Compass Therapeutics Reports 2023 Financial Results and Provides Corporate Update

March 21, 2024

- *Enrollment in COMPANION-002, the Phase 2/3 randomized study of CTX-009 (DLL4 x VEGF-A bispecific antibody) in patients with advanced biliary tract cancer (BTC), continues to progress well; top-line data from this study are expected by the end of 2024.*

- *Enrollment in COMPANION-003, the Phase 2 study of CTX-009 in patients with advanced colorectal cancer (CRC) was completed in the first quarter of 2024; top-line data from Stage 1 of this study are expected by mid-year 2024.*

- *Initiated planning of a Phase 2 monotherapy study of CTX-471 (CD137 agonist antibody) in patients with advanced melanoma whose tumors express a newly identified biomarker of CTX-471 activity. Additionally, enrollment of patients in the combination arm of CTX-471 with KEYTRUDA® Phase 1b study is ongoing.*

- *Advanced CTX-8371 (PD-1 x PD-L1 bispecific antibody) into Phase 1 first-in-human study and expect to dose first patient by early second quarter.*

- *Ended 2023 with $152 million in cash and marketable securities, which is expected to provide cash runway into mid-year 2026.*

BOSTON, March 21, 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 full 2023 financial results and provided business update.

“2023 was an important year for Compass as we strategically shifted our focus toward the clinical development of our lead program, CTX-009, which is currently being evaluated in patients with advanced biliary tract cancer and advanced colorectal cancer,” said Vered Bisker-Leib, PhD, Chief Executive Officer. “This year we expect to report top-line data from Stage 1 of the Phase 2 COMPANION-003 trial by mid-year and top-line data from our Phase 2/3 COMPANION-002 trial by the end of the year. Our balance sheet remains strong and we ended the year with $152 million, extending our cash runway into the middle of 2026.”

“In 2023, we made significant progress across our clinical programs,” said Thomas Schuetz, MD, PhD, Co-Founder and President of Research & Development at Compass. “In the monotherapy study of CTX-471, our novel CD137 agonist antibody, we reported additional partial responses in patients with advanced melanoma, a complete response in a patient with small cell lung cancer, and a partial response in a patient with mesothelioma, all of whom had previously progressed on a checkpoint blocker. Importantly, we have identified a potential biomarker of response in biopsy specimens from this study and we are now planning a Phase 2 study in patients whose tumors express this biomarker. We also initiated the combination arm of the CTX-471 with KEYTRUDA® Phase 1b study under clinical collaboration with Merck. Finally, we filed and obtained regulatory clearance to begin clinical trials with CTX-8371, our novel checkpoint blocker, and advanced this bispecific into a first-in-human study.”

Development Pipeline Updates:

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

- Continue to enroll patients in COMPANION-002, a U.S. Phase 2/3 randomized study of CTX-009 in combination with paclitaxel in patients with advanced BTC.
    - This study is designed to enroll 150 patients who have received one prior systemic therapy.
    - The primary endpoint of the study is overall response rate (ORR), and secondary endpoints include progression free survival (PFS), overall survival (OS), clinical benefit rate (CBR) and duration of response (DOR).
    - Enrollment is expected to be completed by mid-year 2024; top-line data are expected by year end 2024.
- Completed enrollment of patients in Stage 1 of COMPANION-003, a U.S. Phase 2 study of CTX-009 as a monotherapy in patients with advanced, metastatic CRC.
    - The study design is an Adaptive Simon Two-Stage. Stage 1 of the study enrolled 37 patients with CRC who have received two or three prior systemic therapies irrespective of their KRAS mutation status.
    - Top-line data is expected by mid-year 2024.

- If adequate efficacy is observed in Stage 1, the study will continue to Stage 2 where 47 additional patients are expected to be enrolled.

CTX-471 (CD137 agonist antibody)

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

- In the Phase 1B monotherapy study, five responses were observed, all in patients who previously received checkpoint inhibitors. A durable partial response (PR) in a patient with SCLC has converted to a complete response (CR), as confirmed by a PET scan. Additionally, a new PR in a patient with advanced melanoma, was observed, leading to an objective response rate (ORR) in the subset of patients with advanced melanoma of 27% (3 of 11). The fifth response occurred in a patient with mesothelioma.

- Ongoing analysis of biopsy specimens from the Phase 1b study revealed a potential biomarker of response. As a result, planning for a Phase 2 monotherapy study in patients with melanoma whose tumors express this biomarker is underway.

- Ongoing enrollment of up to 60 patients in the Phase 1b dose-expansion cohort of the combination arm of CTX-471 and Merck's anti-PD-1 therapy KEYTRUDA ® (pembrolizumab) with melanoma, NSCLC and SCLC, who will be randomly assigned to one of two doses.

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.

- Following the FDA acceptance of the IND for CTX-8371, clinical sites were opened and the first patient is expected to be dosed by early second quarter.

Financial Results

Net loss for the year ended December 31, 2023, was $42.5 million or $0.33 per common share, compared to $39.2 million or $0.37 per common share for the same period in 2022.

Research and Development (R&D) Expenses

R&D expenses were $38.1 million for the year ended December 31, 2023, as compared to $30.0 million for the same period in 2022, an increase of $8.1 million or 27%. This increase was primarily attributable to a $10.7 million increase in clinical and manufacturing costs related to our lead program, CTX-009.

General and Administrative (G&A) Expenses

G&A expenses were $12.2 million for the year ended December 31, 2023, as compared to $11.7 million for the same period in 2022, an increase of $0.6 million or 5%. The increase was primarily attributable to higher stock compensation expense of $1.0 million offset by lower insurance costs of $0.3 million.

Cash Position

As of December 31, 2023, cash and marketable securities were $152.5 million as compared to $186.6 million as of December 31, 2022, providing the Company with an anticipated cash runway into mid-2026. During 2023, the Company decreased its cash position by $34.1 million, primarily from $40.6 million of net cash used in operating activities.

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
Condensed Consolidated Statements of Operations
(In thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
	(unaudited)			
Operating expenses:				
Research and development	$ 12,428	$ 9,929	$ 38,120	$ 29,997
General and administrative	2,961	2,959	12,243	11,658
Total operating loss	(15,389)	(12,888)	(50,363)	(41,655)
Other income	1,974	1,294	7,869	2,430
Net loss	$ (13,415)	$ (11,594)	$ (42,494)	$ (39,225)
Net loss per share - basic and diluted	$ (0.11)	$ (0.10)	$ (0.33)	$ (0.37)

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

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 24,228	$ 34,946
Marketable securities	128,233	151,663
Prepaid expenses and other current assets	1,420	8,182
Total current assets	153,881	194,791
Property and equipment, net	898	1,567
Operating lease, right-of-use ("ROU") asset	1,776	2,967
Other assets	320	320
Total assets	$ 156,875	$ 199,645
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,090	$ 3,382
Accrued expenses	2,514	11,690
Operating lease obligations, current portion	1,197	1,097
Total current liabilities	7,801	16,169
Operating lease obligations, long-term portion	536	1,838
Total liabilities	8,337	18,007
Total stockholders' equity	148,538	181,638
Total liabilities and stockholders' equity	$ 156,875	$ 199,645