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 31, 2023**

MERSANA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38129**	**04-3562403**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

840 Memorial Drive Cambridge, Massachusetts	**02139**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: **(617) 498-0020**

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 (see General Instruction A.2. below):

☐ 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	MRSN	The Nasdaq Stock Market LLC

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 31, 2023, Mersana Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has lifted the clinical hold that the FDA had previously placed on the Company's Phase 1 clinical trial of XMT-2056. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by the Company on October 31, 2023.
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 hereunto duly authorized.

MERSANA THERAPEUTICS, INC.

Date: October 31, 2023

By: /s/ Brian DeSchuytner
Senior Vice President, Chief Operating Officer and Chief Financial Officer

Exhibit 99.1

Mersana Therapeutics Announces FDA has Lifted Clinical Hold on Phase 1 Clinical Trial of XMT-2056

CAMBRIDGE, Mass., October 31, 2023 – Mersana Therapeutics, Inc. (NASDAQ: MRSN), a clinical-stage biopharmaceutical company focused on discovering and developing a pipeline of antibody-drug conjugates (ADCs) targeting cancers in areas of high unmet medical need, today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the company's Phase 1 clinical trial of XMT-2056. XMT-2056 is a systemically administered Immunosynthen STING-agonist ADC that is designed to target a novel human epidermal growth factor receptor 2 (HER2) epitope and locally activate STING signaling in both tumor-resident immune cells and in tumor cells, providing the potential to treat patients with HER2-high or -low tumors as monotherapy and in combination with standard-of-care agents.

"An in-depth analysis of cytokine, pharmacokinetic and other clinical data from patients enrolled in our Phase 1 trial indicated that XMT-2056 is a highly potent innate immune agonist," said Martin Huber, M.D., President and Chief Executive Officer of Mersana Therapeutics. "Based on these data and with patient safety at the forefront of our efforts, we have lowered the starting dose in our Phase 1 dose escalation design. We are pleased to have aligned with FDA on the path forward and are excited to have the opportunity to continue to investigate the potential of XMT-2056 and our Immunosynthen ADC platform in the clinic."

The multicenter Phase 1 open-label trial is investigating XMT-2056 in previously treated patients with advanced/recurrent solid tumors expressing HER2, including breast, gastric, colorectal and non-small-cell lung cancers. The dose escalation and dose expansion portions of the trial will evaluate and characterize the relationship of safety, tolerability and exposure of XMT-2056 and this candidate's preliminary anti-tumor activity, as measured by overall response rate, duration of response and disease control rate.

The FDA has granted orphan drug designation to XMT-2056 for the treatment of gastric cancer. In August 2022, Mersana entered into a global collaboration providing GSK plc with an exclusive option to co-develop and commercialize XMT-2056. GSK has not exercised this option to date.

About Mersana Therapeutics

Mersana Therapeutics is a clinical-stage biopharmaceutical company focused on the development of novel antibody-drug conjugates (ADCs) and driven by the knowledge that patients are waiting for new treatment options. The company has developed proprietary cytotoxic (Dolasynthen) and immunostimulatory (Immunosynthen) ADC platforms that are generating a pipeline of wholly-owned and partnered product candidates with the potential to treat a range of cancers. Its pipeline includes XMT-1660, a Dolasynthen ADC targeting B7-H4, and XMT-2056, an Immunosynthen ADC targeting a novel epitope of human epidermal growth factor receptor 2 (HER2). Mersana routinely posts information that may be useful to investors on the "Investors & Media" section of its website at www.mersana.com.

Forward-Looking Statements

This press release contains “forward-looking” statements and information within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will” and variations of these words or similar expressions, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements concerning the therapeutic potential of Mersana’s product candidates, including XMT-2056, and its product platforms, including its Immunosynthen platform; the design and objectives of Mersana’s Phase 1 clinical trial of XMT-2056; and Mersana’s collaboration with GSK. Mersana may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including, among other things, uncertainties inherent in research and development, in the initiation, advancement, progression and completion of clinical trials and in the clinical development of Mersana’s product candidates, including XMT-2056; the risk that Mersana may not realize the intended benefits of its platforms, technology and collaborations; whether the outcomes of preclinical studies will be predictive of clinical trial results; risks to clinical trial site initiation, patient enrollment and follow-up, as well as to Mersana’s abilities to meet other anticipated deadlines and milestones; and other important factors, any of which could cause Mersana’s actual results to differ from those contained in the forward-looking statements, that are described in greater detail in the section entitled “Risk Factors” in Mersana’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (“SEC”) on August 8, 2023, as well as in other filings Mersana may make with the SEC in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and Mersana expressly disclaims any obligation to update any forward-looking statements contained herein, whether because of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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