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): August 3, 2023

COMPASS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39696**	**82-4876496**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 August 3, 2023, Compass Therapeutics, Inc. issued a press release announcing financial results for the second quarter ended June 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.	**Exhibit**
99.1	Press Release dated August 3, 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: August 3, 2023

By: /s/ Neil Lerner
Neil Lerner
VP Finance

EXHIBIT 99.1

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

- Continuing to enroll patients in 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 in the second half of 2023
- Opened 20 clinical sites and continues to enroll patients in a U.S. Phase 2 study of CTX-009 in patients with advanced biliary tract cancers (BTC); top line data from this study is now expected in the second half of 2024
- Completed enrollment of the dose-escalation portion of the Phase 1 combination arm of CTX-471 (CD137 agonistic antibody) and KEYTRUDA® (pembrolizumab)
- Added to the Russell 2000® and Russell 3000® Indexes as part of the Russell indexes annual reconstitution
- Ended the second quarter with $169 million in cash and marketable securities, providing cash runway for the company into 2026

BOSTON, Aug. 03, 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 second quarter, and year-to-date, 2023 financial results.

“Enrollment of our Phase 2 study of CTX-009 in patients with advanced CRC is on track and we expect to report initial data from this study in the second half of this year. Enrollment in our Phase 2 study in patients with BTC has been slower than anticipated, but we have taken steps to address this, including opening of a number of key clinical sites, strengthening our clinical operations team, and increasing our collaboration with patient advocacy groups,” said Thomas J. Schuetz, MD, PhD, Co-Founder and Chief Executive Officer.

“While we continue to advance CTX-009 and CTX-471 in the clinic, we are also gearing toward the filing of our third U.S. IND application, which will be for our next generation bispecific checkpoint axis blocker, CTX-8371. We believe that CTX-8371’s unique mechanism-of-action is the reason for its differentiated activity in pre-clinical studies, and we look forward to advancing it to a first-in-human clinical study,” said Vered Bisker-Leib, PhD, President and Chief Operating Officer.

Development Pipeline Update and Highlights:

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

- 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 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 second half of 2023
- Enrolling 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)
  - Enrollment for this study has been slower than anticipated; based on our current enrollment estimate, we expect top line data from this study in the second half of 2024

CTX-471 (CD137 + PD-1)

- Advancing enrollment of the Phase 1 combination arm 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 fully enrolled

Initial results from the combination arm are expected in the second half of 2023

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

- Targeting IND submission in the third quarter of 2023 and initiating a Phase 1 clinical trial in the fourth quarter of 2023

Financial Results

Net loss for the second quarter ended June 30, 2023 was $11.3 million or $0.09 per common share, compared to $8.5 million or $0.08 per common share for the same period in 2022. Net loss for the six months ended June 30, 2022 was $19.1 million or $0.15 per common share, compared to $15.7 million or $0.16 per common share for the same period in 2022.

Cash Position

As of June 30, 2023, cash and marketable securities were $169 million as compared to $187 million as of December 31, 2022, providing the Company with an anticipated cash runway into 2026. During the first half of 2023, the Company used $22 million of cash to fund operations.

Research and development (R&D) Expenses

R&D expenses were $10.2 million for the quarter ended June 30, 2023, as compared to $5.9 million for the same period in 2022, an increase of approximately $4.4 million or 74%. The change for the quarter was primarily attributable to a net increase of $4.6 million in program costs, resulting primarily from $5.9 million additional spending related to CTX-009 clinical and manufacturing costs offset by a $1.3 million decrease in spending on other programs.

R&D expenses were $16.9 million for the six months ended June 30, 2023, as compared to $10.3 million for the same period in 2022, an increase of $6.6 million or 64%. The change for the year was primarily attributable to a net increase of $7.1 million in program costs, resulting primarily from $9.3 million additional spending related to CTX-009 clinical and manufacturing costs offset by a $2.2 million decrease in spending on other programs.

General and Administrative (G&A) Expenses

G&A expenses were $3.1 million for the quarter ended June 30, 2023 and 2022. G&A expenses were $6.2 million for the six months ended June 30, 2023, as compared to $5.9 million for the same period in 2022, an increase of $0.3 million or 5%.

Upcoming Investor Conferences

Compass management will participate in four upcoming investor conferences:

- **Wedbush Securities Healthcare Conference**
  Date: August 8-9, 2023
  Location: New York, NY

- **Citi BioPharma Conference**
  Date: September 6-7, 2023
  Location: Boston, MA

- **HC Wainwright Global Investment Conference**
  Date: September 11-13, 2023
  Location: New York, NY

- **Cantor Healthcare Conference**
  Date: September 26-28, 2023
  Location: New York, NY

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

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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.

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

	June 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 19,278	$ 34,946
Marketable securities	149,474	151,663
Prepaid expenses and other current assets	6,520	8,182
Total current assets	175,272	194,791
Property and equipment, net	1,204	1,567
Operating lease, right-of-use ("ROU") asset	2,385	2,967
Other assets	320	320
Total assets	$ 179,181	$ 199,645
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 724	$ 3,382
Accrued expenses	7,827	11,690
Operating lease obligations, current portion	1,147	1,097
Total current liabilities	9,698	16,169
Operating lease obligations, long-term portion	1,197	1,838
Total liabilities	10,895	18,007
Total stockholders' equity	168,286	181,638
Total liabilities and stockholders' equity	$ 179,181	$ 199,645

Compass Therapeutics, Inc. and Subsidiaries

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 10,223	$ 5,862	$ 16,862	$ 10,278
General and administrative	3,114	3,125	6,183	5,891
Total operating expenses	13,337	8,987	23,045	16,169
Loss from operations	(13,337)	(8,987)	(23,045)	(16,169)
Other income	2,059	493	3,930	513
Net loss	$ (11,278)	$ (8,494)	$ (19,115)	$ (15,656)
Net loss per share - basic and diluted	$ (0.09)	$ (0.08)	$ (0.15)	$ (0.16)