

**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): September 22, 2026

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 7.01. Regulation FD Disclosure.

On September 22, 2026, Compass Therapeutics, Inc. (the “Company”) issued a press release announcing regulatory feedback from the FDA relating to tovecimig in patients with biliary tract cancer (“BTC”).

A copy of the full press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

The information contained in this Item 7.01 (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section and shall not be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements. Statements that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, statements regarding Compass's product candidates, including the potential of tovecimig to provide a treatment option for patients with BTC in the second-line setting, additional results of the COMPANION-002 study, and the timing and nature of any regulatory interactions and subsequent approval pathways, including Compass's intention to discuss the data in the COMPANION-002 Randomized Phase 2/3 Study with the FDA in advance of a planned BLA submission, and the expectation to present the complete dataset at a medical conference this year. 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 Current Report on Form 8-K, 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 and subsequent filings with the SEC.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 22, 2026
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: September 22, 2026

By: /s/ Neil Lerner
Neil Lerner
Chief Accounting Officer

Compass Therapeutics Provides Regulatory Update on Tovecimig in Biliary Tract Cancer Following FDA Feedback

- *The FDA recommended that Compass conduct a trial to demonstrate a survival benefit prior to submitting a BLA for tovecimig.*
- *Compass does not believe that a new trial is warranted prior to submitting a BLA based on the data from the Phase 2/3 COMPANION-002 study and the urgent unmet medical need for patients with BTC.*
- *Compass intends to further engage with the FDA as we continue to prepare a BLA submission for tovecimig.*
- *Compass remains confident in tovecimig based on the positive results from COMPANION-002, including the statistically significant improvements in ORR and PFS.*

BOSTON, Sept. 22, 2026 (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 announced that the U.S. Food and Drug Administration (FDA) recommended that Compass conduct a trial demonstrating a survival benefit before proceeding with a Biologics License Application (BLA) submission for tovecimig in patients with previously treated, advanced biliary tract cancer (BTC).

BTC is an aggressive, life-threatening cancer with poor survival outcomes, and effective options remain limited for patients who have received prior treatment, underscoring the urgent need for new approaches.

As previously disclosed, in the positive Phase 2/3 COMPANION-002 study, tovecimig plus paclitaxel demonstrated a statistically significant improvement in the primary endpoint of objective response rate (ORR) of 18.0% vs. 5.3% with paclitaxel alone ($p=0.0228$) and a highly significant improvement in progression-free survival (PFS) in patients with BTC who had received prior treatment. Median PFS was 4.7 vs. 2.6 months with a hazard ratio of 0.44 ($p<0.0001$), representing a compelling 56% reduction in the risk of disease progression. Overall survival (OS) analyses were confounded by both high crossover and notably prolonged survival in crossover patients randomized to the control arm then treated with tovecimig and, therefore, did not meet statistical significance. The safety profile was generally consistent with previously reported data from prior tovecimig studies.

“While this is not the response we expected, we respect the FDA’s feedback and our priority is to work with the Agency to determine the best path forward to support our planned BLA submission and address this pressing unmet need,” said Thomas Schuetz, M.D., Ph.D., Chief Executive Officer of Compass. “We remain confident that the COMPANION-002 findings, including the statistically significant improvements in PFS and ORR combined with subset analyses on survival, demonstrate clinically meaningful activity in patients with previously treated, advanced BTC.”

About Tovecimig

Tovecimig is an investigational DLL4 x VEGF-A bispecific antibody designed to block two angiogenic pathways simultaneously, representing a first-in-class approach to disrupting tumor angiogenesis. In COMPANION-002, tovecimig was evaluated in combination with paclitaxel in patients with previously treated, advanced biliary tract cancer. Tovecimig has received Fast Track and Orphan Drug Designation from the U.S. Food and Drug Administration.

About Compass Therapeutics

Compass Therapeutics is a clinical-stage, oncology-focused biopharmaceutical company dedicated to transforming the standard of care for patients with cancer through the discovery and development of innovative antibody-based therapeutics. The company leverages deep expertise in tumor biology and proprietary antibody engineering technologies to develop differentiated therapies that target the intersection of angiogenesis, immune activation, and tumor-driven immunosuppression. Compass has a robust pipeline of novel product candidates designed to address significant unmet needs and improve outcomes for patients with cancer. 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 tovecimig, the results of the COMPANION-002 study, and the associated regulatory feedback, plans, and timelines, 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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