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): January 5, 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.

Compass Therapeutics, Inc. (the "Company") estimates that its cash, cash equivalents and marketable securities were approximately $152 million as of December 31, 2023. This amount is unaudited and preliminary and is subject to completion of financial closing procedures. As a result, this amount may differ materially from the amount that will be reflected in the Company's financial statements as of and for the year ended December 31, 2023.

The information in this Item 2.02 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Forward-Looking Statements

The Company cautions readers that statements contained in this report regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include the Company's estimated cash, cash equivalents and marketable securities as of December 31, 2023. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from predicted or expected results. Such risks and uncertainties include, but are not limited to, potential changes in estimated cash and cash equivalents based on the completion of financial closing procedures and release of final 2023 results, and other risks described in the Company's filings with the SEC. The Company cautions readers not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Item 7.01. Regulation FD Disclosure.

On January 5, 2024, the Company issued a press release announcing updated program timelines, additional clinical data, change in management and year-end cash position. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued on January 5, 2024 titled "Compass Therapeutics Provides Corporate Update"
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: January 5, 2024

By: /s/ Neil Lerner
Neil Lerner
VP Finance

Compass Therapeutics Provides Corporate Update

- *We continue to open clinical sites and enroll patients in COMPANION-002, the Phase 2/3 randomized study of CTX-009 (DLL4 x VEGF-A bispecific antibody) in patients with advanced biliary tract cancer (BTC). Consistent with prior guidance, top line data from this study continue to be expected in the second half of 2024.*
- *Enrollment of patients in COMPANION-003, the Phase 2 study of CTX-009 in patients with advanced colorectal cancer (CRC), has been extended into the first quarter of 2024. We expect to report top-line data from this study by mid-year 2024.*
- *Further evidence of clinical activity has been observed in the Phase 1b, monotherapy study of CTX-471. First, one patient with small cell lung cancer with a previously reported partial response has converted to a complete response, as confirmed by a PET scan, while continuing therapy on CTX-471. Second, in addition to the four responses previously reported, a new partial response has been observed in a patient with advanced melanoma, bringing the overall response rate (ORR) in patients with advanced melanoma in this study to 27% (3 of 11).*
- *Following FDA acceptance of the CTX-8371 IND in late 2023, we expect to dose the first patient in 1Q 2024.*
- *As previously disclosed, effective January 9, 2024, Vered Bisker-Leib, PhD, Compass President and COO, will lead Compass as Compass Chief Executive Officer and join the Compass board of directors.*
- *Effective January 9, 2024, Thomas Schuetz, MD, PhD, Compass' Scientific Founder and Chief Executive Officer will transition to President of Research and Development and be appointed Vice Chair of the Compass board of directors.*
- *Ended 2023 with an estimated $152 million in cash and marketable securities, which is expected to provide cash runway for the company into mid-year 2026.*

BOSTON, Jan. 05, 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 a business update.

"We made significant progress in the fourth quarter of the year across our portfolio, and we look forward to reporting top-line data from COMPANION-003 by mid-year and COMPANION-002 in the second half of the year. We are also excited to report additional responses in our Phase 1b monotherapy study of CTX-471, including a complete response in a patient with small cell lung cancer. We hope to see additional efficacy signals in the second part of our Phase 1b study, where we are studying CTX-471 in combination with KEYTRUDA® in patients with melanoma, NSCLC and SCLC," said Vered Bisker-Leib, PhD, incoming Chief Executive Officer of Compass.

"We are excited to have Vered Bisker-Leib elevated to the Chief Executive Officer role recognizing many years of strong performance. We are equally pleased that our founding CEO, Thomas Schuetz, will continue to play a key role at the Company," said Carl Gordon, PhD, Chair of Compass' Board.

Development Pipeline Updates:

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

- We continue to enroll patients in COMPANION-002, a 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 is expected to be completed by mid-year 2024; top line data are expected from this study in the second half of 2024.
- Enrollment of patients in COMPANION-003, a U.S. Phase 2 study of CTX-009 as a monotherapy in patients with advanced, metastatic CRC, has been extended to first quarter 2024.
  - 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.
  - We expect to report top-line data from this study by mid-year 2024.

CTX-471 (CD137 agonist)

- CTX-471 is a CD137 agonistic antibody, which binds to a unique epitope of the co-stimulatory molecule 4-1BB with an optimized affinity.
- We continue to dose and follow patients in the Phase 1b monotherapy study of CTX-471 where five responses have been observed, all in patients who previously received checkpoint blocker(s). A durable PR in a patient with SCLC has converted to a CR, as confirmed by a PET scan. Additionally, a new PR in a patient with advanced melanoma, was observed, leading to an ORR in the subset of patients with advanced melanoma of 27% (3 of 11). The fifth response occurred in a patient with mesothelioma.
- Phase 1b combination arm of CTX-471 and Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with select solid tumors is ongoing. The dose-escalation portion of the study has been fully enrolled and enrollment in the dose

expansion cohorts has begun. In the expansion cohort, we plan on enrolling 60 patients with melanoma, NSCLC and SCLC, who will be randomized into 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.
- Following the FDA acceptance of the IND for CTX-8371, the first patient is expected to be dosed in the Phase 1 clinical trial in the first quarter of 2024.

Corporate Highlights:

- The Company's CEO succession plan is effective as of January 9, 2024, with the elevation of Vered Bisker-Leib, PhD, to Chief Executive Officer and her addition to the Compass board of directors.
- Thomas Schuetz, MD, PhD, Compass' Scientific Founder and current Chief Executive Officer will transition to President of Research and Development and assume the role of Vice Chair of the Compass board of directors.

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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