

**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 4, 2023

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 4, 2023, Compass Therapeutics, Inc. issued a press release announcing financial results for the first quarter ended March 31, 2023. 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 4, 2023 (furnished pursuant to Item 2.02)
104	The cover page from this Current Report on Form 8-K formatted in Inline XBRL (included as Exhibit 101)

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 4, 2023

By: /s/ Neil Lerner
Neil Lerner
VP Finance

Compass Therapeutics Reports First Quarter Financial Results and Provides Corporate Update

- Initiated patient enrollment in a U.S. Phase 2/3 study of CTX-009 (DLL4 /VEGF-A bispecific antibody) in patients with advanced biliary tract cancers (BTC). Top line data is expected in the first half of 2024
- Continue to enroll in a U.S. Phase 2 study of CTX-009 in patients with advanced colorectal cancer (CRC). Initial data expected in the third quarter of 2023
- Presented results of a Phase 2 study of CTX-009 in combination with paclitaxel in patients with BTC at the 2023 ASCO GI Cancers Symposium
- Expanded the management team with the appointment of Minori Rosales, M.D. PhD, as Senior Vice President & Head of Clinical Development
- Appointed Richard Lindahl, M.B.A., EVP & CFO of Emergent BioSolutions, to the Compass Board
- Ended the first quarter with \$175 million in cash and marketable securities, providing cash runway for the company into 2026

BOSTON, May 04, 2023 (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 2023 financial results.

“We are very pleased with the progress we are making toward our enrollment goals in both of our CTX-009 clinical trials and look forward to reaching our goal of making CTX-009 available to patients with various cancers,” said Thomas J. Schuetz, MD, PhD, Co-Founder and Chief Executive Officer. “We anticipate initial results from the CTX-009 colorectal study in Q3 of this year and top-line data from the CTX-009 study in BTC in the first half of 2024. Additionally, we expect initial data from our CTX-471 combination study later this year.”

“In addition to our progress in the clinic, Compass is excited to welcome two experienced leaders to the Company. Dr. Minori Rosales has joined our leadership team as SVP & Head of Clinical Development. She brings with her years of successful oncology drug development from her tenure at Eli Lilly, Merck, MacroGenics and other BioPharma companies. Richard Lindahl, currently the EVP & CFO at Emergent BioSolutions and prior to this the SVP and Treasurer of Sprint-Nextel, was appointed to our board as a new independent director and as the Chair of our Audit Committee,” said Vered Bisker-Leib, PhD, MBA, President and Chief Operating Officer. “We look forward to leveraging Rich’s broad financial expertise on our board and Minori’s unique clinical and medical expertise in advancing our clinical programs.”

Development Pipeline Update and Highlights:

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

- **Initiated enrollment and dosing of patients in the U.S. Phase 2/3 study of CTX-009 in combination with Paclitaxel in BTC**
 - This randomized Phase 2/3 study is designed to enroll 150 patients with BTC 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)
 - Top line data from this study is expected in the first half of 2024
- **Enrolling patients in the U.S. Phase 2 study of CTX-009 as a monotherapy in patients with advanced, metastatic colorectal cancer**
 - The study design is an Adaptive Simon Two-Stage, with Stage 1 of the study enrolling 37 patients. If there are 3 or more responses confirmed in Stage 1, the study will advance to Stage 2 and an additional 47 patients will be enrolled
 - Patients are being evaluated for safety and tolerability, as well as clinical response
 - First patient dosed in January 2023. Initial results from this study are expected in the third quarter of 2023
- **Presented Phase 2 results of CTX-009 in combination with paclitaxel in patients with BTC at the 2023 ASCO GI Cancers Symposium**
 - Data showed 9 confirmed partial responses (PRs) among 24 evaluable patients for an ORR of 37.5% in the second- and third-line settings
 - In the second-line setting, an ORR of 63.6% was observed (7 out of 11 patients responded)

- Median PFS was 9.4 months and median OS was 12.5 months
- Safety and tolerability were consistent with prior studies

CTX-471 (CD137 + PD-1)

- Advancing enrollment of the Phase 1 combination arm of CTX-471 (CD137 agonistic antibody) and KEYTRUDA® (pembrolizumab) in patients with select solid tumors
- The first two dose cohorts in the study (n=6) have been fully enrolled
- Initial results from the combination arm are expected in the second half of 2023

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

- Targeting IND submission in the third quarter of 2023 and initiating a clinical trial in the second half of 2023

Corporate Update

In April 2023, the company appointed Minori Rosales, MD PhD, as Senior Vice President & Head of Clinical Development. Dr. Minori Rosales brings significant clinical experience as a proven leader in both biotech and pharmaceutical industries. Most recently, Dr. Rosales was Chief Development Officer for Sesen Bio. Previously, she served as Vice President, R&D at MacroGenics where she advanced margetuximab in clinical development. Earlier in her career, Minori served in executive and senior clinical leadership roles at Merck and Eli Lilly, where she led label-expansion and registrational studies for pembrolizumab and ramacicurumab respectively in various oncology indications, including biliary tract cancer, gastric, esophageal, and HCC, among others.

Dr. Rosales obtained her medical degree from Yamaguchi University and her PhD in tumor immunology from Kansai Medical University in Japan.

Also in April 2023, the Compass's board of directors unanimously appointed Richard Lindahl, M.B.A, Executive Vice President, Chief Financial Officer and Treasurer at Emergent BioSolutions, as a director and as Chair of the Audit Committee. Mr. Lindahl has over 20 years of experience in financial leadership roles. Prior to Emergent BioSolutions, from 2009-2017, Mr. Lindahl was Chief Financial Officer at CEB, a NYSE-listed technology company. Earlier in his career, Mr. Lindahl was at Sprint Nextel Corporation in roles of increasing responsibility, culminating in the position of Senior Vice President & Corporate Treasurer.

Mr. Lindahl has a BA from Dartmouth College and an MBA from the University of Virginia.

Financial Results

Net loss for the quarter ended March 31, 2023, was \$7.8 million or \$0.06 per share, compared to \$7.2 million or \$0.07 per share for the same period in 2022.

Cash Position

As of March 31, 2023, cash and marketable securities were \$175 million as compared to \$187 million as of December 31, 2022, providing the Company with an anticipated cash runway into 2026. During the first quarter of 2023, the Company used \$12 million of cash to fund operations.

Research and development (R&D) Expenses

R&D expenses were \$6.6 million for the first quarter ended March 31, 2023, as compared to \$4.4 million for the same period in 2022, an increase of \$2.2 million or 50%. The change for the year was primarily attributable to a net increase of \$2.5 million in program costs, resulting primarily from \$3.3 million additional spending related to CTX-009 partially offset by \$0.8 million decrease in spending on other programs.

General and Administrative (G&A) Expenses

G&A expenses were \$3.1 million for the quarter ended March 31, 2023, as compared to \$2.8 million for the same period in 2022, an increase of \$0.3 million or 11%.

Upcoming Investor Conferences

Compass management will participate in three upcoming investor conferences:

- **Inaugural EF Hutton Global Conference**
Date: May 10-11, 2023
Location: New York, NY

- **Jefferies Global Healthcare Conference**

Date: June 7-9, 2023

Location: New York NY

- **2023 World Medical Innovation Forum (Bank of America and Mass General)**

Date: June 12-14, 2023

Location: Boston, MA

Live webcasts presentations, when available, will be under “News & Events” in the Investors section of the Company’s website located at www.compasstherapeutics.com.

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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, their development, regulatory plans with respect thereto and 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 SEC available at www.sec.gov, including without limitation Compass’s latest Form 10-Q and subsequent filings with the SEC.

Investor Contact

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

	Three Months Ended March 31,	
	2023	2022
	(unaudited)	
Operating expenses:		
Research and development	\$ 6,638	\$ 4,415
General and administrative	3,073	2,767
Total operating expenses	<u>9,711</u>	<u>7,182</u>
Loss from operations	<u>(9,711)</u>	<u>(7,182)</u>

Other income	1,874	20
Loss before income tax expense	(7,837)	(7,162)
Income tax expense	—	—
Net loss	<u>\$ (7,837)</u>	<u>\$ (7,162)</u>
Net loss per share - basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.07)</u>
Basic and diluted weighted average shares outstanding	<u>126,375</u>	<u>100,858</u>

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

	March 31, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 27,027	\$ 34,946
Marketable securities	148,143	151,663
Prepaid expenses and other current assets	8,432	8,182
Total current assets	<u>183,602</u>	<u>194,791</u>
Property and equipment, net	1,373	1,567
Operating lease, right-of-use ("ROU") asset	2,680	2,967
Other assets	320	320
Total assets	<u>\$ 187,975</u>	<u>\$ 199,645</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,125	\$ 3,382
Accrued expenses	8,943	11,690
Operating lease obligations, current portion	1,122	1,097
Total current liabilities	<u>11,190</u>	<u>16,169</u>
Operating lease obligations, long-term portion	1,520	1,838
Total liabilities	<u>12,710</u>	<u>18,007</u>
Total stockholders' equity	175,265	181,638
Total liabilities and stockholders' equity	<u>\$ 187,975</u>	<u>\$ 199,645</u>