Compass Therapeutics Reports 2024 Third Quarter Financial Results and Provides Corporate Update

November 12, 2024

- Fully enrolled the Phase 2/3 trial of lead asset CTX-009 (DLL4 and VEGF-A bispecific antibody) in patients with biliary tract cancers (BTC); top-line data readout is on track for the end of the first quarter of 2025.
- Designing a Phase 2 trial of CTX-009 in combination with chemotherapy in patients with DLL4-positive colorectal cancer (CRC) treated in the second-line setting; trial initiation expected in mid-2025.
- Identified neural cell adhesion molecule (NCAM or CD56) as a potential biomarker of response to CTX-471 based on data from the Phase 1 trial; planning a Phase 2 trial in patients with tumors expressing NCAM for mid-2025.
- Fully enrolled the second dosing cohort of the Phase 1 dose-escalation study of CTX-8371 (PD-1 x PD-L1 bispecific antibody); enrollment into the third dosing cohort is expected to begin in the coming month.
- Cash balance of $135 million in cash and marketable securities as of September 30, 2024, which is expected to provide cash runway into the first quarter of 2027.

BOSTON, Nov. 12, 2024 (GLOBE NEWSWIRE) -- Compass Therapeutics, Inc. (Nasdaq: CMPX), a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics to treat multiple human diseases, today reported third quarter 2024 financial results and provided a business update.

“We continue to be extremely encouraged with the progress across our clinical-stage programs, with three drugs already in the clinic and our deepening understanding of the potential clinical and regulatory pathways for each,” said Thomas Schuetz, MD, PhD, CEO of Compass and Vice Chairman of the Board of Directors. “In particular, we recently presented data showing a correlation between NCAM (CD56) expression and disease control with CTX-471 monotherapy. Given the high prevalence of NCAM expression across multiple tumor types, we are planning a Phase 2 monotherapy trial evaluating CTX-471 in patients whose tumors express this biomarker. With respect to our lead asset, CTX-009, we are on track for a top-line data readout in the U.S. at the end of the first quarter of 2025 for COMPANION-002, our Phase 2/3 combination study in patients with advanced BTC. Regarding CTX-009 in CRC, we are designing a Phase 2 study in the second-line setting in patients with metastatic CRC utilizing the DLL4 biomarker based on our observations from COMPANION-003.”

DEVELOPMENT PIPELINE UPDATES:

CTX-009 (DLL4 and VEGF-A bispecific antibody)

- Top-line data readout in the U.S. on track for the end of Q1 2025 for COMPANION-002, the Company’s Phase 2/3 randomized trial of CTX-009 in combination with paclitaxel in patients with advanced BTC (**see press release**).
    - Stage 1 of COMPANION-003, a Phase 2 trial in the U.S. of CTX-009 as a monotherapy in patients with advanced metastatic CRC was completed and, although it is not advancing to Stage 2, showed encouraging preliminary efficacy and safety results. The data from this study has informed the design of a Phase 2 study in the second-line setting in combination with chemotherapy in patients with DLL4-positive CRC.
- An investigator sponsored study of CTX-009 in patients with BTC in the first-line setting at The University of Texas MD Anderson Cancer Center is being initiated. CTX-009 will be added to the standard first-line regimen of gemcitabine, cisplatin, and durvalumab.

CTX-471 (CD137 agonist antibody)

- CTX-471, a novel anti-CD137 agonist antibody, demonstrated durable clinical responses in Phase 1, which were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting earlier this year.
- An analysis of biopsy specimens from patients treated with CTX-471 monotherapy in the Phase 1b study identified pharmacodynamic and response biomarkers. These data were presented at the 39th Society for Immunotherapy of Cancer 2024 Annual Meeting. Specifically, data showed a correlation between the levels of NCAM (CD56) expression and disease control in patients treated with CTX-471 monotherapy.

CTX-8371 (PD-1 x PD-L1 bispecific antibody)

- CTX-8371 is a next generation bispecific checkpoint inhibitor that simultaneously targets PD-1 and PD-L1 and exhibits a unique mechanism-of-action that involves cleavage of cell surface PD-1.
- The second dosing cohort in the Phase 1 dose-escalation study of CTX-8371 is fully enrolled; no dose limiting toxicities (DLTs) have been observed to date. Enrollment into the third dosing cohort is expected to begin in the coming month.

Pre-clinical Research

- Continuing exploration of the synergies observed in pre-clinical and discovery work between VEGF blockade, CD137 agonism, checkpoint inhibition, and other cell engagement to identify novel bispecific antibody drug candidates with complementary anti-tumor activity.

FINANCIAL RESULTS:

Net loss for the quarter ended September 30, 2024, was $10.5 million or $0.08 per share of common stock, compared to $10.0 million or $0.08 per share of common stock for the same period in 2023. Net loss for the nine months ended September 30, 2024, was $34.3 million or $0.25 per share of common stock, compared to $29.1 million or $0.23 per share of common stock for the same period in 2023.

Research and Development (R&D) Expenses

R&D expenses were $8.6 million for the quarter ended September 30, 2024, as compared to $8.8 million for the same period in 2023, a decrease of $0.2 million. R&D expenses were $29.3 million for the nine months ended September 30, 2024, as compared to $25.7 million for the same period in 2023, an increase of $3.6 million. This increase was primarily attributable to a $5.2 million increase in clinical costs related to the COMPANION-002 trial, partially offset by $3.2 million less in manufacturing expense for CTX-009.

General and Administrative (G&A) Expenses

G&A expenses were $3.6 million for the quarter ended September 30, 2024, as compared to $3.1 million for the same period in 2023, an increase of $0.5 million. The increase was due to $0.5 million more stock compensation expense than prior year. G&A expenses were $11.6 million for the nine months ended September 30, 2024, as compared to $9.3 million for the same period in 2023, an increase of $2.3 million. The increase was due to expenses related to the departure of the CEO in the second quarter and more stock compensation expense than prior year.

CASH POSITION:

As of September 30, 2024, cash and marketable securities were $135 million as compared to $152 million as of December 31, 2023, which gives a cash runway into the first quarter of 2027.

During the first nine months of 2024, Compass decreased its cash position by $17 million, primarily by cash used in operating activities partially offset by $18 million cash received from issuance of stock through its at-the-market offering program.

About CTX-009

CTX-009 is a bispecific antibody that simultaneously blocks Delta-like ligand 4 (DLL4) and vascular endothelial growth factor A (VEGF-A) signaling pathways, which are critical to angiogenesis and tumor vascularization. Preclinical and early clinical data of CTX-009 suggest that blockade of both pathways provides robust anti-tumor activity across several solid tumors, including colorectal, gastric, cholangiocarcinoma, pancreatic and non-small cell lung cancer. Partial responses to CTX-009 as a monotherapy have been observed in heavily pre-treated patients with cancer who were resistant to approved anti-VEGF therapies. COMPANION-002, a Phase 2/3 trial of CTX-009 (DLL4 and VEGF-A bispecific antibody) plus paclitaxel versus paclitaxel monotherapy in patients with previously treated, unresectable advanced metastatic or recurrent biliary tract cancers (BTC) is ongoing. Clinical Trial information: NCT05506943.

About CTX-471

CTX-471 is a fully human monoclonal antibody that binds and activates a novel epitope of the co-stimulatory receptor CD137, also known as 4-1BB, a member of the tumor necrosis factor receptor superfamily. The antibody is currently being evaluated in a Phase 1b clinical trial in patients with solid tumors that have progressed after at least three months on an approved PD-1 or PD-L1 inhibitor. Initial results reported from a monotherapy cohort of the study included five clinical responses, all in patients who previously received checkpoint inhibitors, including a durable partial response (PR) in a patient with small-cell lung cancer that converted to a complete response (as confirmed by PET scan) and four additional PRs (one unconfirmed) in patients with melanoma and mesothelioma. CTX-471 has been generally well tolerated. In preclinical studies, CTX-471 has demonstrated potent monotherapy activity against multiple syngeneic tumor models, including the generation of long-term functional immunological memory. Clinical Trial information: NCT03881488.

About CTX-8371

CTX-8371 is a next generation bispecific checkpoint inhibitor that simultaneously targets PD-1 and PD-L1 and exhibits a unique mechanism-of-action that involves cleavage of cell surface PD-1. CTX-8371 received FDA clearance of the IND in October 2023. The Phase 1 CTX-8371 study design includes five ascending doses (0.1, 0.3, 1.0, 3.0, and 10 mg/kg) and the study is enrolling patients with melanoma, non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), Hodgkin Lymphoma, and triple negative breast cancer (TNBC) who have progressed on at least one prior regimen containing checkpoint blocker. No DLTs observed in the first dosing cohort and the second dosing cohort has been initiated. Clinical Trial information: NCT06150664.

About Compass Therapeutics

Compass Therapeutics, Inc. is a clinical-stage oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics to treat multiple human diseases. Compass's scientific focus is on the relationship between angiogenesis, the immune system, and tumor growth. The company pipeline of novel product candidates is designed to target multiple critical biological pathways required for an effective anti-tumor response. These include modulation of the microvasculature via angiogenesis-targeted agents, induction of a potent immune response via activators on effector cells in the tumor microenvironment, and alleviation of immunosuppressive mechanisms used by tumors to evade immune surveillance. Compass plans to advance its product candidates through clinical development as both standalone therapies and in combination with proprietary pipeline antibodies based on supportive clinical and nonclinical data. The company was founded in 2014 and is headquartered in Boston, Massachusetts. For more information, visit the Compass Therapeutics website at https://www.compasstherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to Compass's financial position to continue advancing its product

candidates, expectations about cash runway, business and development plans, and statements regarding Compass's product candidates, including their development and clinical trial milestones such as the expected trial design, timing of enrollment, patient dosing and data readouts, regulatory plans with respect to Compass's product candidates and the therapeutic potential thereof. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, Compass's ability to raise the additional funding it will need to continue to pursue its business and product development plans, the inherent uncertainties associated with developing product candidates and operating as a development stage company, Compass's ability to identify additional product candidates for development, Compass's ability to develop, complete clinical trials for, obtain approvals for and commercialize any of its product candidates, competition in the industry in which Compass operates and market conditions. These forward-looking statements are made as of the date of this press release, and Compass assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents Compass files with the U.S. Securities and Exchange Commission (SEC) available at www.sec.gov, including without limitation Compass's latest Annual Report on Form 10-K, Quarterly Report on Form 10-Q and subsequent filings with the SEC.

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Compass Therapeutics, Inc. and Subsidiaries
Consolidated Statement of Operations (unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
License revenue	$ —	$ —	$ 850	$ —
Operating expenses:				
Research and development	8,612	8,831	29,304	25,694
General and administrative	3,627	3,095	11,597	9,276
Loss from operations	(12,239)	(11,926)	(40,051)	(34,970)
Other income	1,758	1,962	5,709	5,891
Net loss	$ (10,481)	$ (9,964)	$ (34,342)	$ (29,079)
Net loss per share - basic and diluted	$ (0.08)	$ (0.08)	$ (0.25)	$ (0.23)

Compass Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(In thousands, except par value)

	September 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 36,801	$ 24,228
Marketable securities	98,601	128,233
Prepaid expenses and other current assets	5,738	1,420
Total current assets	141,140	153,881
Property and equipment, net	493	898
Operating lease, right-of-use ("ROU") asset	6,950	1,776
Other assets	568	320
Total assets	$ 149,151	$ 156,875
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 960	$ 4,090
Accrued expenses	2,916	2,514
Operating lease obligations, current portion	557	1,197
Total current liabilities	4,433	7,801

Operating lease obligations, long-term portion	6,320	536
Total liabilities	10,753	8,337
Total stockholders' equity	138,398	148,538
Total liabilities and stockholders' equity	$ 149,151	$ 156,875