Boundless Bio Reports Third Quarter 2024 Financial Results and Business Highlights

November 7, 2024

Enrollment progressing in BBI-355 POTENTIATE and BBI-825 STARMAP clinical trials, with initial proof-of-concept data expected in the second half of 2025

Cash position of $167 million, with operating runway into the fourth quarter of 2026

SAN DIEGO, Nov. 07, 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 and reported financial results for the third quarter of 2024.

“The third quarter was marked by steady execution across the portfolio, with the POTENTIATE and STARMAP trials continuing to enroll patients,” said Zachary Hornby, President and Chief Executive Officer of Boundless Bio. "In September, together with our development partner, SOPHiA GENETICS, we presented analytical validation for our proprietary ecDNA diagnostic, ECHO, a critical first step in identifying ecDNA positive patients for our clinical programs. We are capitalized to advance our lead programs through proof-of-concept data and remain focused on delivering impactful results for our patients and stakeholders.”

Program Highlights and Upcoming Milestones

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

- Enrollment is proceeding in the Phase 1/2 POTENTIATE clinical trial evaluating BBI-355 as a single agent and in combination with targeted therapies in patients with oncogene amplified solid tumors.
- No new safety signals have been observed.
- The company anticipates reporting initial clinical proof-of-concept data 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

- Enrollment continues to progress in the single agent, dose-escalation portion of the STARMAP clinical trial, with initial clinical proof-of-concept data 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, continues to advance through lead optimization.

ECHO, a proprietary diagnostic for detection of ecDNA amplified oncogenes

- In September, analytical validation data was presented at the European Society for Medical Oncology (ESMO) Congress for the company’s proprietary ecDNA diagnostic ECHO (ecDNA Harboring Oncogenes). ECHO is currently being used as a clinical trial assay to determine ecDNA status of patients enrolled in the BBI-355 POTENTIATE trial.

Third Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, and short-term investments totaled $167.1 million as of September 30, 2024.
- **R&D Expenses:** Research and development (R&D) expenses were $14.1 million for the third quarter of 2024 compared to $11.6 million for the same period in 2023.
- **G&A Expenses:** General and administrative (G&A) expenses were $4.6 million for the third quarter of 2024 compared to $3.3 million for the same period in 2023.
- **Net Loss:** Net loss totaled $16.5 million for the third quarter of 2024 compared to $13.2 million for the same period in 2023.

About BBI-355

Boundless Bio’s lead ecDNA-directed therapy (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 therapy (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 timing of expected data readouts; the sufficiency of our cash position to fund operations through initial clinical proof-of-concept data readouts and into the fourth quarter of 2026; the potential safety and therapeutic benefits of our ecDTx in treating patients with oncogene amplified cancers; the potential clinical validity and utility of our ecDNA diagnostic ECHO; and the potential for one or more of our ecDTx, if approved, to be the first ecDNA-directed therapy. 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; analytical validation of an ecDNA diagnostic not necessarily being predictive of its clinical validity and utility; 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 March 31, 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.

Investor Contacts:

Ben Flaum, Boundless Bio
bflaum@boundlessbio.com

Renee Leck, THRUST Strategic Communications
renee@thrustsc.com

BOUNDLESS BIO, INC.
Condensed Financial Information
(Unaudited)

Condensed Statements of Operations Data:	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
(In thousands, except per share amounts)	**2024**	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 14,089	$ 11,645	$ 41,953	$ 32,223
General and administrative	4,626	3,308	13,036	8,777
Total operating expenses	18,715	14,953	54,989	41,000
Loss from operations	(18,715)	(14,953)	(54,989)	(41,000)
Other income, net:				
Interest income	2,174	1,748	5,977	3,662
Other income, net	32	32	97	48
Total other income, net	2,206	1,780	6,074	3,710
Net loss	$ (16,509)	$ (13,173)	$ (48,915)	$ (37,290)
Net loss per share, basic and diluted	$ (0.74)	$ (10.71)	$ (3.22)	$ (30.89)
Weighted-average shares used in calculation	22,254	1,230	15,204	1,207

Condensed Balance Sheet Data:	**September 30, 2024**	**December 31, 2023**
(In thousands)		
Cash, cash equivalents, and short-term investments	$ 167,135	$ 120,752
Total assets	$ 175,093	$ 129,894
Total liabilities	$ 10,010	$ 9,359

Convertible preferred stock	$	-	$	247,617
Accumulated deficit	$	(185,024)	$	(136,109)
Total stockholders' equity (deficit)	$	165,083	$	(127,082)
Working capital (1)	$	160,439	$	114,845

_____

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