx in treating patients with oncogene amplified cancers. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: we are early in our development efforts and our approach to discover and develop ecDTx directed against ecDNA in oncogene amplified cancers is novel and unproven; results from preclinical studies or early clinical trials not necessarily being predictive of future results; potential delays in the commencement, enrollment, data readouts or completion of clinical trials or preclinical studies; our dependence on third parties in connection with clinical trials, preclinical studies, ecDNA diagnostic development, and manufacturing; unfavorable results from clinical trials or preclinical studies; we may expend our limited resources to pursue a particular ecDTx and fail to capitalize on ecDTx with greater development or commercial potential; unexpected adverse side effects or inadequate efficacy of our ecDTx that may limit their development, regulatory approval, and/or commercialization; the potential for our programs and prospects to be negatively impacted by developments relating to our competitors, including the results of studies or regulatory determinations relating to our competitors; regulatory developments in the United States and foreign countries; efforts to streamline operations may not produce the efficiencies expected; we may use our capital resources sooner than we expect; and other risks described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our quarterly report on Form 10-Q for the quarter ended June 30, 2024 and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking

statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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BOUNDLESS BIO, INC.
Condensed Financial Information
(Unaudited)

Condensed Statements of Operations Data:	**Three months ended June 30**		**Six months ended June 30**	
(In thousands, except per share amounts)	**2024**	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 14,735	$ 11,075	$ 27,864	$ 20,577
General and administrative	4,656	2,885	8,410	5,470
Total operating expenses	19,391	13,960	36,274	26,047
Loss from operations	(19,391)	(13,960)	(36,274)	(26,047)
Other income, net:				
Interest income	2,382	1,551	3,803	1,914
Other income, net	33	11	65	16
Total other income, net	2,415	1,562	3,868	1,930
Net loss	$ (16,976)	$ (12,398)	$ (32,406)	$ (24,117)
Net loss per share, basic and diluted	$ (0.77)	$ (10.28)	$ (2.78)	$ (20.18)
Weighted-average shares used in calculation	22,023	1,206	11,641	1,195

Condensed Balance Sheet Data:	**June 30, 2024**	**December 31, 2023**
(In thousands)		
Cash, cash equivalents, and short-term investments	$ 179,290	$ 120,752
Total assets	$ 188,203	$ 129,894
Total liabilities	$ 8,957	$ 9,359
Convertible preferred stock	$ -	$ 247,617
Accumulated deficit	$ (168,515)	$ (136,109)
Total stockholders' equity (deficit)	$ 179,246	$ (127,082)
Working capital (1)	$ 174,175	$ 114,845

(1) We define working capital as current assets less current liabilities.