

**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): November 9, 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 November 9, 2023, Compass Therapeutics, Inc. issued a press release announcing financial results for the third quarter ended September 30, 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. **Description**

99.1	Press Release dated November 9, 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: November 9, 2023

By: /s/ Neil Lerner
Neil Lerner
VP Finance

Compass Therapeutics Reports Third Quarter 2023 Financial Results and Provides Corporate Update

- Opened 29 clinical sites and continue to enroll patients in COMPANION-002, a U.S. Phase 2/3 study of CTX-009 in combination with Paclitaxel in patients with advanced biliary tract cancers (BTC); top line data from this study is expected in the second half of 2024
- Continue to enroll and follow patients in COMPANION-003, a U.S. Phase 2 study of CTX-009 (DLL4 /VEGF-A bispecific antibody) in patients with advanced colorectal cancer (CRC); initial data from this study is expected before the end of the year
- Received IND clearance for CTX-8371, a next generation bispecific checkpoint inhibitor that simultaneously targets PD-1 and PD-L1; anticipate initiating a first-in-human clinical study in the fourth quarter of 2023
- Announces a CEO succession plan; Vered Bisker-Leib, PhD, Compass President and COO, to transition to Compass Chief Executive Officer and join Compass board of directors and Thomas Schuetz, MD, PhD, Compass' Scientific Founder and Chief Executive Officer, to transition to President of Research and Development and appointed Vice Chair of the Compass board of directors. Transition to take place on January 9th 2024
- Ended the third quarter with \$164 million in cash and marketable securities, providing cash runway for the company into 2026

BOSTON, Nov. 09, 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 third quarter and year-to-date, 2023 financial results.

“Enrollment in our Phase 2/3 study, COMPANION-002, in patients with advanced BTC has increased in the third quarter in part based on our opening of several clinical sites at large academic medical centers around the country. In addition, data are continuing to evolve in our COMPANION-003 study in patients with advanced CRC, and we expect to report initial data from this study in the fourth quarter of this year,” said Vered Bisker-Leib, PhD, President and Chief Operating Officer.

“We are very excited to announce that the FDA cleared the IND for CTX-8371, our PD-1 and PD-L1 bispecific antibody, the first StitchMabs[®] generated bispecific to advance to the clinic. We believe this next generation checkpoint inhibitor with its unique mechanism-of-action may have improved activity compared with first generation checkpoint blockers in a range of solid tumors. We look forward to initiating a first-in-human clinical study prior to the end of the year,” said Thomas J. Schuetz, MD, PhD, Co-Founder and Chief Executive Officer.

Carl Gordon, Chairman of Compass' Board of Directors, “Vered is a seasoned biotech executive who has played a key role in building our pipeline and operations, and she is well positioned to lead Compass through this next phase of strategic growth. Additionally, Tom's expertise and leadership as President of Research and Development will be invaluable as we continue to deliver on our mission of advancing next generation antibodies into transformative cancer therapies. Both Vered and Tom's commitment to Compass over the past decade have been instrumental in the value creation of the company, and I look forward to continuing our work together.”

Development Pipeline Update and Highlights:

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

- Enrolling patients in a U.S. Phase 2 study of CTX-009 as a monotherapy in patients with advanced, metastatic CRC (COMPANION-003)
 - The study design is an Adaptive Simon Two-Stage, with Stage 1 of the study enrolling 37 patients; if 3 or more responses are confirmed in Stage 1, the study will advance to Stage 2, and an additional 47 patients will be enrolled
 - The study is enrolling patients with CRC who have received two or three prior systemic therapies irrespective of their KRAS mutation status
 - Patients are being evaluated for safety and tolerability, as well as clinical response
 - Initial results from Stage 1 of this study are expected in the fourth quarter of 2023
- Enrolling patients in a U.S. Phase 2/3 study of CTX-009 in combination with Paclitaxel in BTC (COMPANION-002)
 - 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)
 - Enrollment in the third quarter has increased relative to the first half of 2023 in part due to the opening of several clinical sites at large academic medical centers across the country
 - Top line data is expected from this study in the second half of 2024

CTX-471 (CD137 + PD-1)

- This Phase 1 study is assessing the safety and activity of the combination of CTX-471 (CD137 agonistic antibody) and Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with select solid tumors
- The dose-escalation portion of the study (n=9) has been completed with no dose limiting toxicities observed
- The cohort expansion phase of the trial is expected to begin in the first quarter of 2024

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

- 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
- FDA cleared the IND for CTX-8371 and we expect to initiate a Phase 1 clinical trial in the fourth quarter of 2023

Financial Results

Net loss for the third quarter ended September 30, 2023 was \$10.0 million or \$0.08 per common share, compared to \$12.0 million or \$0.12 per common share for the same period in 2022. Net loss for the nine months ended September 30, 2023 was \$29.1 million or \$0.23 per common share, compared to \$27.6 million or \$0.27 per common share for the same period in 2022.

Cash Position

As of September 30, 2023, cash and marketable securities were \$164 million as compared to \$187 million as of December 31, 2022, providing the Company with an anticipated cash runway into 2026. During the first nine months of 2023, the Company used \$28 million of cash to fund operations.

Research and development (R&D) Expenses

R&D expenses were \$8.8 million for the quarter ended September 30, 2023, as compared to \$9.8 million for the same period in 2022, a decrease of approximately \$1.0 million or 10%. The decrease was primarily attributable to lower manufacturing expense related to CTX-009 of \$1.6M.

R&D expenses were \$25.7 million for the nine months ended September 30, 2023, as compared to \$20.1 million for the same period in 2022, an increase of \$5.6 million or 28%. The increase was primarily attributable to higher clinical costs of \$3.8 million and higher manufacturing costs of \$1.1 million.

General and Administrative (G&A) Expenses

G&A expenses were \$3.1 million for the quarter ended September 30, 2023, as compared to \$2.8 million for the same period in 2022, an increase of \$0.3 million or 10%. The increase was primarily attributable to higher stock compensation expense of \$0.3 million. G&A expenses were \$9.3 million for the nine months ended September 30, 2023, as compared to \$8.7 million for the same period in 2022, an increase of \$0.6 million or 7%. The increase was primarily attributable to higher stock compensation expense of \$0.5 million.

Upcoming Investor Conferences

Compass management will participate in two upcoming investor conferences:

- **Stifel Healthcare Conference**
Date: November 14-15, 2023
Location: New York, NY
- **Jefferies London Healthcare Conference**
Date: November 14-16, 2023
Location: London, UK

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 8,831	\$ 9,791	\$ 25,694	\$ 20,069
General and administrative	3,095	2,807	9,276	8,698
Total operating expenses	<u>11,926</u>	<u>12,598</u>	<u>34,970</u>	<u>28,767</u>
Loss from operations	<u>(11,926)</u>	<u>(12,598)</u>	<u>(34,970)</u>	<u>(28,767)</u>
Other income	1,962	623	5,891	1,136
Net loss	<u>\$ (9,964)</u>	<u>\$ (11,975)</u>	<u>\$ (29,079)</u>	<u>\$ (27,631)</u>
Net loss per share - basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.12)</u>	<u>\$ (0.23)</u>	<u>\$ (0.27)</u>

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

	September 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,426	\$ 34,946
Marketable securities	133,277	151,663
Prepaid expenses and other current assets	2,881	8,182
Total current assets	<u>166,584</u>	<u>194,791</u>
Property and equipment, net	1,051	1,567
Operating lease, right-of-use ("ROU") asset	2,083	2,967
Other assets	<u>320</u>	<u>320</u>

Total assets	\$ 170,038	\$ 199,645
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,306	\$ 3,382
Accrued expenses	5,644	11,690
Operating lease obligations, current portion	1,174	1,097
Total current liabilities	<u>9,124</u>	<u>16,169</u>
Operating lease obligations, long-term portion	869	1,838
Total liabilities	<u>9,993</u>	<u>18,007</u>
Total stockholders' equity	<u>160,045</u>	<u>181,638</u>
Total liabilities and stockholders' equity	<u>\$ 170,038</u>	<u>\$ 199,645</u>