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): October 08, 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 8.01 Other Events.

On October 8, 2021, Compass Therapeutics, Inc. (the “Company”) issued a press release titled “CTX-009 (ABL001/ES104) Clinical Data Presented Today at the New Drugs on the Horizon Plenary Session of the 2021 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics." 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 October 8, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: October 8, 2021

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

CTX-009 (ABL001/ES104) Clinical Data Presented Today at the New Drugs on the Horizon Plenary Session of the 2021 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics

- CTX-009 was well tolerated and demonstrated single agent activity in heavily pre-treated patients with solid tumor who are resistant to anti-VEGF therapies, mostly of colorectal and gastric origins
- The structural differences between CTX-009 and other bispecifics targeting these pathways, as well as the affinities and avidities to their targets, may be the drivers for the differentiated safety and efficacy data observed
- The maximum tolerated dose (MTD) was not reached, and the recommended Phase 2 doses (RP2D) of CTX-009 were determined to be 10.0 and 12.5 mg/kg biweekly
- Overall response rate (ORR) of CTX-009 as a monotherapy across all doses tested (0.3 - 17.5 mg/kg) was 8% and the disease control rate (DCR) was 62% in patients treated at the 3rd and 4th line settings
- Treatment with CTX-009 at the RP2D (10.0 mg/kg and 12.5 mg/kg) led to 19% (n=3/16) ORR, not including an additional unconfirmed partial response, and a 69% DCR (n=11/16)
- A Phase 1b study of CTX-009 in combination with chemotherapy and a Phase 2 study are underway

BOSTON, Mass, USA, SEONGNAM, S. Korea, SHANGHAI/SUZHOU, China, Oct. 8th, 2021 - Compass Therapeutics, Inc. (OTC:CMPX) and ABL Bio (KOSDAQ: 298380) presented today clinical trial data for CTX-009 (ABL001/ES104), a dual anti-angiogenic bispecific antibody targeting DLL4 and VEGF-A, at an oral plenary session during the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics (**Abstract Number:** 4749; **Session Title:** Plenary Session 2: New Drugs on the Horizon I).

The first in human Phase 1 single agent dose escalation and expansion study evaluated CTX-009 across nine dose levels. The study enrolled 45 heavily pre-treated patients with cancers primarily of colorectal and gastric origin. CTX-009 was well tolerated across all doses evaluated, with no dose-limiting toxicities reported. The most frequent treatment related adverse event was hypertension, observed in 17 patients of the 45 patients enrolled. Among those, 7 patients

reported Grade 3 hypertension and the rest had Grade 1 or Grade 2 (16%). Only 4 mild cases of pulmonary hypertension were reported that were all reversible, and CTX-009 demonstrated significant clinical activity as a stand-alone therapy. The majority (87%) of the patients enrolled in the study had ECOG performance status of 1; 42% (n=19) were patients with gastric cancer and 40% (n=18) were patients with colorectal cancer with a median of three prior lines of systemic anticancer therapies. Importantly, 62% of the patients enrolled were previously treated with anti-VEGF antibodies containing regimens. There were 4 partial responses (including three partial responses confirmed by RECIST 1.1 and one partial response which was unconfirmed) and 20 stable diseases among 39 evaluable patients. The confirmed overall response rate (ORR) across all dose levels tested (0.3 – 17.5mg/kg) was 8%, not including 1 unconfirmed partial response, and the disease control rate (DCR) across all dose levels was 62%. The ORR at the recommended phase 2 doses (RP2D) of 10.0-12.5 mg/kg was 19% (n=3/16) not including one unconfirmed partial response, and the DCR at the RP2D was 69% (n=11/16).

“This is a significant clinical result because current approved anti-angiogenic drugs have little efficacy as a monotherapy. Furthermore, 94% of the colorectal patients and 58% of the gastric patients in this study were previously treated with Avastin® (bevacizumab) or Cyramza® (ramucirumab), respectively; the response rate is almost three times that seen for current 3rd and 4th line therapies in patients with colorectal and gastric cancers.” said Jeeyun Lee, MD, a Professor at the Samsung Medical Center, Seoul, South Korea and the principal investigator of the study.

“The responses to CTX-009 as a monotherapy in this refractory patient population combined with the excellent tolerability profile suggests that CTX-009 can become an important drug for a broad range of solid tumors” said Thomas Schuetz, MD, PhD, CEO and scientific Founder of Compass Therapeutics. “We look forward to developing CTX-009 in the United States and other geographies and to unlocking its full potential”. Compass Therapeutics of Boston, Massachusetts holds the global rights to CTX-009 with the exception of S. Korea (rights held by Handok) and China (rights were out-licensed to Elpiscience Biopharma).

“We are pleased to present the clinical data of CTX-009 (ABL001) for the first time at a prominent international conference,” said Sang Hoon Lee, PhD, CEO of ABL Bio. “CTX-009 has demonstrated its potential to benefit cancer patients, especially those that have been unable to experience improvements with standard treatments. We expect to further validate the therapeutic value of CTX-009 as it progresses through clinical trials in the U.S., China and South Korea.”

“We are happy to see the next frontier of anti-angiogenic therapies, CTX-009 (ES104) showing promising anti-tumor activity in a Phase 1 study as monotherapy,” said Steve Chin, MD, CMO of Elpiscience Biopharma, “We look forward to initiating the clinical trials in China to explore its therapeutic potential in the heavily pre-treated digestive tract cancer patients.”

About CTX-009

CTX-009 (ABL001/ES104) 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. Pre-clinical and early clinical data of CTX-009 suggests 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 expansion study. Phase 1b and Phase 2 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' 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.

About ABL Bio

ABL Bio, Inc. (KOSDAQ: 298380) is a clinical-stage biotechnology company developing antibody therapeutics for immune-oncology and neurodegenerative diseases. With internal R&D and global partnerships, ABL has developed multiple bispecific antibody platforms, such as 'Grabody-T,' 'Grabody-I' and 'Grabody-B' and built an innovative pipeline of multiple clinical and pre-clinical stage drug candidates. In the oncology area, ABL has developed Grabody-T, a modular 4-1BB engaging platform that has demonstrated superior efficacy and safety. In the neurodegenerative disorder space, ABL has developed Grabody-B, which is designed to maximize blood-brain barrier (BBB) penetration. Grabody-B is applicable to various CNS targets across a plethora of neurological disorders, potentially providing a breakthrough to address the high unmet medical needs in neurodegeneration.

About Elpiscience BioPharma

Elpiscience is a clinical stage biopharmaceutical company focusing on innovating and developing the next generation of cancer immunotherapy. Elpiscience has developed a pipeline of globally innovative molecules, covering a wide range of targets with a particular focus on turning "cold" tumors "hot". The company has four assets in clinical stage (ES101, ES102, ES104 and ES002). Elpiscience's sustainable pipeline forms a strong cornerstone for

developing the next generation and more effective immunotherapies. Founded and managed by seasoned executives in the biopharma industry, Elpiscience is backed by renowned investors such as Lilly Asia Ventures, Hillhouse Capital, Hyfinity Investments, Greater Bay Area Homeland Development Fund, CDH, Cormorant Asset Management and Superstring Capital. Elpiscience endeavors to advance at least one world-class molecule into the clinic each year, providing clinical benefits to cancer patients worldwide.

Forward-Looking Statement

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 our product candidate, CTX-009, and the development 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, our ability to raise the additional funding we 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, our ability to identify additional product candidates for development, our ability to develop, complete clinical trials for, obtain approvals for and commercialize any of our product candidates, and competition in the industry in which we operate 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 we file with the SEC available at www.sec.gov.

COMPASS Contacts

Investor Inquiries
Vered Bisker-Leib
info@compasstherapeutics.com
+1 617 500 8099

Media Inquiries
Anna Gifford
media@compasstherapeutics.com
+1 617 500 8099

ABL Contacts

Investor Inquiries
Hyunjun Kim
investor.relations@ablbio.com
+82 31 8018 9845

Media Inquiries
Hee Jun Park
media.relations@ablbio.com
+82 31 8014 7032

ELPISCIENCE Contact
Judy Shi
judyshi@elpiscience.com
+86 21 50651310