Compass Therapeutics Reports 2025 First Quarter Financial Results and Provides Corporate Update

May 8, 2025

- *Tovecimig (DLL4 x VEGF-A bispecific antibody) met the primary endpoint in the ongoing randomized Phase 2/3 Study in patients with biliary tract cancer (BTC).*
  - *Achieved a 17.1% overall response rate (ORR), including one complete response, compared to a 5.3% ORR for paclitaxel alone, in patients with BTC treated in the second-line setting.*
- *First patient dosed and actively enrolling patients in an Investigator Sponsored Trial (IST) evaluating tovecimig in patients with BTC in the first-line setting.*
- *Successfully completed a pre-IND meeting for CTX-10726 (PD-1 x VEGF-A bispecific antibody), maintaining progress towards expected Q4 2025 IND filing and 2026 clinical data.*
- *Advanced the Phase 1 dose-escalation study of CTX-8371 in a post-checkpoint inhibitor patient population to the fourth dosing cohort with no dose-limiting toxicities observed to date; data from this study are expected in the second half of 2025.*
- *Ended Q1 with $113 million in cash and marketable securities, which is expected to provide cash runway into the first quarter of 2027.*

BOSTON, May 08, 2025 (GLOBE NEWSWIRE) -- Compass Therapeutics, Inc. (Nasdaq: CMPX), a clinical-stage, oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics, today reported first quarter 2025 financial results and provided a business update.

“We’re proud of the progress we’ve made this quarter, especially the achievement of the primary endpoint in our COMPANION-002 trial. These positive data reinforce the potential for tovecimig to fill a striking gap in the treatment paradigm for patients with BTC. We expect to share analyses of the secondary endpoints, including progression free survival (PFS), overall survival (OS) and duration of response (DoR), in the fourth quarter of this year,” said Thomas Schuetz, MD, PhD, Chief Executive Officer and Vice Chairman of the Board of Directors. “In parallel, the first patient has been dosed in the IST at The University of Texas MD Anderson Cancer Center evaluating tovecimig in the front-line setting for patients with BTC, and the study continues to actively enroll.”

“We continue to advance CTX-10726, our differentiated PD-1 x VEGF-A bispecific antibody, with IND filing expected in Q4. There has been very promising clinical data from other drugs in this class, and we look forward to beginning Phase 1 studies and reporting clinical data for CTX-10726 in 2026.”

“CTX-8371, our PD-1 x PD-L1 bispecific has also progressed to the fourth dosing cohort in patients in whom checkpoint inhibitors have failed, and we look forward to sharing data from the study later this year.” Dr. Schuetz continued, “Finally, our balance sheet remains strong and we ended the quarter with $113 million, funding our cash runway into 2027.”

Development Pipeline Updates:

Tovecimig (DLL4 and VEGF-A bispecific antibody)

- Met the primary endpoint in the ongoing randomized Phase 2/3 COMPANION-002 Study in patients with BTC (see press release). The study enrolled 168 adult patients, randomized in a 2:1 ratio to receive tovecimig plus paclitaxel (n=111) or paclitaxel alone (n=57).
  - Tovecimig in combination with paclitaxel achieved a 17.1% ORR, including one complete response, compared to a 5.3% ORR for paclitaxel alone, in patients with BTC treated in the second-line setting.
  - At a prespecified analysis, conducted by blinded independent central radiology (BICR) review, tovecimig plus paclitaxel demonstrated a statistically significant (p=0.031) and clinically meaningful improvement in ORR (the primary endpoint) compared to paclitaxel alone.
  - The study also showed differences between treatment arms for other efficacy measures, including progressive disease (PD) rates of 16.2% in patients on tovecimig in combination with paclitaxel versus 42.1% in patients on paclitaxel alone.

    - The pre-specified number of events required to trigger the analyses of the secondary endpoints, including PFS, OS and DoR, has not yet been met due to fewer of these events occurring than were originally modeled. The Company expects to report the results of the analyses of these endpoints in Q4 of this year.

- The first patient has been dosed in an IST at The University of Texas MD Anderson Cancer Center, and the study is actively enrolling. In the IST, tovecimig is being added to the standard first-line regimen of gemcitabine, cisplatin, and durvalumab (see press release).

- The previously planned Phase 2 colorectal cancer study will be replaced by a Phase 2 basket study of tovecimig, which is expected to begin following the analyses of the secondary endpoint data from the COMPANION-002 BTC trial. The basket study will include a broader set of DLL4+ cancers, such as gastric, ovarian, renal, hepatocellular, and colorectal.

CTX-10726 (PD-1 x VEGF-A bispecific antibody)

- CTX-10726 is a tetravalent PD-1 x VEGF-A bispecific antibody discovered and engineered at Compass. CTX-10726 is designed to synergistically deliver VEGF-A blockade and checkpoint inhibition, potentially applicable to multiple solid tumor indications. The bispecific antibody demonstrates a highly stable structure with high affinity target binding. CTX-10726 has exhibited more potent PD-1 blockade in preclinical studies, compared with data reported for other drugs in the class.

- Advanced preclinical development and IND-enabling studies for CTX-10726.

- Successfully completed a pre-IND Meeting with the FDA, with expected IND submission in Q4 2025.

CTX-471 (CD137 agonist antibody)

- CTX-471 is a CD137 agonist antibody, which has been shown to bind to a unique epitope of the co-stimulatory molecule 4-1BB with an optimized affinity.

- In 2024, CTX-471 clinical data were presented at multiple scientific meetings, including data demonstrating durable clinical responses in Phase 1 presented at the American Society of Clinical Oncology (ASCO) Annual Meeting and data showing a correlation between levels of NCAM (CD56) expression and disease control presented at the 39th Society for Immunotherapy of Cancer 2024 Annual Meeting.

- Phase 2 trial initiation of CTX-471 in patients with tumors expressing NCAM (CD56) is expected in the second half of 2025.

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 has been shown to exhibit a unique mechanism-of-action that involves cleavage of cell surface PD-1.

- No dose-limiting toxicities (DLTs) have been observed in the first three dosing cohorts in the Phase 1 dose-escalation study of CTX-8371.

- Currently evaluating the fourth dosing cohort with preliminary data expected in the second half of 2025.

Financial Results

Net loss for the quarter ended March 31, 2025, was $16.6 million or $0.12 per share of common stock, compared to $10.8 million or $0.08 per share of common stock for the same period in 2024.

Research and Development (R&D) Expenses

R&D expenses were $13.1 million for the quarter ended March 31, 2025, as compared to $9.5 million for the same period in 2024, an increase of $3.6 million, or 37%. This increase was primarily attributable to additional spending on manufacturing for tovecimig and CTX-10726 of $2.5 million and $0.9 million on additional personnel costs for R&D personnel.

General and Administrative (G&A) Expenses

G&A expenses were $4.9 million for the quarter ended March 31, 2025, as compared to $3.2 million for the same period in 2024, an increase of $1.7 million or 51%. The increase was primarily attributable to $1.3 million of additional G&A personnel costs including $1.0 million related to share-based compensation.

Cash Position

As of March 31, 2025, cash and marketable securities were $113 million as compared to $127 million as of December 31, 2024, providing the Company with an anticipated cash runway into 2027. During the first three months of 2025, $13 million of net cash was used in operating activities.

About Compass Therapeutics

Compass Therapeutics, Inc. is a clinical-stage oncology-focused biopharmaceutical company developing proprietary antibody-based therapeutics. Compass's scientific focus is on the relationship between angiogenesis, the immune system, and tumor growth. The company's 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 preclinical and clinical 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, initiate and 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
Condensed Consolidated Statements of Operations
(In thousands, except per share data)

	Three Months Ended March 31,	
	2025	2024
	(unaudited)	
Operating expenses:		
Research and development	$ 13,054	$ 9,522
General and administrative	4,912	3,248
Loss from operations	(17,966)	(12,770)
Other income	1,333	1,983
Net loss	$ (16,633)	$ (10,787)
Net loss per share - basic and diluted	$ (0.12)	$ (0.08)
Basic and diluted weighted average shares outstanding	138,236	136,608

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

	March 31, 2025	December 31, 2024
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 41,048	$ 43,483

Marketable securities	71,587	83,239
Prepaid expenses and other current assets	11,510	6,029
Total current assets	124,145	132,751
Property and equipment, net	231	353
Operating lease, right-of-use ("ROU") asset	6,507	6,731
Other assets	568	568
Total assets	$ 131,451	$ 140,403
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,577	$ 2,249
Accrued expenses	13,214	6,287
Operating lease obligations, current portion	109	338
Total current liabilities	14,900	8,874
Operating lease obligations, long-term portion	6,272	6,296
Total liabilities	21,172	15,170
Total stockholders' equity	110,279	125,233
Total liabilities and stockholders' equity	$ 131,451	$ 140,403