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 20, 2022

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)

(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 8.01. Other Events.

On January 20, 2022, Compass Therapeutics, Inc. (the "Company") issued a press release titled "Compass Therapeutics Announces US FDA Clearance of Investigational New Drug Application for a Phase 2 Study of CTX-009, a bispecific antibody that simultaneously targets Delta-like ligand 4 (DLL4) and vascular endothelial growth factor A (VEGF-A)" A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated January 20, 2022

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 20, 2022

By: /s/ NEIL LERNER
Neil Lerner
VP of Finance

Compass Therapeutics Announces US FDA Clearance of Investigational New Drug Application for a Phase 2 Study of CTX-009, a Bispecific Antibody That Simultaneously Targets Delta-like Ligand 4 (DLL4) and Vascular Endothelial Growth Factor A (VEGF-A)

BOSTON, Jan. 20, 2022 (GLOBE NEWSWIRE) -- Compass Therapeutics, Inc. (Nasdaq: CMPX), a clinical-stage biopharmaceutical company developing proprietary antibody-based therapeutics to treat cancer, today announced that the U.S. Food and Drug Administration (FDA) has cleared its IND application for CTX-009, enabling the company to initiate a global Phase 2 clinical trial for CTX-009 in patients who have advanced Biliary Tract Cancers (BTC) in the United States and South Korea. Compass plans to include the existing Phase 2 in South Korea in this global study, allowing it to expand the ongoing study of CTX-009 under this IND. CTX-009 is a bispecific antibody that simultaneously targets Delta-like ligand 4 (DLL4) and vascular endothelial growth factor A (VEGF-A).

“We are extremely pleased to announce today the FDA has accepted our IND application for CTX-009. We thank the reviewers at the FDA for their review and comments on the Phase 2 study design,” said Thomas J. Schuetz, MD, PhD, CEO and Scientific Founder of Compass. “The ongoing Phase 2 study in South Korea will now be expanded to a global study with the opening of US clinical sites in Q2. We believe that CTX-009 has the potential to be an important new therapy for patients with biliary tract cancers, including cholangiocarcinomas,” added Dr. Schuetz.

About CTX-009

CTX-009 is a bispecific antibody that simultaneously targets Delta-like ligand 4 (DLL4) and vascular endothelial growth factor A (VEGF-A). This next generation angiogenesis inhibitor has completed a Phase 1 dose escalation and expansion study, and a Phase 1b study in combination with chemotherapy. As a monotherapy, CTX-009 demonstrated clinical benefit in heavily pre-treated patients who had progressed after prior therapy with chemotherapy regimens containing VEGF blockers such as bevacizumab and ramucirumab. Several clinical responses were observed in patients with advanced colorectal cancer and in patients with gastric cancer. Additional durable responses were also observed in the combination study with chemotherapy in patients with cholangiocarcinoma.

About the Phase 2 Clinical Trial

A Phase 2 study was initiated in Q1 2021 in South Korea evaluating CTX-009 in combination with paclitaxel in patients with advanced Biliary Tract Cancers (cholangiocarcinoma) in whom multiple prior regimens had failed. The study is a Simon Two-Stage adaptive Phase 2 Study. Enrollment in Stage 1 of the study has been completed and the criteria to advance to Stage 2 of the study have been met. Notably, five partial responses (PRs) have already been observed among the first 17 patients evaluated leading to a preliminary overall response rate (ORR) of 29%, and all patients evaluated have had stable disease or better with a decline in tumor burden observed in 16 of the 17 patients leading to a Clinical Benefit Rate (CBR) of 100%. The study is being conducted by Handok Pharmaceuticals and the clinicaltrials.gov identifier for the study is NCT04492033. Compass plans to add sites in the United States to this study and plans to initiate Stage 2 of the Phase 2 study with Handok in Q2 of this year.

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’ 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 on Compass, please visit the company’s website at: 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, statements regarding the Company’s product candidates, their development, regulatory plans with respect thereto and therapeutic potential thereof, planned interactions with regulatory authorities, planned clinical development, use of proceeds from our recent public offering, our cash resources and financial runway. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the Company’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, the Company’s ability to identify additional product candidates for development, the Company’s ability to develop, complete clinical trials for, obtain approvals for and commercialize any of its product candidates, competition in the industry in which the Company operates and market conditions. These forward-looking statements are made as of the date of this press release, and the Company 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 the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents the Company files with the SEC available at www.sec.gov.

Investor Contact
Vered Bisker-Leib, President & Chief Operating Officer
ir@compasstherapeutics.com

Media Contact
Anna Gifford, Communications Manager
media@compasstherapeutics.com
617-500-8099