Compass Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

March 15, 2023

- Initiated U.S. Phase 2/3 study of CTX-009 (DLL4 /VEGF-A bispecific antibody) in patients with advanced biliary tract cancers (BTC); initial results are expected in the first half of 2024
- Initiated U.S. Phase 2 study of CTX-009 in patients with advanced colorectal cancer (CRC) and dosed the first patient; initial results expected in the third quarter of 2023
- Presented results of the Phase 2 study of CTX-009 in combination with paclitaxel in patients with BTC at the 2023 ASCO GI Cancers Symposium
- Completed enrollment of the Phase 1 monotherapy arm of CTX-471 (CD137 agonistic antibody) and initiated enrollment in the combination arm of CTX-471 with KEYTRUDA® (pembrolizumab) in patients with select solid tumors; initial combination results are expected in the second half of 2023
- Completed GMP manufacturing and toxicology studies of CTX-8371 (PD-1 /PD-L1 bispecific antibody) in non-human primates; IND submission on track and planned for the first half of 2023
- Ended 2022 with $187 million in cash and marketable securities providing cash runway for the company into 2026, including $80 million in gross proceeds raised in a private investment in public equity (PIPE) financing executed in November 2022

BOSTON, March 15, 2023 (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 fourth quarter and full year 2022 financial results.

“Compass made tremendous progress last year as we advanced the development of our three drug candidate programs. Importantly, we initiated two key studies with CTX-009: a Phase 2/3 study in patients with biliary tract cancers and a Phase 2 study in patients with advanced colorectal cancer,” said Thomas J. Schuetz, MD, PhD, Co-Founder and Chief Executive Officer. “We look forward to initial results from the CTX-009 colorectal study and the CTX-471 combination study later this year and in 2024 for CTX-009 in BTC.”

“Completing the $80 million PIPE offering in the fourth quarter of 2022 has positioned us well to reach key milestones over the next year with continued investment in our pipeline programs,” said Vered Bisker-Leib, PhD, MBA, President and Chief Operating Officer.

Development Pipeline Update and Highlights:

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

- **Presented Phase 2 results of CTX-009 in combination with paclitaxel in patients with BTC at the 2023 ASCO GI Cancers Symposium**
  - Data showed 9 confirmed partial responses (PRs) for an overall response rate (ORR) of 37.5% in the second and third line settings (n= 24 patients dosed)
  - In the second line setting, an ORR of 63.6% in 11 patients treated was observed
  - Median progression free survival (PFS) was 9.4 months and median overall survival (OS) was 12.5 months
  - Safety and tolerability were consistent with prior studies
- **In January 2023, announced first patient dosed in the U.S. Phase 2 study of CTX-009 as a monotherapy in patients with metastatic colorectal cancer**
  - The study design is an Adaptive Simon Two-Stage, with Stage 1 of the study enrolling 37 patients. If there are 3 or more responses confirmed in Stage 1, the study will advance to Stage 2 and an additional 47 patients will be enrolled

- Patients are being evaluated for safety and tolerability, as well as clinical response
- Initial results from this study are expected in the third quarter of 2023

- **Initiated U.S. Phase 2/3 study of CTX-009 in combination with Paclitaxel in BTC**
  - The study will enroll 150 patients with BTC who have received one prior systemic therapy, randomized 2:1 to receive either CTX-009 combined with paclitaxel or paclitaxel alone
  - The primary endpoint of the study is ORR, and secondary endpoints include PFS, OS, clinical benefit rate (CBR) and duration of response (DOR)
  - Initial results from this study are expected in the first half of 2024

CTX-471 (CD137 agonistic monoclonal antibody)

- **Generated monotherapy evidence of activity for CTX-471**
  - Phase 1 of CTX-471 in patients with various metastatic or locally advanced solid tumors who initially benefited from a checkpoint blocker has been fully enrolled
  - Four PRs were observed in the monotherapy arm of the Phase 1 study, three of which were confirmed by RECIST 1.1

- **In November 2022, opened and dosed the first patient in the combination arm of the study of the Phase 1 study of CTX-471 with KEYTRUDA®**
  - This arm of the study is enrolling patients with metastatic or locally advanced cancers of the lung, head and neck and melanoma who have progressed after treatment with a checkpoint inhibitor. Patients enrolled in the study are treated with CTX-471 in combination with KEYTRUDA® with the goal of restoring a response
  - CTX-471 is supplied by Compass, which is the sponsor of the study, and KEYTRUDA® is provided by Merck under a clinical trial collaboration and supply agreement
  - Initial results from the combination arm are expected in the second half of 2023

CTX-8371 (PD-1 and PD-L1 bispecific antibody)

- **Completed GMP manufacturing campaign and toxicology studies in non-human primates**
  - An investigational new drug (IND) application is on track and planned for the first half of 2023

Financial Results

Net loss for the year ended December 31, 2022, was $39.2 million or $0.37 per share, compared to $82.2 million or $1.31 per share for the same period in 2021. The net loss for 2021 includes $50.6 million non-recurrent in-process R&D expense related to the acquisition of TRIGR Therapeutics which was completed in June 2021.

Research and development (R&D) Expenses

R&D expenses were $30.0 million for the year ended December 31, 2022, as compared to $20.3 million for the same period in 2021, an increase of $9.7 million or 47%. The increase for the year was primarily attributable to $10.3 million of project costs related to our three development programs (CTX-009, CTX-471 and CTX-8371) resulting from increased clinical, manufacturing, and toxicology activities.

General and Administrative (G&A) Expenses

G&A expenses were $11.7 million for the year ended December 31, 2022, as compared to $10.9 million for the same period in 2021, an increase of $0.7 million or 7%. The increase was primarily attributable to a higher stock compensation expense of $1.2 million, partially offset by lower legal costs of $0.5 million.

Cash Position

As of December 31, 2022, cash and marketable securities were $186.6 million as compared to $144.5 million as of December 31, 2021, providing the Company with an anticipated cash runway into 2026. During 2022, the Company increased its cash position by $80.3 million from financing activities that generated net proceeds of $75.8 million. The Company used $34.1 million of cash to fund operations.

Upcoming Investor Conferences

Compass management will participate at four upcoming investor conferences:

- **Cantor’s The Future of Oncology Virtual Symposium**

Date: April 3-5, 2023
Location: virtual

- **Stifel's Virtual Targeted Oncology Event**
  Date: April 25-26, 2023
  Location: virtual

- **Inaugural EF Hutton Global Conference**
  Date: May 10-11, 2023
  Location: The Plaza Hotel, New York, NY

- **2023 World Medical Innovation Forum (Bank of America and Mass General)**
  Date: June 12-14, 2023
  Location: Westin Seaport District, Boston

Live webcasts presentations, when available, will be under "News & Events" in the Investors section of the Company's website located at www.compasstherapeutics.com.

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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, their 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 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 SEC available at www.sec.gov, including without limitation Compass's latest Form 10-Q and subsequent filings with the SEC.

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Compass Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations
(In thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:	(unaudited)			
Research and development	$ 9,929	$ 9,574	$ 29,997	$ 20,337
General and administrative	2,959	3,426	11,658	10,927
In Process R&D	—	—	—	50,618
Total operating expenses	12,888	13,000	41,655	81,882
Loss from operations	(12,888)	(13,000)	(41,655)	(81,882)
Other income (expense), net	1,294	7	2,430	(299)
Loss before income tax expense	(11,594)	(12,993)	(39,225)	(82,181)

Income tax expense	—	13	—	—
Net loss	$ (11,594)	$ (12,980)	$ (39,225)	$ (82,181)
Net loss per share - basic and diluted	$ (0.10)	$ (0.15)	$ (0.37)	$ (1.31)

Compass Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(In thousands, except par value)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 34,946	$ 144,514
Marketable securities	151,663	—
Prepaid expenses and other current assets	8,182	2,591
Total current assets	194,791	147,105
Property and equipment, net	1,567	2,243
Operating lease, right-of-use ("ROU") asset	2,967	4,089
Other assets	320	320
Total assets	$ 199,645	$ 153,757
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,382	$ 867
Accrued expenses	11,690	8,775
Operating lease obligations, current portion	1,097	989
Total current liabilities	16,169	10,631
Operating lease obligations, long-term portion	1,838	3,048
Total liabilities	18,007	13,679
Total stockholders' equity	181,638	140,078
Total liabilities and stockholders' equity	$ 199,645	$ 153,757