

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): May 13, 2024

COMPASS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-39696
(Commission File Number)

82-4876496
(I.R.S. Employer Identification No.)

80 Guest Street, Suite 601
Boston, Massachusetts 02135
(Address of Principal Executive Offices) (Zip Code)

(617) 500-8099
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	CMPX	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On May 13, 2024, Compass Therapeutics, Inc. issued a press release announcing financial results for the quarter ended March 31, 2024. A copy of the press release is furnished as Exhibit 99.1 to this report and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. **Exhibit**

99.1	Press Release dated May 13, 2024 (furnished pursuant to Item 2.02)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Compass Therapeutics, Inc.

Date: May 13, 2024

By: /s/ Neil Lerner
Neil Lerner
VP Finance

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

- Received FDA Fast Track Designation for the investigation of CTX-009 in combination with paclitaxel for the treatment of patients with metastatic or locally advanced biliary tract tumors.
- Enrollment is progressing well in COMPANION-002, a Phase 2/3 randomized study of CTX-009 (DLL4 x VEGF-A bispecific antibody) in patients with advanced biliary tract cancer (BTC). Enrollment is expected to be completed by mid-year 2024 with top-line data expected in the first quarter of 2025.
- Completed enrollment of patients in COMPANION-003, a Phase 2 study of CTX-009 in patients with advanced colorectal cancer (CRC); top-line data from Stage 1 are expected by mid-year 2024.
- Enrollment in the Phase 1b combination study of CTX-471 (CD137 agonist antibody) and KEYTRUDA[®] in patients with non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC) and melanoma is ongoing.
- Advanced CTX-8371 (PD-1 x PD-L1 bispecific antibody) into a first-in-human clinical study and dosed the first patient in April.
- Initiated planning of a Phase 2 monotherapy study of CTX-471 in patients with advanced melanoma whose tumors express a newly identified biomarker of CTX-471 activity.
- Ended the first quarter with \$156 million in cash and marketable securities, which is expected to provide cash runway into late 2026.

BOSTON, May 13, 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 first quarter 2024 financial results and provided a business update.

“Compass continues to make considerable progress across all of our clinical programs, with the recently announced receipt of FDA Fast Track Designation for CTX-009, showcasing the large unmet need in patients with advanced BTC where current therapies have low, single digit response rates, and limited effects on patient survival,” said Vered Bisker-Leib, PhD, Chief Executive Officer.

“We are excited that we are less than a year from reporting top-line data from COMPANION-002, our Phase 2/3 study in patients with BTC. By mid-year, we plan to report top-line data from the first part of COMPANION-003, our Phase 2 study in patients with advanced CRC. Finally, we will embark on COMPANION-004, our study of CTX-009 in a third indication. We also continue to advance CTX-471, our CD137 agonistic antibody and CTX-8371, our novel bispecific checkpoint blocker. Recently, we discovered a potential biomarker of activity of CTX-471, and preparations are underway for a Phase 2 study of CTX-471 in patients with melanoma,” added Thomas Schuetz, MD, PhD, President of R&D and Vice Chair of Compass Board.

Development Pipeline Updates:

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

- Continuing 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.
 - Received FDA Fast Track Designation.
 - The primary endpoint of the study is overall response rate, and secondary endpoints include progression free survival, overall survival, clinical benefit rate and duration of response.
 - Enrollment is expected to be completed by mid-year 2024 with top-line data expected in the first quarter of 2025.
- Completed enrollment of 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 is designed to enroll 37 evaluable patients with CRC who have received two or three prior systemic therapies irrespective of their KRAS mutation status.
 - In line with prior guidance, top-line data from Stage 1 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 converted to a complete response, as confirmed by a PET scan. Additionally, the objective response rate in the subset of patients with advanced melanoma was 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.
- Enrollment is ongoing 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, non-small cell lung cancer and small cell lung cancer, 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.
- In April 2024, the first patient in this study was dosed; dosing of additional patients and opening additional clinical sites is in progress.

Financial Results

Net loss for the quarter ended March 31, 2024, was \$10.8 million or \$0.08 per share of common stock, compared to \$7.8 million or \$0.06 per share of common stock for the same period in 2023.

Research and Development (R&D) Expenses

R&D expenses were \$9.5 million for the quarter ended March 31, 2024, as compared to \$6.6 million for the same period in 2023, an increase of \$2.9 million. This increase was primarily attributable to a \$2.2 million increase in clinical costs related to the lead program, CTX-009.

General and Administrative (G&A) Expenses

G&A expenses were \$3.2 million for the quarter ended March 31, 2024, as compared to \$3.1 million for the same period in 2023.

Cash Position

As of March 31, 2024, cash and marketable securities were \$156.3 million as compared to \$152.5 million as of December 31, 2023, extending our cash runway into late 2026.

During the first quarter of 2024, Compass increased its cash position by \$3.8 million, primarily from \$18.0 million cash received from issuance of stock through its at-the-market offering program, partially offset by \$13.9 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	
	March 31,	
	2024	2023
	(unaudited)	
Operating expenses:		
Research and development	\$ 9,522	\$ 6,638
General and administrative	3,248	3,073
Total operating expenses	<u>12,770</u>	<u>9,711</u>
Loss from operations	(12,770)	(9,711)
Other income	1,983	1,874
Loss before income tax expense	<u>(10,787)</u>	<u>(7,837)</u>
Income tax expense	—	—
Net loss	<u>\$ (10,787)</u>	<u>\$ (7,837)</u>
Net loss per share - basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.06)</u>
Basic and diluted weighted average shares outstanding	<u>136,608</u>	<u>126,375</u>

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

	March 31,	December 31,
	2024	2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,674	\$ 24,228
Marketable securities	132,581	128,233
Prepaid expenses and other current assets	2,356	1,420
Total current assets	<u>158,611</u>	<u>153,881</u>
Property and equipment, net	744	898
Operating lease, right-of-use ("ROU") asset	1,467	1,776
Other assets	320	320
Total assets	<u>\$ 161,142</u>	<u>\$ 156,875</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 854	\$ 4,090
Accrued expenses	1,815	2,514
Operating lease obligations, current portion	1,224	1,197
Total current liabilities	<u>3,893</u>	<u>7,801</u>
Operating lease obligations, long-term portion	189	536
Total liabilities	<u>4,082</u>	<u>8,337</u>

Total stockholders' equity
Total liabilities and stockholders' equity

	<u>157,060</u>		<u>148,538</u>
\$	<u>161,142</u>	\$	<u>156,875</u>