Section 1: 8-K (8-K)

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 7, 2019

MIRAGEN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-36483	47-1187261
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6200 Lookout Rd. Boulder, CO	80301
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (720) 643-5200

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 obligations 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, $0.01 par value	MGEN	The Nasdaq Capital 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. ☐

Section 2 - Financial Information

Item 2.02 Results of Operations and Financial Condition.

On November 7, 2019, miRagen Therapeutics, Inc. issued a press release reporting financial results for the three- and nine-month period ended September 30, 2019.

The press release is attached hereto as Exhibit 99.1, which is furnished under Item 2.02 of this Current Report on Form 8-K and shall not be deemed to be "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "***Exchange Act***"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Section 9 - Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Exhibit Description**
99.1	Press release, dated November 7, 2019.

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.

Miragen Therapeutics, Inc.

Date: November 7, 2019

By: /s/ Jason A. Leverone
Jason A. Leverone
Chief Financial Officer, Treasurer, and Secretary

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Section 2: EX-99.1 (EXHIBIT99.1)

Exhibit 99.1

MIRAGEN REPORTS THIRD QUARTER 2019 RESULTS AND PROVIDES CORPORATE UPDATE

- *Announced positive data from two Phase 1 clinical trials of MRG-110*
- *Remain on track to announce interim top-line data from its Phase 2 clinical trial of remlarsen in keloids by year end*
- *Implemented restructuring to focus resources primarily on the development of cobomarsen and microRNA-29 mimics, including remlarsen*
- *Reported $33.8 million in cash, cash equivalents, and short-term investments as of September 30, 2019*
- *Management to host conference call today at 4:30 p.m. ET*

BOULDER, CO, November 7, 2019 - miRagen Therapeutics, Inc. (NASDAQ: MGEN), a clinical-stage biopharmaceutical company developing proprietary RNA-targeted therapies with a specific focus on microRNAs, today reported financial results for the third quarter ended September 30, 2019 and provided a corporate update.

“The miRagen team continues to generate clinical data essential to advancing our portfolio of microRNA targeting therapies being developed to address a number of complex diseases. We believe that this remains an exciting and underappreciated field of therapeutic development, and that our product candidates have the potential to become promising therapies for patients in need,” stated William S. Marshall, Ph.D., President and Chief Executive Officer of miRagen Therapeutics.

“We recently released data from two Phase 1 clinical trials in which MRG-110, one of our three clinical stage product candidates, was observed to positively impact tissue repair and new blood vessel growth in humans. We believe the clinical and preclinical data we have accumulated for MRG-110 supports advancing this product candidate into additional clinical trials for multiple indications. We believe this new data and recent events provide an opportunity for the company to potentially collaborate with a partner to advance this Phase 2 ready asset as a potential treatment for patients who may benefit from increased vascular flow and accelerated healing,” concluded Dr. Marshall.

Cobomarsen Update

Cobomarsen is currently being evaluated in three clinical trials for multiple indications. The company’s primary clinical trial of cobomarsen is its global Phase 2 SOLAR trial, in which cobomarsen is being evaluated in patients with mycosis fungoides (MF), the most common type of cutaneous T-cell lymphoma (CTCL). To date, the study has opened approximately 70% of the total sites currently planned. miRagen now expects to report primary endpoint data from SOLAR in the second half of 2021. The company’s decision to update its guidance today is based on longer than anticipated time to activate the number of sites to support its previous patient enrollment projections resulting in slower than anticipated

patient enrollment.

The SOLAR trial is supported, in part, by a collaboration with the Leukemia & Lymphoma Society ® (LLS) and its affiliate. LLS and its affiliate have agreed to provide up to $5.0 million through the purchase of miRagen common stock to help support the SOLAR trial. In October 2019, the company achieved one of the enrollment milestones and, as a result, the LLS affiliate invested an additional $0.5 million through the purchase of miRagen common stock.

Cobomarsen is also being evaluated in a Phase 1 clinical trial in three potential expansion indications where the disease process appears to be correlated with an increase in miR-155 levels, the target of cobomarsen. The trial has initially focused on treating patients with adult T-cell leukemia/lymphoma (ATLL), a rare and highly morbid disease.

Remlarsen and Other Related Product Candidates

Remlarsen is currently being evaluated in a Phase 2 clinical trial assessing its safety, tolerability, and activity in the potential prevention or reduction of keloid formation in subjects with a history of keloid scars, a form of pathological scarring. miRagen expects to report interim Phase 2 data from this clinical trial by the end of the year.

Based on preclinical data together with safety data from its Phase 1 clinical trial, the company believes that remlarsen may also be a product candidate in ophthalmic indications where fibrosis has been implicated. miRagen has also discovered and

is developing new miR-29 mimics that it believes could have utility as a systemic treatment in indications where fibrosis has been implicated such as idiopathic pulmonary fibrosis (IPF) and nonalcoholic steatohepatitis (NASH).

miRagen believes its fibrosis program has the potential to deliver distinct therapies in multiple indications where pathologic fibrosis has been implicated, providing an opportunity for the company and potential collaborators to deliver promising therapies for patients in need.

MRG-110

In October 2019, the company announced data from two Phase 1 clinical trials of MRG-110. In one of the clinical trials, administration of MRG-110 was observed to increase angiogenesis, as demonstrated by increased perfusion and histological markers of neoangiogenesis, as well as reduce alpha-smooth muscle actin (α-SMA) expression, which has been shown to correlate with activation of myofibroblasts. The data generated in these clinical trials is expected to provide clinically translatable biomarkers that may support future clinical trials for the treatment of heart failure and other conditions such as complicated lacerations in high risk patients. In both clinical trials, MRG-110 was generally safe and well tolerated and we believe that the program is ready to advance to Phase 2 clinical development.

Financial Condition and Operating Results

Cash, cash equivalents, and short-term investments were $33.8 million as of September 30, 2019 compared to $62.5 million as of December 31, 2018. Cash used in operating activities was $9.3 million for the third quarter of 2019 and $28.3 million for the nine months ended September 30, 2019. miRagen believes that its current cash, cash-equivalents, and short-term investments will be sufficient to fund the company's operations through the second quarter of 2020.

Revenue was $0.7 million for the third quarter of 2019 compared to $0.9 million for the third quarter of 2018. The decrease in revenue was primarily due to a decrease in research and development and intellectual property activities reimbursable to us under a license and collaboration agreement with Les Laboratoires Servier and Institut de Recherches Servier.

In August 2019, the company announced a cost restructuring plan focused on reducing costs and directing its resources to advance cobomarsen and microRNA-29 mimics, including remlarsen, while reducing investments in new discovery research. The initial total cost restructuring plan included approximately $1.5 million of identified restructuring charges, of which $1.0 million is associated with retention, $0.3 million is associated with severance, and $0.2 million is associated with other restructuring-related costs. Restructuring charges of $1.1 million were recorded during the three months ended September 30, 2019.

Research and development expenses were $9.0 million for the third quarter of 2019 compared to $7.4 million for the third quarter of 2018. The increase in research and development expenses is primarily due to increased clinical trial and manufacturing related costs of $1.3 million primarily related to increases in the SOLAR and PRISM clinical trials of cobomarsen, increased personnel-related costs, including share-based compensation charges, consulting, contract labor, and restructuring costs of $0.6 million, and decreases in technology license fees and other expenses.

General and administrative expenses were $2.9 million for the third quarter of 2019 compared to $2.7 million for the third quarter of 2018. The increase in general and administrative expenses of $0.2 million was driven primarily by increases in corporate legal and accounting professional fees.

The company's net loss was $11.2 million, or $0.36 per share, for the third quarter of 2019, and $31.8 million, or $1.02 per share, for the nine months ended September 30, 2019, compared to $9.0 million, or $0.29 per share, for the third quarter of 2018, and $22.4 million, or $0.77 per share, for the nine months ended September 30, 2018.

Conference Call Information

miRagen will host a conference call today at 4:30 p.m. ET to discuss its financial results for the third quarter of 2019. Participants may access the call by dialing 855-327-6837 in the U.S. or 631-891-4304 outside the U.S. and providing the conference ID number: 10007827. The call will also be webcast and can be accessed from the Investors and Media section of miRagen's website at www.miragen.com. A replay of this conference call will be available on miRagen's website approximately one hour after the event.

About Cobomarsen

Cobomarsen is an oligonucleotide inhibitor of microRNA-155 being developed in a type of blood cancer known as cutaneous T-cell lymphoma (CTCL) as well as several other blood cancers including adult T-cell leukemia/lymphoma (ATLL), diffuse large B-cell lymphoma (DLBCL), and chronic lymphocytic leukemia (CLL). In these types of blood

cancers, the disease process appears to correlate with the increase in microRNA-155 levels, the target of cobomarsen. miRagen believes that abnormally high levels microRNA-155 may lead to the proliferation of blood and lymph cells in these types of blood cancers.

About CTCL

The most advanced clinical trial of cobomarsen is the Company's global Phase 2 clinical trial, known as SOLAR. In the SOLAR trial, cobomarsen is being evaluated in patients who have been diagnosed with a blood cancer called mycosis fungicides (MF). MF is the most common form of CTCL, which occurs when certain types of T-cells become cancerous and lead to the development of neoplastic lesions on the skin that progress to cover the body surface. There are currently no curative therapies for CTCL, and concurrent and consecutive treatments, many with significant adverse effects, tend to be given until loss of response. The Company believes there is a need for new and improved therapies in CTCL to treat the disease and reduce symptoms, such as pruritis (itching) and pain, and to prolong survival in patients with aggressive disease. There is no universally accepted standard of care for MF.

About miRagen Therapeutics

miRagen Therapeutics, Inc. is a clinical-stage biopharmaceutical company discovering and developing proprietary RNA-targeted therapies with a specific focus on microRNAs and their role in diseases where there is a high unmet medical need. miRagen has three clinical stage product candidates, cobomarsen, remlarsen, and MRG-110. miRagen's clinical product candidate for the treatment of certain cancers, cobomarsen, is an inhibitor of microRNA-155, which is found at abnormally high levels in malignant cells of several blood cancers. miRagen's clinical product candidate for the treatment of pathological fibrosis, remlarsen, is a replacement for microRNA-29, which is found at abnormally low levels in a number of pathological fibrotic conditions, including cutaneous, cardiac, renal, hepatic, pulmonary and ocular fibrosis, as well as in systemic sclerosis. MRG-110, an inhibitor of microRNA-92, is miRagen's product candidate for the treatment of heart failure and other ischemic disease. In addition to these programs, miRagen is developing a pipeline of preclinical product candidates. The goal of miRagen's translational medicine strategy is to progress rapidly to first-in-human studies once it has established the pharmacokinetics, pharmacodynamic, safety, and manufacturability of the product candidate in preclinical studies. For more information, please visit www.miragen.com. For information on clinical trials please visit www.clinicaltrials.gov.

Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact, including statements regarding miRagen's strategy, anticipated clinical development milestones, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management or the expected features of or potential indications for miRagen's product candidates are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation: that miRagen has incurred losses since its inception, and anticipates that it will continue to incur significant losses for the foreseeable future; future financing activities may cause miRagen to restrict its operations or require it to relinquish rights; miRagen may fail to demonstrate safety and efficacy of its product candidates; miRagen's product candidates are unproven and may never lead to marketable products; miRagen's product candidates are based on a relatively novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all; miRagen's product candidates may cause undesirable side effects or have other properties that could delay or prevent the regulatory approval; and the results of miRagen's clinical trials to date are not sufficient to show safety and efficacy of miRagen's product candidates and may not be indicative of future clinical trial results.

miRagen has based these forward-looking statements largely on its current expectations and projections about future events and trends. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in miRagen's Annual Report on Form 10-K and subsequent periodic reports filed with the Securities and Exchange Commission. Moreover, miRagen operates in a very competitive and rapidly changing environment. New risks emerge from time to time.

It is not possible for its management to predict all risks, nor can it assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements it may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this press release may not occur and actual results could differ materially and adversely from those

anticipated or implied in the forward-looking statements. miRagen undertakes no obligation to revise or publicly release the results of any revision to such forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

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Miragen Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	$ 625	$ 814	$ 3,471	$ 6,938
Grant revenue	70	130	110	972
Total revenue	695	944	3,581	7,910
Operating expenses:				
Research and development	9,027	7,399	26,377	22,187
General and administrative	2,898	2,696	9,112	8,354
Total operating expenses	11,925	10,095	35,489	30,541
Loss from operations	(11,230)	(9,151)	(31,908)	(22,631)
Other income (expense):				
Interest and other income	204	362	818	890
Interest and other expense	(204)	(222)	(665)	(645)
Net loss	(11,230)	(9,011)	(31,755)	(22,386)
Change in unrealized gain (loss) on investments	(8)	(10)	6	(6)
Comprehensive loss	$ (11,238)	$ (9,021)	$ (31,749)	$ (22,392)
Net loss	$ (11,230)	$ (9,011)	$ (31,755)	$ (22,386)
Net loss per share, basic and diluted	$ (0.36)	$ (0.29)	$ (1.02)	$ (0.77)
Weighted-average shares used to compute basic and diluted net loss per share	31,081,594	30,723,704	30,984,582	29,182,872

Miragen Therapeutics, Inc.
Selected Financial Information
Condensed Consolidated Balance Sheet Data
(amounts in thousands)
(unaudited)

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 24,857	$ 32,606
Short-term investments	$ 8,981	$ 29,875
Total assets	$ 38,813	$ 66,147
Note payable, inclusive of current portion	$ 9,231	$ 10,298
Total liabilities	$ 15,644	$ 14,803
Total stockholders' equity	$ 23,169	$ 51,344

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