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): November 9, 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.)

02139

(Zip Code)

840 Memorial Drive Cambridge, MA

(Address of principal executive offices)

(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:

		Name of each exchange on which
Title of each class	Trading Symbol(s)	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 \Box

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 November 9, 2021, Mersana Therapeutics, Inc., issued a press release announcing its financial results for the third quarter ended September 30, 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>	Press Release by Mersana Therapeutics, Inc., on November 9, 2021				
104	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.

By: /s/ Brian DeSchuytner Brian DeSchuytner

Chief Financial Officer

Date: November 9, 2021

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

- Reported updated data from the UpRi ovarian cancer expansion cohort further bolstering confidence in UPLIFT registration strategy
- Introduced UP-NEXT, a Phase 3 study of UpRi monotherapy maintenance in platinum-sensitive ovarian cancer
- Presented preclinical data for XMT-2056, a HER2-targeted Immunosynthen STING-agonist ADC, demonstrating robust activity and broad combination potential
- Ended third quarter with approximately \$192 million in cash and equivalents; strengthened financial flexibility with new credit facility of up to \$100 million

CAMBRIDGE, Mass., November 9, 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 third quarter ended September 30, 2021 and provided a business update.

"We have made significant progress towards our vision of building UpRi into a foundational medicine in ovarian cancer and advancing a diverse pipeline addressing areas of high unmet medical need. Over the course of next year, we expect UPLIFT to be fully enrolled, UP-NEXT to be initiated and enrolling, UPGRADE to be charting the path in combinations and to have multiple assets in the clinic addressing a diverse set of targets," said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. "Our promising pipeline assets are generated by our innovative platforms Dolaflexin, Dolasynthen and Immunosynthen, which act as efficient product engines creating value now and into the future."

Recent Highlights and Anticipated Milestones

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

• **Reported updated interim data in almost 100 patients from the UpRi ovarian cancer expansion cohort.** Data continued to demonstrate a clinically meaningful and consistent profile for UpRi with a confirmed objective response rate (ORR) of 34% in the two-thirds of patients with NaPi2b high ovarian cancer. Data continued to show a differentiated tolerability profile for UpRi without the severe neutropenia, neuropathy and ocular toxicities seen with other ADC platforms. These data support the potential for UpRi to demonstrate a clinically meaningful benefit in the ongoing registration-enabling UPLIFT study in platinum-resistant ovarian cancer, a setting in which the single-agent chemotherapy standard of care has an ORR of no more than 12% and carries substantial toxicities.

- **Introduced UP-NEXT, a Phase 3 study of UpRi monotherapy maintenance, informed by FDA feedback.** UP-NEXT is designed to establish UpRi as a maintenance agent following treatment with platinum doublets in platinum-sensitive ovarian cancer. Watch-and-wait remains the standard of care for patients who have previously received or are poorly served by existing maintenance agents, as well as patients who achieve only stable disease to platinum doublets. UP-NEXT is designed to provide data to address these unmet needs. The Company plans to provide more details on the final design of UP-NEXT and expects to initiate the study in 2022.
- **UPLIFT, a single-arm registration study in platinum-resistant ovarian cancer, continues to enroll.** UPLIFT is enrolling a broader population of patients with platinum-resistant ovarian cancer than other studies in this indication through more flexible inclusion criteria with respect to lines of therapy and underlying comorbidities, the use of a robust diagnostic assay capturing two-thirds of the patients as NaPi2b high for the primary endpoint, as well as a secondary endpoint in the overall population. The Company plans to enroll approximately 100 patients with high NaPi2b expression and up to 180 patients overall and expects the study to be substantially enrolled during the summer of 2022.
- Enrollment continues in UPGRADE, the Company's Phase 1 combination umbrella study. UPGRADE is a Phase 1 dose-escalation study evaluating the combination of carboplatin with UpRi followed by UpRi continued until progression. The dose escalation portion of the study is intended to determine the recommended Phase 2 dose in combination with carboplatin. The expansion portion of the study is intended to provide proof of concept for a potential new standard of care for platinum-sensitive ovarian cancer earlier in the disease by demonstrating that the combination of platinum and UpRi followed by UpRi continuation could result in improved efficacy and tolerability with the ultimate goal of improved clinical benefit for patients. The study will inform further development of UpRi in this broader and earlier line patient population.
- **Completed enrollment and evaluation of UpRi in the NSCLC adenocarcinoma expansion cohort.** The Company observed modest singleagent activity that did not meet its internal threshold for advancement and has decided to deprioritize further clinical evaluation of UpRi in this indication. The safety profile of UpRi in lung adenocarcinoma was generally consistent with the favorable profile observed with UpRi at the 36 mg/m² dose level selected for further advancement in ovarian cancer.

XMT-1592, first Dolasynthen ADC targeting NaPi2b:

Phase 1 dose escalation study of XMT-1592 is ongoing. The Company continues dose exploration in order to determine the recommended Phase 2 dose and expects this to continue into 2022. The Company plans to provide further details of the XMT-1592 development plan alongside its 2022 milestones and goals early next year.

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 could 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.

XMT-2056, first-in-class HER2-targeted Immunosynthen STING-agonist ADC:

Presented new preclinical data for XMT-2056 at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics (Triple Meeting) in October 2021. In vitro and in vivo studies demonstrate that Immunosynthen STING-agonist ADCs activate the STING pathway in both tumor-resident immune cells and tumor cells, offering the potential for an increased therapeutic index and an advantage over other innate immune activating pathways. The Company developed XMT-2056 based on a differentiated anti-HER2 antibody that binds a novel epitope, providing the opportunity for combinations with well-established anti-HER2 therapies. In preclinical models, XMT-2056 showed efficacy in combination with trastuzumab. In both high and low HER2 models, XMT-2056 demonstrated increased efficacy in comparison to benchmark agents such as a trastuzumab-TLR7/8 agonist ADC as well as a small molecule systemically-administered STING agonist. XMT-2056 was generally well-tolerated in non-human primate studies with no clinical signs and no adverse findings in clinical pathology or histopathology after single and repeat IV doses. The Company plans to initiate a Phase 1 study of XMT-2056 in early 2022.

Corporate:

- Increased financial flexibility with additional access to capital. The Company entered into a new credit facility at favorable terms for up to \$100 million with Oxford and Silicon Valley Bank of which \$60 million is available immediately, with remaining balance primarily available upon achievement of certain pipeline and UpRi related milestones. In connection with this new facility, the Company retired the prior debt financing agreement with Silicon Valley Bank.
- Strengthened leadership team with key appointments. In August 2021, the Company announced the appointment of Tushar Misra, Ph.D., as Chief Manufacturing Officer. Dr. Misra was most recently EVP, Head of Technical Development & Manufacturing at Laronde and has held senior leadership positions at Wave Life Sciences, Takeda Pharmaceuticals and Sunovion Pharmaceuticals. In October, the Company appointed Mohan Bala, Ph.D., as SVP, Strategic Product Planning & Program Leadership. Dr. Bala was most recently Chief Operating Officer at Constellation Pharmaceuticals and has over 20 years of clinical development and commercialization experience.

Upcoming Events

- Mersana plans to present a poster entitled, "STING-agonist ADCs targeting tumor-associated antigens coordinate immune-mediated killing of antigen-negative cancer cells," at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) during the live poster display session available from November 12 – 13, 2021.
- Mersana plans to give a corporate presentation at the 2021 Stifel Virtual Healthcare Conference scheduled for November 17, 2021.
- Mersana plans to participate in a fireside chat at the Evercore ISI 4th Annual HealthconX scheduled for December 1, 2021.

Third Quarter 2021 Financial Results

Cash and cash equivalents as of September 30, 2021, were \$191.7 million, compared to \$255.1 million in cash and cash equivalents as of December 31, 2020. Net cash used in operating activities in the third quarter of 2021 was \$36.1 million.

The Company expects that its available funds will be sufficient to support its operating plan commitments into the first half of 2023.

- Research and development expenses for the third quarter of 2021 were \$35.3 million, compared to \$16.5 million for the same period in 2020. The difference was primarily due to an increase in manufacturing, clinical and regulatory expenses, an increase in headcount and advancement of diagnostic development efforts for the NaPi2b biomarker. Non-cash stock-based compensation expense included in these research and development expenses increased by \$1.7 million.
- General and administrative expenses for the third quarter of 2021 were \$10.1 million, compared to \$5.9 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 these general and administrative expenses increased by \$1.4 million.
- Net loss for the third quarter of 2021 was \$45.5 million, or \$0.63 per share, compared to net loss of \$22.5 million, or \$0.33 per share, for the same period in 2020. Weighted average common shares outstanding for the quarters ended September 30, 2021 and September 30, 2020 were 71,753,004 and 68,419,192, respectively.

Conference Call Details

Mersana Therapeutics will host a conference call today at 8:00 a.m. ET to report financial results for the third 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 2116349. A live webcast of the presentation will be available on the Investors & Media section of the Mersana website at <u>www.mersana.com</u>.

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 UPGRADE, a Phase 1 umbrella study in combination with other ovarian cancer therapies.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 and targeting a novel epitope of human epidermal growth factor receptor 2 (HER2). In addition, multiple partners are using Mersana's Dolaflexin platform to advance their ADC pipelines. The Company routinely posts information that may be useful to investors on the "Investors and Media" section of our website at www.mersana.com.

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. Forwardlooking statements include information concerning the Company's business strategy and the design, progression and timing of its clinical or preclinical studies and the release of data from those studies, 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 Oxford Finance and 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 Quarterly Report on Form 10-Q filed on August 6, 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, the severity of additional strains of the virus, 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)

	Sept	September 30,		December 31,	
		2021	2020		
Cash and cash equivalents	\$	191,707	\$	255,094	
Working capital ⁽¹⁾		155,334		228,577	
Total assets		217,586		273,399	
Total stockholders' equity		155,549		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			Nine months ended				
	Sej	ptember 30, 2021	Se	eptember 30, 2020	September 30, 2021		September 30, 2020	
Collaboration revenue	\$	11	\$	11	\$	32	\$	817
Operating expenses:								
Research and development		35,275		16,546		94,645		44,179
General and administrative		10,124		5,881		26,214		15,988
Total operating expenses		45,399		22,427		120,859		60,167
Total other income (expense), net		(83)		(73)		(250)		147
Net loss	\$	(45,471)	\$	(22,489)	\$	(121,077)	\$	(59,203)
Net loss per share attributable to common stockholders — basic and								
diluted	\$	(0.63)	\$	(0.33)	\$	(1.73)	\$	(1.00)
Weighted-average number of common shares used in net loss per share								
attributable to common stockholders — basic and diluted		71,753,004		68,419,192		70,129,236		59,086,202
	###							

Contact:

Investor & Media Contact Sarah Carmody, 617-844-8577 <u>scarmody@mersana.com</u>