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): November 01, 2021

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)**	**(IRS Employer Identification No.)**

80 Guest Street **Suite 601** **Boston, Massachusetts**	**02135**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 617 500-8099

(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	OTCQB Stock Exchange

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.

In connection with a proposed public offering of its Common Stock, Compass Therapeutics, Inc. (the "Company") intends to file a preliminary prospectus supplement to the base prospectus included in the Company's shelf registration statement on Form S-3 (No. 333-257821), filed with the U.S. Securities and Exchange Commission (the "SEC") on July 9, 2021 and declared effective by the SEC on July 20, 2021. The preliminary prospectus supplement describes certain elements of the Company's business strategy and certain recent developments, including those set forth below.

Preliminary financial results for the third quarter ended September 30, 2021

We are currently finalizing our financial quarterly closing process for the three months ended September 30, 2021. While complete financial information and operating data are not yet available, we estimate that cash and cash equivalents are expected to be $25.5 million. However, our actual results may differ materially from this estimate due to the completion of our financial closing procedures, final adjustments and other developments that may arise between now and the time the financial results for the three and nine months ended September 30, 2021 are finalized.

The Company cautions you that statements included in this Current Report on Form 8-K that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "could," "should," "expects," "intends," "target,", "contemplates," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue," or the negative of these words or other similar terms or expressions that concern its' expectations, strategy, plans, prospects or intentions. Such statements include, without limitation, statements regarding the Company's financial data and intention to commence a public offering of its common stock. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company's actual future results may differ materially from its current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all, the Company's product candidates, the therapeutic potential thereof and its development plans therefor; and other risks set forth under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K, as updated by the Company's other subsequently filed SEC filings. The Company assumes no obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

The information contained in Item 2.02 of this Form 8-K regarding the Company's unaudited cash balance as of September 30, 2021 is unaudited and preliminary and does not present all information necessary for an understanding of the Company's financial condition as of September 30, 2021.

The information in this Item 2.02 regarding the Company's unaudited cash balance as of September 30, 2021 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On November 1, 2021, the Company issued a press release titled "Compass Reports the Advancement of CTX-009, a Bispecific Antibody, to Phase 2a Development in Patients with Biliary Tract Cancers, and the Clearance of a Key Clinical Hurdle". A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On November 1, 2021, the Company issued a press release titled “Compass Therapeutics Announces Proposed Public Offering of Common Stock and Uplisting to Nasdaq Capital Market". A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference. 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.

99.1 Press release titled "Compass Reports the Advancement of CTX-009..."
99.2 Press release titled "Compass Therapeutics Announces Proposed Public Offering of Common Stock and Uplisting to Nasdaq Capital Market"

SIGNATURES

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 thereunto duly authorized.

Compass Therapeutics, Inc.

Date: 11/01/2021

By: /s/ Thomas J. Schuetz
Thomas J. Schuetz, MD
Chief Executive Officer

Exhibit 99.1

Compass Reports the Advancement of CTX-009, a Bispecific Antibody, to Phase 2a Development in Patients with Biliary Tract Cancers (BTC), and the Clearance of a Key Clinical Hurdle

- Phase 2a study was initiated by Handok Pharmaceuticals in Q1 2021 in patients with Biliary Tract Cancers (cholangiocarcinoma).
- Enrollment in the first part of the study has been completed and the criteria to advance to the second part of the study have been met.
- Notably, five partial responses have already been observed among the first 17 patients evaluated leading to a preliminary overall response rate of 29% (ORR=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 of 100% (CBR=100%).
- Compass plans to submit an Investigational New Drug (IND) application to the United States Food and Drug Administration (FDA) this quarter, and subject to the IND clearance with the FDA, to initiate a Phase 2 study in Q2 2022.

BOSTON, November 1, 2021 - Compass Therapeutics, Inc. (OTC:CMPX) today provided an update on the clinical development of CTX-009 (also known as ABL001), a dual anti-angiogenic bispecific antibody targeting DLL4 and VEGF-A.

A Phase 2a study for CTX-009 in combination with paclitaxel was initiated by Handok Pharmaceuticals, Inc. (KOSDAQ: 002390) in Q1 2021 in patients with BTC and the enrollment in the first part of the study has been completed. The study has been enrolling patients who have unresectable advanced, metastatic, or relapsed BTC's who have received one or two prior systemic therapies. The Phase 2a design was informed by the CTX-009 Phase 1b study, where CTX-009 in combination with either paclitaxel or irinotecan led to an overall response rate of 23.5% and a clinical benefit rate of 76.5%, including two confirmed and durable partial responses among four patients with advanced cholangiocarcinoma (clinicaltrials.gov Identifier: NCT04492033).

The Phase 2a study utilizes a Simon Two-Stage adaptive design where the criteria to advance to the second stage of the study is three or more partial responses observed in 21 patients. So far, there have been five partial responses observed among the first 17 patients evaluated, which is an overall response rate of 29%, and accordingly, the criteria to advance to the second part of the study has been met. In the second part of the Phase 2a study, 45 additional patients will be enrolled. The preliminary adverse event profile of CTX-009 in this Phase 2a study is consistent with prior studies of CTX-009 with hypertension and neutropenia being the most

common events related to CTX-009 and paclitaxel, respectively. Handok initiated the study in Q1 2021 at four leading medical centers in South Korea. Compass plans on submitting an IND for CTX-009 in the United States later this quarter and subject to the IND going into effect with the FDA, plans on initiating a Phase 2 study in the United States in Q2 2022.

“Patients with cholangiocarcinoma have limited treatment options following front line combination chemotherapy. In the Phase 1b and Phase 2a studies, we have seen a total of seven partial responses in 21 total patients evaluated. Impressively, there have been measurable tumor declines in 19 of the 21 advanced patients treated across both studies. We are looking forward to filing our IND in the United States this quarter and pursuing the global development of CTX-009,” said Thomas Schuetz, M.D., Ph.D., CEO and scientific founder of Compass. Compass holds the global rights to CTX-009 with the exception of South Korea rights, which are held by Handok, and China rights, which were out-licensed to Elpiscience Biopharma.

About CTX-009

CTX-009 is a bispecific antibody that simultaneously blocks Delta-like ligand 4/Notch (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 cancer patients, who were resistant to currently approved anti-VEGF therapies. CTX-009 has completed a Phase 1 monotherapy dose escalation and dose expansion study. Phase 1b and Phase 2a combination studies are ongoing.

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.

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 product candidate, CTX-009, its 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 our 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 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.

COMPASS Contacts

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Exhibit 99.2

Compass Therapeutics Announces Proposed Public Offering of Common Stock and Uplisting to Nasdaq Capital Market

BOSTON, November 1, 2021 — Compass Therapeutics, Inc. (the "Company"), a clinical stage biopharmaceutical company developing proprietary antibody-based therapeutics to treat cancer, today announced that it intends to offer and sell shares of common stock in an underwritten public offering. All of the shares of common stock are being offered by the Company. In addition, the Company expects to grant the underwriters a 30-day option to purchase up to an additional 15% of the aggregate shares of common stock offered in the public offering at the public offering price, less the underwriting discount. In connection with the offering, the Company also announced that its common stock has been approved for listing on the Nasdaq Capital Market under the symbol "CMPX", subject to the pricing of the public offering on the terms proposed.

The offering is subject to customary closing conditions. The Company intends to use the net proceeds from the public offering, together with its existing cash and cash equivalents,
(i) to secure the listing of its common stock on the Nasdaq Capital Market, (ii) for funding of ongoing operations including clinical trials for its existing programs, which may change based on clinical and preclinical results and (iii) for general corporate purposes.

SVB Leerink is serving as the book-running manager for the proposed offering.

The securities described above are being offered by the Company pursuant to a shelf registration statement on Form S-3 (No. 333-257821) that was declared effective by the Securities and Exchange Commission on July 20, 2021. A preliminary and final prospectus supplement relating to and describing the terms of the offering will be filed with the SEC describing the terms of the offering will be filed with the SEC and will be available on the SEC's website located at www.sec.gov. When available, copies of the preliminary prospectus supplement and the accompanying prospectus relating to the offering may be obtained from SVB Leerink LLC, Attention: Syndicate Department, One Federal Street, 53 State Street, 40th Floor, Boston, MA 02109, by telephone at (800) 808-7525, ext. 6105, or by email at syndicate@svbleerink.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. Any offer, if at all, will be made only by means of the prospectus supplement and accompanying prospectus forming a part of the effective registration statement.

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.

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 intention to conduct an offering and sale of securities, the size of the offering, the completion of the proposed offering and the expected use of proceeds from the proposed offering, references to the Company's product candidate, CTX-009, its 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, 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

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