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 12, 2024

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 12, 2024, Compass Therapeutics, Inc. issued a press release announcing financial results for the quarter ended June 30, 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.	Description
99.1	Press Release dated August 12, 2024 (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 12, 2024

By: /s/ Neil Lerner
Neil Lerner
VP Finance

EXHIBIT 99.1

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

- Completed enrollment of the 150 patients in the COMPANION-002 Study, a Phase 2/3 trial of CTX-009 (DLL4 and VEGF-A bispecific antibody) plus paclitaxel versus paclitaxel monotherapy in patients with previously treated, unresectable advanced metastatic or recurrent biliary tract cancers (BTC); top-line data expected in the first quarter of 2025.

- Approved an Investigator Sponsored Trial (IST) of CTX-009 in patients with BTC in the first-line setting.

- Completed review of encouraging preliminary data from Stage 1 of COMPANION-003, a Phase 2 trial of CTX-009 in patients with advanced colorectal cancer (CRC) treated in the third- and fourth-line settings. Based on the data, designs of a Phase 2 study in the second-line setting combining CTX-009 with chemotherapy in patients with DLL4-positive CRC are being evaluated.

- Planning a Phase 2 monotherapy trial of CTX-471 (CD137 agonist antibody) in patients with a set of tumors that express a newly identified biomarker that correlates with CTX-471 activity. This biomarker was identified in an analysis of biopsy specimens from the Phase 1 Study; biopsy and biomarker data from the Phase 1 Study will be presented at a scientific conference later this year.

- Observed a suppression of proinflammatory cytokines in the Phase 1b study of CTX-471 in combination with KEYTRUDA® (pembrolizumab) which was not observed with CTX-471 as a monotherapy; therefore, the combination study of CTX-471 and KEYTRUDA will be discontinued.

- Completed enrollment of the first dosing cohort in a Phase 1 dose-escalation study of CTX-8371 (PD-1 x PD-L1 bispecific antibody) with no dose limiting toxicities (DLTs) observed; began enrolling patients in the second dosing cohort.

- Ended the first quarter with $146 million in cash and marketable securities, which is expected to provide cash runway into the first quarter of 2027.

BOSTON, Aug. 12, 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 second quarter 2024 financial results and provided a business update.

“We are excited to report the achievement of an important milestone in our CTX-009 BTC program with the completion of enrollment in COMPANION-002, our Phase 2/3 trial in patients with BTC,” said Thomas Schuetz, MD, PhD, CEO of Compass and Vice Chairman of the Board of Directors. “In addition, we approved an Investigator Sponsored Trial at The University of Texas MD Anderson Cancer Center, which will evaluate CTX-009 for the first time in the front-line setting in patients with BTC.”

Dr. Schuetz continued, “We are pleased to confirm the CTX-009 monotherapy Phase 1 data in patients with advanced CRC. There is a significant unmet medical need in this patient population; VEGF-targeted therapies have response rates of 1.5% or less and median overall survival is approximately 7 months. Our monotherapy data demonstrate an important efficacy signal in the third- and fourth-line patient populations. In particular, the observed median overall survival with CTX-009 monotherapy is encouraging in this very advanced patient population. Based on these results and the previously reported response data from the Phase 1 trial, we are designing the next study combining CTX-009 with chemotherapy to treat patients with advanced CRC in the second-line setting, selecting patients whose tumors are DLL4-positive. Based on our Phase 1 data, we believe these patients are more likely to respond to therapy with CTX-009. Beyond CTX-009, we continue to execute across our portfolio, with planning underway for a Phase 2 monotherapy study of CTX-471 in patients whose tumors express a potential biomarker of CTX-471 activity. Additionally, our first-in-human study of CTX-8371 is progressing well, having initiated the second dosing cohort.”

DEVELOPMENT PIPELINE UPDATES:

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

- Completed enrollment (n=150) in COMPANION-002 in the U.S., a Phase 2/3 randomized trial of CTX-009 in combination with paclitaxel in patients with advanced BTC (see press release).
    - Received FDA Fast Track Designation.
    - Top-line data expected in the first quarter of 2025.

- Approved an IST of CTX-009 in patients with BTC in the first-line setting to be conducted at The University of Texas MD Anderson Cancer Center. CTX-009 will be added to the standard first-line regimen of gemcitabine, cisplatin, and durvalumab.

- Preliminary results (as of August 6, 2024) from Stage 1 of COMPANION-003, a Phase 2 trial in the U.S. of CTX-009 as a monotherapy in patients with advanced, metastatic CRC:

- Objective response rate (ORR) of 5% (2 out of 41 patients), median progression free survival (PFS) of 3.9 months, disease control rate (DCR) of 71% (29 out of 41 patients with a partial response or stable disease as the observed best overall response), and median overall survival (OS) is currently 10.2 months.
- 26 out of the 41 patients (63%) were treated in the fourth-line setting.
- The safety profile was consistent with prior CTX-009 trials with hypertension as the most common adverse event.

- Based on these preliminary results, including the OS data, and the previously observed correlation between DLL4 expression and responses to CTX-009, evaluating designs of a Phase 2 study in the second-line setting in combination with chemotherapy in patients with DLL4-positive CRC instead of continuing to Stage 2 of the current trial.

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 small cell lung cancer converted to a complete response, as confirmed by a PET scan. Additionally, the ORR in the subset of patients with advanced melanoma was 27% (3 of 11) with a fifth response occurring in a patient with mesothelioma. Data were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June.
- Ongoing analysis of biopsy specimens from the Phase 1b study revealed a potential biomarker of response; planning a Phase 2 monotherapy study of CTX-471 in patients whose tumors express this biomarker is underway. Data will be presented at a scientific conference later this year.
- In the Phase 1b dose-expansion cohort of CTX-471 in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab), an unexpected suppression of proinflammatory cytokines was observed which did not occur with CTX-471 as a monotherapy; as a result, the combination study will be discontinued.

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 in the Phase 1 study. The first cohort of this trial was completed in June 2024 with no dose limiting toxicities observed. The second cohort has been initiated.

General Updates

- Compass continues to explore the synergies observed in pre-clinical and discovery work between VEGF blockade and CD137 agonism, as well as other cell engagers, to identify novel drug candidates with complementary anti-tumor activity, some of which is reported in this poster at the American Association for Cancer Research meeting earlier this year.
- Announced two promotions on our executive leadership team: Jonathan Anderman, J.D., was promoted to Senior Vice President, General Counsel & Corporate Secretary and Bing Gong, Ph.D, was promoted to Senior Vice President, Discovery Research.

FINANCIAL RESULTS:

Net loss for the quarter ended June 30, 2024, was $13.1 million or $0.10 per share of common stock, compared to $11.3 million or $0.09 per share of common stock for the same period in 2023. Net loss for the six months ended June 30, 2024, was $23.9 million or $0.17 per share of common stock, compared to $19.1 million or $0.15 per share of common stock for the same period in 2023. The company received a $1 million milestone payment based on the completion of a phase 1 trial of CTX-009 in China, reflected as $850 thousand of license revenue (net of sublicense royalty) in the statements of operations.

Research and Development (R&D) Expenses

R&D expenses were $11.2 million for the quarter ended June 30, 2024, as compared to $10.2 million for the same period in 2023, an increase of $1.0 million. This increase was primarily attributable to a $2.5 million increase in clinical costs related to the COMPANION-002 trial, partially offset by $1.8 million less in manufacturing expense for CTX-009. R&D expenses were $20.7 million for the six months ended June 30, 2024, as compared to $16.9 million for the same period in 2023, an increase of $3.8 million. This increase was primarily attributable to a $4.8 million increase in clinical costs related to the COMPANION-002 trial, partially offset by $2.1 million less in manufacturing expense for CTX-009.

General and Administrative (G&A) Expenses

G&A expenses were $4.7 million for the quarter ended June 30, 2024, as compared to $3.1 million for the same period in 2023, an increase of $1.6 million. G&A expenses were $8.0 million for the six months ended June 30, 2024, as compared to $6.2

million for the same period in 2023, an increase of $1.8 million. The quarter and year-to-date increases were due to expenses related to the departure of the CEO in the quarter.

CASH POSITION:

As of June 30, 2024, cash and marketable securities were $146 million as compared to $152 million as of December 31, 2023, which gives a cash runway into the first quarter of 2027.

During the first six months of 2024, Compass decreased its cash position by $6 million, primarily by cash used in operating activities partially offset by $18 million cash received from issuance of stock through its at-the-market offering program.

About CTX-009
CTX-009 is a bispecific antibody that simultaneously blocks Delta-like ligand 4 (DLL4) and vascular endothelial growth factor A (VEGF-A) signaling pathways, which are critical to angiogenesis and tumor vascularization. Preclinical and early clinical data of CTX-009 suggest that blockade of both pathways provides robust anti-tumor activity across several solid tumors, including colorectal, gastric, cholangiocarcinoma, pancreatic and non-small cell lung cancer. Partial responses to CTX-009 as a monotherapy have been observed in heavily pre-treated patients with cancer who were resistant to approved anti-VEGF therapies.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
License revenue	$ 850	$ —	$ 850	$ —

Operating expenses:				
Research and development	11,174	10,223	20,695	16,862
General and administrative	4,721	3,114	7,969	6,183
Total operating expenses	15,895	13,337	28,664	23,045
Loss from operations	(15,045)	(13,337)	(27,814)	(23,045)
Other income	1,969	2,059	3,951	3,930
Net loss	$ (13,076)	$ (11,278)	$ (23,863)	$ (19,115)
Net loss per share - basic and diluted	$ (0.10)	$ (0.09)	$ (0.17)	$ (0.15)
Basic and diluted weighted average shares outstanding	137,589	126,729	137,098	126,539

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

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 19,404	$ 24,228
Marketable securities	126,823	128,233
Prepaid expenses and other current assets	7,319	1,420
Total current assets	153,546	153,881
Property and equipment, net	592	898
Operating lease, right-of-use ("ROU") asset	1,153	1,776
Other assets	320	320
Total assets	$ 155,611	$ 156,875
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,192	$ 4,090
Accrued expenses	7,227	2,514
Operating lease obligations, current portion	1,088	1,197
Total current liabilities	9,507	7,801
Operating lease obligations, long-term portion	—	536
Total liabilities	9,507	8,337
Total stockholders' equity	146,104	148,538
Total liabilities and stockholders' equity	$ 155,611	$ 156,875