
**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): **July 26, 2023**

MERSANA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38129
(Commission
File Number)

04-3562403
(IRS Employer
Identification No.)

840 Memorial Drive
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02139
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 2.02 Results of Operations and Financial Condition.

On July 27, 2023, Mersana Therapeutics, Inc. (the “Company” or “Mersana”) shared with investors the amount of cash, cash equivalents and marketable securities it had on hand as of June 30, 2023. Although the Company has not finalized its financial results for the three and six months ended June 30, 2023, the Company preliminarily estimates that its cash, cash equivalents and marketable securities as of June 30, 2023 was \$286.6 million.

The information in this Item 2.02 is unaudited and preliminary and does not present all information necessary for an understanding of the Company’s financial condition as of June 30, 2023 and its results of operations for the three and six months ended June 30, 2023. The Company’s actual consolidated cash, cash equivalents and marketable securities balance as of June 30, 2023 may differ from this estimate due to the completion of the Company’s quarter-end closing and financial reporting procedures.

The information furnished in this Item 2.02 shall not be deemed to be “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 such information be deemed incorporated by reference in any filing by the Company with the Securities and Exchange Commission (“SEC”) under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, regardless of any general incorporation language contained in such filing, except as expressly set forth by specific reference in such a filing.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On July 27, 2023, the Company announced decisions to reprioritize its areas of focus and to discontinue its clinical development of upifitamab rilsodotin (“UpRi”) following an evaluation of top-line data from the Company’s UPLIFT Phase 2 clinical trial of UpRi in patients with platinum-resistant ovarian cancer, which did not meet its primary endpoint. In connection with these decisions, on July 26, 2023, the Company’s board of directors approved certain expense reduction measures, including a reduction of approximately 50% of the Company’s current employee base (the “Restructuring”). The Restructuring is expected to be complete by the end of 2023.

As a result of the Restructuring, the Company estimates that it will incur approximately \$7-8 million in costs resulting from cash expenditures consisting of severance and benefit payments, notice pay, outplacement services and related expenses. The estimate of costs that the Company expects to incur and the expected timing to complete the Restructuring are subject to a number of assumptions, and actual results may differ. The Company may also incur other cash or non-cash charges or cash expenditures not currently contemplated due to events that may occur as a result of, or in association with, the Restructuring.

Item 7.01 Regulation FD Disclosure.

On July 27, 2023, the Company issued a press release announcing top-line data from its UPLIFT Phase 2 clinical trial of UpRi in patients with platinum-resistant ovarian cancer, its strategic reprioritization, the Restructuring and the Company’s expectation that its available funds will be sufficient to fund the Company’s operating plan commitments into 2026, a copy of which press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company with the SEC under the Securities Act or the Exchange Act, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.*UPLIFT Top-Line Data*

On July 27, 2023, the Company announced that its Phase 2 UPLIFT clinical trial of UpRi did not meet its primary endpoint. UpRi is an antibody-drug conjugate (“ADC”) targeting the sodium-dependent phosphate transport protein NaPi2b and was developed utilizing the Company’s Dolaflexin platform.

UPLIFT was a single-arm clinical trial that enrolled platinum-resistant ovarian cancer patients with one to four prior treatment regimens. The primary endpoint for UPLIFT was the investigator-assessed objective response rate (“ORR”) in the NaPi2b-positive population. NaPi2b-positive status was defined by a tumor proportion score (“TPS”) of $\geq 75\%$. Secondary endpoints for the trial included the investigator-assessed ORR among all patients in the trial, duration of response (“DOR”), and safety and tolerability. The trial also included an assessment of ORR and DOR by independent radiology review (“IRR”).

UPLIFT enrolled a total of 268 patients, 141 of whom were determined to be NaPi2b positive. The median prior lines of systemic therapy among all patients was three, with 31% of the population having received four prior lines of treatment. Additionally, 84% of patients received prior bevacizumab and 69% received prior PARP inhibitor treatment.

Top-line results from UPLIFT as of the May 31, 2023 data cutoff date are as follows:

NaPi2b-Positive Population (n=141)

	Investigator Assessment	IRR Assessment
ORR, n (%) [95% confidence interval]	22 (15.6%) [10.0%, 22.7%]	23 (16.3%) [10.6%, 23.5%]
Partial Response, n (%)	20 (14.2%)	16 (11.3%)
Complete Response, n (%)	2 (1.4%)	7 (5.0%)
Median DOR, months	7.4	Not Reached

Total Population (n=268)

	Investigator Assessment	IRR Assessment
ORR, n (%)	35 (13.1%)	35 (13.1%)
Partial Response, n (%)	32 (11.9%)	24 (9.0%)
Complete Response, n (%)	3 (1.1%)	11 (4.1%)
Median DOR, months	7.4	10.7

Safety and tolerability data in UPLIFT were generally consistent with the Company's prior disclosures. Following the completion of its analyses, the Company plans to share detailed efficacy and safety data with the medical and scientific community in an appropriate forum.

While the duration of response observed in UPLIFT was longer than that observed in the dose expansion portion of the Company's Phase 1b clinical trial of UpRi, the lower bound of the confidence interval for the primary endpoint did not meet the Company's goal of excluding a 12% ORR seen with standard-of-care single-agent chemotherapy. The Company is in the process of conducting an in-depth analysis of various factors to better understand the results, as well as the characteristics of patients who responded to UpRi therapy, particularly those whose responses were deep and durable.

Strategic Reprioritization

On July 27, 2023, the Company further announced that its primary focus moving forward would be on advancing product candidates and collaborations utilizing its next-generation ADC platforms, Dolasynthen and Immunosynthen. The Company plans to complete the dose escalation portion of its Phase 1 clinical trial of XMT-1660 in 2023 and initiate the dose expansion portion of the trial in 2024. The Company continues working diligently to address the clinical hold on its Phase 1 clinical trial of XMT-2056.

The Company plans to wind-down UpRi-related development activities, including its UP-NEXT and UPGRADE-A clinical trials and the Company's regulatory and commercial readiness efforts. If analyses of data enable the identification of a path forward for UpRi, the Company will consider strategic alternatives for the asset, including partnering.

Forward-Looking Statements

This Current Report on Form 8-K (this “Report”) 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 Company’s further data analysis related to its clinical evaluation of UpRi and the presentation of UPLIFT trial data; its strategic priorities; its restructuring plans, including with respect to discontinuing clinical development of UpRi and related efforts and reducing its workforce; any potential path forward for UpRi and consideration of potential strategic alternatives for this asset; plans regarding the clinical development of XTM-1660; the Company’s efforts to address the clinical hold on XMT-2056; the Company’s cash runway; the Company’s financial closing procedures and its expectations to report additional financial information for the period ended June 30, 2023; and the development and potential of the Company’s product candidates, platforms, technology and pipeline of ADC candidates. The Company 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 the Company’s product candidates, including XMT-1660 and XMT-2056; the risks that the Company may be unable to resolve the clinical hold with respect to its Phase 1 clinical trial of XMT-2056 and may not be able to resume that trial or to develop or commercialize XMT-2056; the occurrence of impediments to the Company’s ability to execute its planned restructuring and strategic reprioritization as currently contemplated; the risk that restructuring costs and charges may be greater than anticipated; the risk that the Company’s restructuring efforts may adversely affect its ability to retain skilled and motivated personnel and may be distracting to employees and management; the risk that the Company’s restructuring efforts may negatively impact its business operations and reputation; the risk that the Company’s restructuring efforts may not generate their intended benefits to the extent or as quickly as anticipated; the risk that the Company may not realize the intended benefits of its platforms, technology and collaborations; and other important factors, any of which could cause the Company’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 the Company’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 the Company may make with the SEC in the future. Any forward-looking statements contained in this Report speak only as of the date hereof, and the Company 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press Release issued by the Company on July 27, 2023.
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104	Cover Page Interactive Data File (embedded within the Inline XBRL document).
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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: July 27, 2023

By: /s/ Brian DeSchuytner

Brian DeSchuytner

Senior Vice President, Chief Financial Officer

Mersana Therapeutics Announces Topline Data from UPLIFT Clinical Trial in Patients with Platinum-Resistant Ovarian Cancer and Strategic Reprioritization

- UPLIFT clinical trial did not meet its primary endpoint
- Company realigns focus and significantly reduces expenses to extend cash runway into 2026
- Conference call today at 8:00 a.m. ET

Cambridge, Mass., July 27, 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 UPLIFT clinical trial of upifitamab rilsodotin (UpRi) did not meet its primary endpoint. UpRi is an ADC targeting the sodium-dependent phosphate transport protein NaPi2b and was developed utilizing the company's Dolaflexin platform.

UPLIFT was a single-arm clinical trial that enrolled platinum-resistant ovarian cancer patients with one to four prior treatment regimens. The primary endpoint for UPLIFT was the investigator-assessed objective response rate (ORR) in the NaPi2b-positive population. NaPi2b-positive status was defined by a tumor proportion score (TPS) of $\geq 75\%$. Secondary endpoints for the trial included the investigator-assessed ORR among all patients in the trial, duration of response (DOR), and safety and tolerability. The trial also included an assessment of ORR and DOR by independent radiology review (IRR).

UPLIFT enrolled a total of 268 patients, 141 of whom were determined to be NaPi2b positive. The median prior lines of systemic therapy among all patients was three, with 31% of the population having received four prior lines of treatment. Additionally, 84% of patients received prior bevacizumab and 69% received prior PARP inhibitor treatment.

Top-line results from UPLIFT as of the May 31, 2023 data cutoff date are as follows:

NaPi2b-Positive Population (n=141)

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Median DOR, months	7.4	10.7

Safety and tolerability data in UPLIFT were generally consistent with prior disclosures. Following the completion of its analyses, the company plans to share detailed efficacy and safety data with the medical and scientific community in an appropriate forum.

“We are deeply disappointed that UPLIFT’s efficacy failed to replicate previous data from approximately 100 patients in the dose expansion portion of our Phase 1b clinical trial,” said Dr. Arvin Yang, Senior Vice President and Chief Medical Officer of Mersana Therapeutics. “While the duration of response was longer than that from the dose expansion portion of UpRi’s Phase 1b clinical trial, the lower bound of the confidence interval for the primary endpoint did not meet our goal of excluding a 12% ORR seen with standard-of-care single-agent chemotherapy. We are in the process of conducting an in-depth analysis of various factors to better understand the results as well as the characteristics of patients who responded to UpRi therapy, particularly those whose responses were deep and durable. We extend our deepest gratitude to all of the patients, family members, caregivers and investigators who contributed to UPLIFT.”

Strategic Reprioritization and Financial Update

“As an organization driven by a mission to discover and develop potentially life-changing ADCs for patients fighting cancer, UPLIFT’s outcome is clearly disappointing and requires us to reprioritize our areas of focus,” said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. “In recent years, Mersana has advanced new product candidates and developed new partnerships utilizing its next-generation ADC platforms, Dolasynthen and Immunosynthen. These will be our primary focus moving forward. We plan to complete the dose escalation portion of our Phase 1 clinical trial of XMT-1660 in 2023 and initiate the dose expansion portion of the trial in 2024. Our team continues working diligently to address the clinical hold on the Phase 1 clinical trial of XMT-2056. Additionally, we intend to strongly support Mersana’s collaborators as they leverage our next-generation ADC platforms and advance their product candidates.”

“We also are taking decisive action to extend our cash runway and ensure we have the resources to evaluate the clinical potential of our next-generation ADC product candidates,” Ms. Protopapas continued. “Unfortunately, this necessitates reducing our workforce by approximately 50%. A very talented group of employees who helped to build Mersana will be departing as a result of this strategic reprioritization. We are grateful for their many contributions and intend to provide strong support through their transition.”

Mersana’s restructuring plan includes a wind-down of UpRi-related development activities, including its UP-NEXT and UPGRADE-A clinical trials and the company’s regulatory and commercial readiness efforts. If analyses of data enable the identification of a path forward for UpRi, the company will consider strategic alternatives for the asset, including partnering.

Mersana estimates that its balance of cash, cash equivalents and marketable securities as of June 30, 2023 was \$286.6 million. This figure is preliminary and is subject to completion of the company’s financial closing procedures. The company expects to report its cash, cash equivalents and marketable securities, as well as other information necessary for a complete understanding of its financial position, in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2023. The company expects that its available funds will be sufficient to support its current operating plan commitments into 2026.

Conference Call Notice

Mersana will host a conference call today at 8:00 a.m. ET. To access the call, please dial (877) 270-2148 (domestic) or (412) 902-6510 (international). A live webcast of the presentation will be available on the Investors & Media section of the Mersana website at www.mersana.com, and a replay of the webcast will be available in the same location following the conference call for approximately 90 days.

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

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