

**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): **May 10, 2021**

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, MA 02139
Cambridge, MA**

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:

- 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 Global Select Market

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 May 10, 2021, Mersana Therapeutics, Inc., issued a press release announcing its financial results for the first quarter ended March 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
<u>99.1</u> 104	<u>Press Release by Mersana Therapeutics, Inc., on May 10, 2021</u> The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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: May 10, 2021

By: /s/ Brian DeSchuytner
Brian DeSchuytner
Senior Vice President, Finance & Product Strategy

Mersana Therapeutics Announces First Quarter 2021 Financial Results and Provides Business Update

- Initiated UPLIFT single-arm registration strategy for evaluation of UpRi in platinum-resistant ovarian cancer

- Ended first quarter of 2021 with \$228 million in cash

CAMBRIDGE, Mass., May 10, 2021 -- 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 reported financial results for the first quarter ended March 31, 2021 and provided a business update.

“The recent initiation of UPLIFT, a single-arm registrational strategy evaluating UpRi in platinum-resistant ovarian cancer, speaks to the team’s commitment to achieving key milestones and dedication to developing therapies for people living with cancer. We believe UpRi has demonstrated promising activity and a differentiated tolerability profile in studies to date in patients with heavily-pretreated ovarian cancer and limited options. UPLIFT has been designed to increase the potential for label differentiation, speed to market, and the probability of success. We also remain on track to initiate the UPGRADE umbrella combination study in the third quarter of 2021 as a first step in bringing UpRi to patients in earlier lines of therapy and establishing UpRi as a foundational medicine in ovarian cancer,” said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. “We are excited to continue this productive year by building out our maturing pipeline of innovative ADC candidates with the potential to address unmet medical needs across multiple different tumor types.”

Recent Highlights and Anticipated Milestones

Upifitamab Rilsodotin (UpRi, previously XMT-1536), first-in-class Dolaflexin ADC targeting NaPi2b:

- **Initiated UPLIFT, a single-arm registration strategy in platinum-resistant ovarian cancer.** In April 2021, the Company announced the initiation of patient dosing in UPLIFT, a single-arm registration strategy evaluating the safety and efficacy of UpRi in patients with platinum-resistant ovarian cancer who have received up to four lines of therapy. Consistent with the bevacizumab label, patients previously treated with three or four lines of therapy may enroll without regard to prior bevacizumab treatment. There is no exclusion for patients with baseline peripheral neuropathy. Patients may enroll without regard to NaPi2b expression; however, the role of the biomarker will be evaluated. The primary endpoint will be the objective response rate (ORR) in the high NaPi2b population and the secondary endpoints will be the ORR regardless of NaPi2b expression, as well as duration of response and safety. UPLIFT is an amendment to the ongoing multinational, multi-center, open label study protocol, and the Company expects to enroll approximately 100 patients with high NaPi2b expression and up to 180 patients overall.
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- **In April 2021, the Company announced its plans to use Tumor Proportion Score (TPS) greater than or equal to 75% as the predefined threshold for high NaPi2b expression in UPLIFT.** In the ovarian cancer expansion study data presented to date, $TPS \geq 75\%$ resulted in an objective response rate (ORR) of 39% in high NaPi2b patients relative to an ORR of 28% in the overall population. As part of its diagnostic development plan, the Company evaluated TPS methodology in the expansion portion of the Phase 1 study in ovarian cancer and demonstrated that TPS captures a broad dynamic range of expression values, enriches for response, and offers reproducibility advantages across commercial labs. The Company also disclosed the steps it has taken to develop a robust, predictive and reproducible commercial diagnostic assay which will be used in a prospectively defined retrospective analysis in UPLIFT.
- **UPGRADE combination dose escalation umbrella study in ovarian cancer expected to initiate in the third quarter of 2021.** The Company plans to initiate the UPGRADE study in the third quarter of 2021 to evaluate the combination of UpRi with other agents, starting with a platinum combination. The Phase 1, open-label, dose-escalation portion of the study will determine the maximum tolerated dose (MTD) and safety and tolerability of a once-every-four-week (Q4W) administration of UpRi in combination with Q4W administration of carboplatin for six cycles followed by UpRi monotherapy in platinum-sensitive patients with high-grade serous ovarian cancer who have received 1-2 prior platinum-based regimens. Patients will not be preselected for NaPi2b expression; however, archival or fresh tissue will be required for retrospective assessment of expression. Upon completion of the dose-escalation portion of the study, the Company plans to initiate the expansion portion in combination with carboplatin for six cycles followed by UpRi monotherapy to assess feasibility as well as efficacy to inform next steps in this broader and less heavily- pretreated patient population.
- **NSCLC adenocarcinoma cohort of the expansion portion of Phase 1 study continues to enroll patients.** The Company is on track to recruit approximately 40 patients in the expansion phase of the study. The Company plans to report interim data in the second half of 2021.

XMT-1592, first Dolasynthen ADC targeting NaPi2b:

- **Phase 1 dose escalation study of XMT-1592 is ongoing, with interim data anticipated in the second half of 2021.** The Company has exceeded the maximum tolerated dose and continues to further explore dose and schedule. The Company plans to disclose interim data in the second half of 2021 and further outline the XMT-1592 development plan in NSCLC in the fourth quarter of 2021.
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XMT-1660, first-in-class Dolasynthen ADC targeting B7-H4:

- **Investigational New Drug (IND)-enabling studies of XMT-1660 ongoing with Phase 1 studies expected to start in early 2022.** B7-H4 is expressed in high unmet need tumors such as breast, endometrial and ovarian. B7-H4 is expressed on both tumor cells and immunosuppressive tumor-associated macrophages (TAMs). This provides the potential for both a direct, cytotoxic antitumor effect as well as for additional payload delivery to the tumor microenvironment that can further contribute to immunogenic cell death, dendritic cell activation, and stimulation of an immune response consistent with the features of the Company's unique DolaLock payload. In a poster presented at the Virtual 2021 American Association for Cancer Research (AACR) Annual Meeting in April, the Company presented preclinical data demonstrating XMT-1660's superior efficacy compared to other potential candidate B7-H4 ADCs, covering a range of drug-to-antibody ratios, in multiple triple-negative breast cancer models as well as a ER+/HER2- breast cancer model. These data further support the clinical development of XMT-1660 for the treatment of B7-H4-expressing tumors.

XMT-2056, first Immunosynthen STING-agonist ADC:

- **IND-enabling studies of XMT-2056 ongoing with Phase 1 studies expected to start in early 2022.** In April 2021, the Company presented two posters at AACR highlighting preclinical efficacy of XMT-2056 as well as mechanistic data representative of the Immunosynthen platform. These data demonstrated the differentiation of XMT-2056 and its ability to induce robust anti-tumor immune activity, with only minimal increases in systemic cytokine levels, and a significant benefit over the benchmark IV-administered free STING-agonist in mice. Preclinical mechanistic data suggests that the tumor cell-intrinsic STING pathway can be activated in the presence of cues from immune cells, a potential key differentiator from other innate immune activation approaches. Further, *in vitro* studies showed that blocking Type III interferons (IFNs) inhibits the production of key cytokines and cancer cell killing induced by STING-agonist ADC treatment, pointing to a potentially important role for Type III IFNs in anti-tumor immune responses downstream of STING pathway activation in tumor cells. The Company plans to disclose the target for the XMT-2056 in the fourth quarter of 2021.

Corporate

- **Appointed Alejandra Carvajal as Senior Vice President and Chief Legal Officer.** Ms. Carvajal was most recently the Chief Legal Officer, General Counsel & Secretary at Momenta Pharmaceuticals, where she led the company's legal operations through both business restructuring and successful execution of an acquisition by Johnson & Johnson for \$6.5 billion. She also served as a key strategic legal partner in the company's financing, business development, and contractual decision-making efforts. Prior to joining Momenta, Ms. Carvajal served as the Vice President, General Counsel at Cerulean Pharma. Previously, she worked at Millennium Pharmaceuticals in several positions of increasing seniority.
 - **Appointed Allene Diaz to Board of Directors.** Ms. Diaz has over thirty years of experience in the pharmaceutical industry most recently serving as Senior Vice President of R&D portfolio management and decision sciences at GlaxoSmithKline. She previously held senior strategic product planning and commercial roles at Tesaro and Merck KGaA. She has contributed to the development, launch and commercialization of multiple global cancer therapies. Ms. Diaz is currently on the board of both BCLS Acquisition Corporation and Allena Pharmaceuticals, having previously served as a non-executive director at Erytech for three years before her current board positions.
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Upcoming Events

- Mersana will participate in a virtual presentation at the Jefferies Healthcare Conference scheduled for June 1-4, 2021.
- A Trial in Progress poster detailing the design of the UPLIFT single-arm registration strategy evaluating UpRi in platinum resistant ovarian cancer will be presented at the American Society of Clinical Oncology (ASCO) Virtual Annual Meeting scheduled for June 4-8, 2021.

First Quarter 2021 Financial Results

Cash and cash equivalents as of March 31, 2021, were \$228.4 million, compared to \$255.1 million in cash and cash equivalents as of December 31, 2020. In addition, the Company has the option to draw additional funds through its debt financing agreement with Silicon Valley Bank.

Net cash used in operating activities in the first quarter of 2021 was \$27.0 million. The Company expects that its available funds will be sufficient to support its operating plan commitments for approximately two years.

- Research and development expenses for the first quarter of 2021 were approximately \$27.4 million, compared to \$12.2 million for the same period in 2020. The difference was primarily due to an increase in UpRi and XMT-1592 manufacturing, clinical and regulatory expenses, an increase in manufacturing activities for preclinical and discovery stage programs and an increase in headcount. Non-cash stock-based compensation expense included in research and development expenses increased by \$1.5 million, primarily related to an increase in the valuation of stock-based awards as a result of stock appreciation.
- General and administrative expenses for the first quarter of 2021 were approximately \$7.2 million, compared to \$4.9 million during the same period in 2020 primarily due to an increase in headcount and consulting and professional fees. Non-cash stock-based compensation expense included in general and administrative expenses increased by \$0.9 million, primarily related to an increase in the valuation of stock-based awards as a result of stock appreciation.
- Net loss for the first quarter of 2021 was \$34.7 million, or \$0.50 per share, compared to net loss of \$16.9 million, or \$0.35 per share, for the same period in 2020. Weighted average common shares outstanding for the quarters ended March 31, 2021 and March 31, 2020 were 68,987,857 and 47,988,630, respectively.

Conference Call Details

Mersana Therapeutics will host a conference call and webcast today at 4:30 p.m. ET to report financial results for the first quarter 2021 and provide certain business updates. To access the call, please dial 877-303-9226 (domestic) or 409-981-0870 (international) and provide the Conference ID 5046849. A live webcast of the presentation will be available on the Investors & Media section of the Mersana website at www.mersana.com.

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 and is being studied in UPLIFT, a single-arm registration strategy in patients with platinum-resistant ovarian cancer, as well as in the expansion portion of a Phase 1 proof-of-concept clinical study in patients with NSCLC adenocarcinoma. XMT-1592, Mersana's second ADC product candidate targeting NaPi2b-expressing tumors, was created using Mersana's customizable and homogeneous Dolasynthen platform and is in the dose escalation portion of a Phase 1 proof-of-concept clinical study. The Company's early-stage programs include XMT-1660, a Dolasynthen ADC targeting B7-H4, as well as XMT-2056, a STING-agonist ADC developed using the Company's Immunosynthen platform. In addition, multiple partners are using Mersana's Dolaflexin platform to advance their ADC pipelines.

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of federal securities laws. These forward-looking statements are not statements of historical facts and are based on management's beliefs and assumptions and on information currently available to management. Forward-looking statements include information concerning the Company's business strategy and the design, progression and timing of its clinical trials and the release of data from those trials, the ability of the single-arm UPLIFT cohort to enable registration, the development and potential of our pipeline of innovative ADC candidates, expectations regarding future clinical trial results, including with respect to the timing of the commencement and future disclosures, and the sufficiency of the Company's cash on hand and funds available through its debt financing agreement with Silicon Valley Bank. Forward-looking statements generally can be identified by terms such as "aims," "anticipates," "believes," "contemplates," "continues," "could," "designed to," "efforts," "estimates," "expects," "goal," "intends," "may," "on track," "opportunity," "plans," "poised for," "possible," "potential," "predicts," "projects," "promises to be," "seeks," "should," "strategy," "target," "will," "would" or similar expressions and the negatives of those terms. Forward-looking statements represent management's beliefs and assumptions only as of the date of this press release. The Company's operations involve risks and uncertainties, many of which are outside its control, and any one of which, or combination of which, could materially affect its results of operations and whether the forward-looking statements ultimately prove to be correct. Factors that may materially affect the Company's results of operations and whether these forward-looking statements prove to be correct include, among other things, that the results of our ongoing or future clinical studies may be inconclusive with respect to the efficacy of our product candidates, that we may not meet clinical endpoints with statistical significance or there may be safety concerns or adverse events associated with our product candidates, that preclinical testing or early clinical results may not be predictive of the results or success of ongoing or later preclinical or clinical studies, that the identification, development and testing of the Company's product candidates and new platforms will take longer and/or cost more than planned, and that our clinical studies may not be initiated or completed on schedule, if at all, as well as those listed in the Company's Annual Report on Form 10-K filed on February 26, 2021, with the Securities and Exchange Commission ("SEC"), and subsequent SEC filings. In addition, while we expect that the COVID-19 pandemic might adversely affect the Company's preclinical and clinical development efforts, business operations and financial results, the extent of the impact on the Company's operations and the value of and market for the Company's common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, physical distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

Mersana Therapeutics, Inc.
Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	March 31,	December 31,
	2021	2020
Cash and cash equivalents	\$ 228,430	\$ 255,094
Working capital ⁽¹⁾	197,033	228,577
Total assets	247,911	273,399
Total stockholders' equity	197,938	228,087

⁽¹⁾ The Company defines working capital as current assets less current liabilities. See the Company's condensed consolidated financial statements for further detail regarding its current assets and current liabilities.

Mersana Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share data)
(unaudited)

	Three months ended	
	March 31, 2021	March 31, 2020
Collaboration revenue	\$ 11	\$ 11
Operating expenses:		
Research and development	27,415	12,219
General and administrative	7,208	4,936
Total operating expenses	34,623	17,155
Total other income (expense), net	(81)	218
Net loss	\$ (34,693)	\$ (16,926)
Net loss per share attributable to common stockholders — basic and diluted	\$ (0.50)	\$ (0.35)
Weighted-average number of common shares used in net loss per share attributable to common stockholders — basic and diluted	68,987,857	47,988,630

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Contact:

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