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): **June 15, 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 June 15, 2023, Mersana Therapeutics, Inc. issued a press release announcing a partial clinical hold on its UP-NEXT and UPGRADE-A clinical trials and refining timing expectations for its anticipated top-line data disclosure from its UPLIFT clinical trial. 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 June 15, 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: June 15, 2023

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

Exhibit 99.1

Mersana Therapeutics Announces Partial Clinical Hold on UP-NEXT and UPGRADE-A Clinical Trials

UPLIFT top-line data expected by early August

CAMBRIDGE, Mass., June 15, 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 issued a partial clinical hold pausing new patient enrollment in UP-NEXT and UPGRADE-A, the company's ongoing clinical trials of UpRi in platinum-sensitive ovarian cancer. UPLIFT, Mersana's ongoing clinical trial of UpRi in platinum-resistant ovarian cancer, completed enrollment in October 2022. Patients who are already enrolled in these trials may continue receiving UpRi. Mersana expects to lock its UPLIFT clinical trial database and disclose UPLIFT top-line data by early August.

The partial clinical hold follows a submission by Mersana of a recent aggregate safety report of all patients dosed with UpRi (approximately 560 patients) evaluating bleeding events. As noted in FDA guidance, aggregate analyses generally become more informative as a drug progresses through development and accumulates data. Detection of a clinically meaningful risk, particularly in single-arm clinical trials, typically requires a large safety database to detect differences in rates of adverse events compared to those that are expected in the population being studied.

Although data on the background rate of bleeding in platinum-resistant ovarian cancer are limited, Mersana's recent assessment determined that serious bleeding events appear to occur at a higher rate than background. While most bleeding cases in this aggregate safety analysis were low-grade, five (<1%) Grade 5 (fatal) bleeding events were observed among the approximately 560 patients dosed to date. The causes of bleeding events remain under investigation.

"Patient safety is always at the forefront for us, and work is now underway to compile further analyses that may inform FDA," said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. "Additionally, with UPLIFT top-line data on the near-term horizon, we will soon have a much more complete assessment of both the efficacy and safety profile for UpRi in platinum-resistant ovarian cancer."

The company is awaiting the FDA's written correspondence regarding the partial clinical hold and expects the FDA will request a comprehensive assessment of UpRi safety data, inclusive of bleeding events. In addition, Mersana plans to submit to the FDA the UPLIFT safety and efficacy data once available. The company plans to seek alignment with the FDA to lift the partial clinical hold and resume enrollment in UP-NEXT and UPGRADE-A.

About Mersana Therapeutics

Mersana Therapeutics is a clinical-stage biopharmaceutical company using its differentiated and proprietary ADC platforms to rapidly develop novel ADCs with optimal efficacy, safety and tolerability to meaningfully improve the lives of people fighting cancer. Mersana's lead product candidate, upifitamab rilsodotin (UpRi), is a Dolaflexin ADC targeting NaPi2b that is being studied in UPLIFT, a single-arm registrational trial in patients with platinum-resistant ovarian cancer; UPGRADE-A, a Phase 1 clinical trial evaluating UpRi in combination with carboplatin; and UP-NEXT, a Phase 3 clinical trial of UpRi as monotherapy maintenance following treatment with platinum doublets in recurrent platinum-sensitive ovarian cancer. Mersana's pipeline also includes XMT-1660, a Dolasynthen ADC targeting B7-H4 in a Phase 1 clinical trial, and XMT-2056, an Immunosynthen ADC targeting a novel epitope of human epidermal growth factor receptor 2 (HER2), in addition to other earlier-stage assets. In addition, multiple partners are using Mersana's platforms to advance their ADC pipelines. 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 Mersana’s expectations regarding the timing of database lock and top-line data disclosure from its UPLIFT clinical trial; the rate of occurrence of serious bleeding events in patients dosed with UpRi; Mersana’s ongoing investigation of the causes of bleeding events; anticipated communications and interactions with the FDA; Mersana’s ability to align with the FDA and any future lift of the partial clinical hold on and resumption of enrollment in Mersana’s UP-NEXT and UPGRADE-A clinical trials; and the development and potential of Mersana’s product candidates, platforms, technology and pipeline of ADC candidates. 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 advancement, progression and completion of clinical trials and in the clinical development of Mersana’s product candidates, including UpRi; the risks that Mersana may be unable to resolve the partial clinical hold with respect to its UP-NEXT and UPGRADE-A clinical trials and may not be able to continue to advance those trials or to develop or commercialize UpRi; uncertainties related to regulatory interactions, applications and related filing and approval timelines; the possibility of unfavorable results from clinical trials; whether initial, interim or top-line results from a clinical trial will be predictive of the final results of the trial or the results of future trials; the risk that Mersana may not realize the intended benefits of its platforms, technology and collaborations; 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 May 9, 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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