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): August 7, 2019 (August 5, 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 Exchange 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 1 - Registrant's Business and Operations

Item 1.02 Termination of a Material Definitive Agreement.

On August 5, 2019, Les Laboratoires Servier and Institut de Recherches Servier ("***Servier***") delivered notice to Miragen Therapeutics, Inc., a Delaware corporation (the "***Company***"), that, based on a strategic review of its portfolio, Servier anticipates terminating that certain License and Collaboration Agreement (as amended, the "***Servier Agreement***") between the Company and Servier, effective February 1, 2020. Per the terms of the Servier Agreement, the Company shall be responsible for specified transition and termination costs related to the termination of the Servier Agreement.

In October 2011, the Company entered into the Servier Agreement with Servier for the research, development, and commercialization of RNA-targeting therapeutics in cardiovascular disease. Under the Servier Agreement, the Company granted Servier an exclusive license to research, develop, manufacture, and commercialize RNA-targeting therapeutics for certain microRNA targets in the cardiovascular field. In 2017, the Servier Agreement was amended to remove all existing targets and add one new target (miR-92). Under the Servier Agreement, Servier's rights to each named target were limited to therapeutics in the field of cardiovascular disease and in their territory, which was worldwide except for the United States and Japan. As a result of the termination of the Servier Agreement, the Company shall regain all global rights to MRG-110, the Company's product candidate for the treatment of heart failure, as well as surgical incisions in high risk populations, severe lacerations, and severe burns, in all indications.

The foregoing description and the information contained in Item 1.02 with respect to the Servier Agreement are not intended to be complete and are qualified in their entirety by reference to the full text of (i) the Servier Agreement, which was filed as Exhibit 10.17 to the Company's Annual Report on Form 10-K, as filed with the U.S. Securities and Exchange Commission (the "***SEC***") on March 14, 2019 (the "***Annual Report***"), (ii) the First Amendment to the Servier Agreement, dated as of May 13, 2013, by and between the Company and Servier which was filed as Exhibit 10.17.1 to the Annual Report, (iii) the Second Amendment to the Servier Agreement, dated as of April 10, 2014, by and between the Company and Servier which was filed Exhibit 10.17.2 to the Annual Report, (iv) the Third Amendment to the Servier Agreement, dated as of May 28, 2015, by and between the Company and Servier which was filed as Exhibit 10.17.3 to the Annual Report, (v) the Fourth Amendment to the Servier Agreement, dated as of September 22, 2016, by and between the Company and Servier which was filed as Exhibit 10.17.4 to the Annual Report, (vi) the Fifth Amendment to the Servier Agreement, dated as of May 2, 2017, by and between the Company and Servier which was filed as Exhibit 10.17.5 to the Annual Report, (vii) the Sixth Amendment to the Servier Agreement, dated as of September 27, 2017, by and between the Company and Servier which was filed as Exhibit 10.17.6 to the Annual Report, (viii) the Seventh Amendment to the Servier Agreement, dated as of April 3, 2018, by and between the Company and Servier which was filed as Exhibit 10.17.7 to the Annual Report, (ix) the Eighth Amendment to the Servier Agreement, dated as of January 21, 2019, by and between the Company and Servier which was filed as Exhibit 10.17.8 to the Annual Report, each of which is incorporated by reference herein.

Section 2 - Financial Information

Item 2.02 Results of Operations and Financial Condition.

On August 7, 2019, the Company issued a press release reporting financial results for the three- and six-month period ended June 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.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On August 7, 2019, the Company announced it will implement 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 Company conducted a review of its cost structure, which resulted in a reduction of approximately 26 positions. The reductions are primarily in positions relating to research and corresponding project, general, and administrative support and other costs related to these areas.

The Company estimates incurring an aggregate of $1.5 million in restructuring charges, for which approximately $1.1 million is expected to be for employee retention costs and approximately $0.4 million is expected to be for severance and other restructuring-related costs, primarily during the third quarter of 2019.

At this time, the estimates of the costs related to the Company's cost restructuring are preliminary and subject to change. Furthermore, such estimates constitute forward-looking statements, which are not based on historical facts but instead reflect the Company's expectations, estimates, or projections concerning future results or events. Forward-looking statements are not guarantees and are inherently subject to known and unknown risks, uncertainties, and assumptions that are difficult to predict and could cause the estimated costs to differ materially from those indicated within this document. Any updates to these estimates will be included in the Company's future quarterly reports on Form 10-Q.

Section 9 - Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Exhibit Description**
99.1	Press release, dated August 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: August 7, 2019

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

(Back To Top)

Section 2: EX-99 (EX-99)

Exhibit 99.1

MIRAGEN REPORTS SECOND QUARTER 2019 RESULTS; REGAINS GLOBAL RIGHTS TO MRG-110 AND ANNOUNCES CORPORATE RESTRUCTURING

- *miRagen to regain global rights to MRG-110 after Servier provides notice of portfolio realignment; expects to announce Phase 1 data during the second half of 2019*
- *Company anticipates reporting primary endpoint data from the SOLAR clinical trial in the first half of 2021*
- *Restructuring to focus resources primarily on the clinical development of cobomarsen and microRNA-29 mimics, including remlarsen*
- *Reported $43.9 million in cash, cash equivalents, and short-term investments as of June 30, 2019*
- *Management to host conference call today at 4:30 p.m. ET*

BOULDER, CO, August 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 second quarter ended June 30, 2019 and provided a corporate update.

“The data generated in our Phase 1 trials of MRG-110 demonstrated good safety and tolerability as well as preliminary proof of mechanism of action in humans. We appreciate the collaborative support we’ve received from Servier in the MRG-110 program up to this point and understand that due to a strategic evaluation of their pipeline, they have decided to discontinue development of MRG-110. While we are currently evaluating the impact on the MRG-110 development timeline, we are pleased to have regained global rights to this Phase 2-ready asset, and will seek a new development partner or potentially pursue other development strategies for this program,” stated William S. Marshall, Ph.D., President and Chief Executive Officer of miRagen Therapeutics.

“Looking ahead, we will continue to focus on the advancement of our lead programs for cobomarsen and remlarsen, both of which have ongoing Phase 2 studies. Under this strategy, we are implementing a cost reduction plan that will concentrate our resources on the advancement of these lead programs, as well as activities in support of our licensing efforts. Implementing this cost reduction program was a difficult decision to make, but we believe that it is important to extend our cash runway and deliver on important milestones.”

“We have a number of clinical data announcements and updates expected to occur in the second half of 2019 that are expected to further support future development decisions and the prioritization of our clinical programs. In the second half of this year, miRagen expects to (i) report the results of the Phase 1 clinical trials for MRG-110 that assessed safety, tolerability and proof of mechanism in humans; (ii) report interim data from the Phase 2 clinical trial of remlarsen in the prevention or reduction of keloid scarring; and (iii) provide updates on the SOLAR trial of cobomarsen in CTCL,” concluded Dr. Marshall.

MRG-110 and miRagen’s Collaboration Agreement with Servier

miRagen announced today that it received notice of Servier’s intention to end the collaboration, which included development of MRG-110. MRG-110 is being evaluated in two Phase 1 trials, which are expected to support future clinical trials for the treatment of heart failure and other conditions where patients may benefit from increased vascular flow and accelerated healing, such as complicated lacerations in high risk patients. Based on a strategic review of its portfolio, Servier decided not to proceed with the collaboration. As a result, miRagen will regain rights to MRG-110 in all indications and all territories globally including rights in the US and Japan which it already controlled under the collaboration and licensing agreement with Servier. Under the terms of the agreement, Servier will continue to support certain costs of development until February 2020.

The Company expects to report Phase 1 clinical data of MRG-110 at an upcoming scientific conference in the fourth quarter of 2019. In these trials, MRG-110 was generally safe and well tolerated, and the Company believes the program is ready to advance to Phase 2 clinical development. With the corporate restructuring announced today, miRagen is currently evaluating development strategies for MRG-110, which may include seeking a new development and licensing partner.

Cost Restructuring Plan

miRagen announced it will also implement 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 Company conducted a review of its cost structure, which resulted in a reduction of approximately 26 positions. The reductions are primarily in positions relating to research and corresponding project, general, and administrative support and other costs related to these areas. miRagen estimates that it will incur approximately $1.5 million in restructuring charges for retention, severance and other restructuring-related costs primarily during the third quarter of 2019.

As a result of this cost restructuring plan, the Company expects that its current cash, cash-equivalents, and short-term investments will be sufficient to fund the Company's operations into the second quarter of 2020.

Cobomarsen Update

In April 2019, the first cutaneous T-cell lymphoma (CTCL) patients were dosed in the SOLAR Phase 2 clinical trial. The SOLAR trial is designed to evaluate the safety and efficacy of cobomarsen given in 300 mg doses by intravenous (IV) infusion in an active control comparison trial versus Zolinza (vorinostat). Currently, miRagen has opened more than 50% of the total sites currently planned for this clinical trial. While miRagen has experienced delays in activating sites, recruitment rates at these sites are now approximately on pace with the Company's expectations. miRagen currently expects to report primary endpoint data from this clinical trial in the first half of 2021, instead of the second half of 2020 as previously guided.

The primary endpoint of the SOLAR trial is the rate of an objective response that is durable for four months, defined as 50% or greater improvement in the severity of a patient's skin disease over the entire body with no evidence of disease progression in the blood, lymph nodes, or viscera. Progression-free survival is a secondary endpoint, and miRagen plans to use patient-reported outcomes as additional endpoints to monitor quality of life improvements. Based on discussions with the U.S. Food and Drug Administration (FDA), the Company believes that primary endpoint data from this clinical trial could allow miRagen to apply for accelerated approval in the United States.

Patients in the SOLAR Phase 2 clinical trial who randomize to the active control, Zolinza, and have disease progression, may be eligible to enroll in the PRISM clinical trial, which is an open-label, global Phase 2 extension clinical trial where all patients will receive 300 mg of cobomarsen given by IV infusion. The PRISM clinical trial is currently in the start-up phase, with the first sites eligible for initiation, and is planned to be initiated at all active centers in the SOLAR clinical trial. The PRISM clinical trial endpoints are the same as the SOLAR clinical trial endpoints, and the clinical trial will assess responses to cobomarsen when patients cross-over following disease progression with Zolinza treatment.

Remlarsen and Other MicroRNA-29 Mimics Update

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. The trial has completed its enrollment, and miRagen expects to report Phase 2 data from this clinical trial before the end of this year.

In April 2019, miRagen announced preclinical data from its studies exploring the antifibrotic effects of remlarsen in the cornea. These data followed data announced earlier this year from miRagen's preclinical studies investigating the antifibrotic effects of remlarsen in corneal ulceration, which suggest that topical application of remlarsen may be an effective treatment to improve vision in patients suffering from multiple conditions resulting in corneal scarring. miRagen believes these data further supports that the topical application of remlarsen may be an effective treatment to inhibit corneal fibrosis and scarring.

In May 2019, at the 2019 American Thoracic Society Conference, the Company reported new data demonstrating that systemic administration of its second generation microRNA-29 mimic, miRagen's preclinical micro-RNA targeted therapeutics candidate for idiopathic pulmonary fibrosis (IPF), efficiently reduced extracellular matrix deposition in a series of preclinical studies. The Company believes these data coupled with previous observations in humans with IPF support the role of microRNA-29 in pathologic fibrosis, as well as the use of microRNA-29 replacements as potential therapeutics in pulmonary fibrosis.

Financial Condition and Operating Results

Cash, cash equivalents, and short-term investments were $43.9 million as of June 30, 2019 compared to $62.5 million as of December 31, 2018. Cash used in operating activities was $7.2 million for the second quarter of 2019. miRagen believes that its current cash, cash-equivalents, and short-term investments will be sufficient to fund the Company's operations into the second quarter of 2020.

Revenue was $2.5 million for the second quarter of 2019 compared to $2.2 million for the second quarter of 2018. The increase in revenue is due to an increase in research and development and intellectual property activities reimbursable to miRagen by Servier under the Servier Collaboration Agreement, partially offset by a decrease in grant revenue.

Research and development expenses were $8.6 million for the second quarter of 2019 compared to $8.4 million for the second quarter of 2018. The increase in research and development expenses is primarily due to increased personnel-related costs, offset by lower clinical trial costs associated with the Phase 1 clinical trial of MRG-110, lower costs related to the Phase 1 clinical trial of cobomarsen, and lower manufacturing and other costs related to the SOLAR and PRISM clinical trials of cobomarsen.

General and administrative expenses were $2.9 million for the second quarter of 2019 compared to $2.7 million for the second quarter of 2018. The increase in general and administrative expenses is primarily due to increases in personnel-related costs resulting primarily from the growth of miRagen's general and administrative team and higher share-based compensation charges.

The Company's net loss was $8.9 million, or $0.29 per share, for the second quarter of 2019, and $20.5 million, or $0.66 per share, for the first half of 2019, compared to $8.7 million, or $0.29 per share, for the second quarter of 2018, and $13.4 million, or $0.47 per share, for the first half of 2018.

Conference Call Information

miRagen will host a conference call today at 4:30 p.m. ET to discuss its financial results for the second quarter of 2019. Participants may access the call by dialing 877-407-0789 in the U.S. or 201-689-8563 outside the U.S. and providing the conference ID number 13692701. 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.

Investor/Media Contact:
Dan Ferry
LifeSci Advisors
(617) 535-7746
daniel@lifesciadvisors.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	$ 2,498	$ 1,368	$ 2,846	$ 6,124
Grant revenue	16	814	40	842
Total revenue	2,514	2,182	2,886	6,966
Operating expenses:				
Research and development	8,599	8,375	17,350	14,788
General and administrative	2,857	2,668	6,214	5,658
Total operating expenses	11,456	11,043	23,564	20,446
Loss from operations	(8,942)	(8,861)	(20,678)	(13,480)
Other income (expense):				
Interest and other income	275	361	614	528
Interest and other expense	(229)	(214)	(461)	(423)
Net loss	(8,896)	(8,714)	(20,525)	(13,375)
Change in unrealized gain on investments	9	4	14	4
Comprehensive loss	$ (8,887)	$ (8,710)	$ (20,511)	$ (13,371)
Net loss	$ (8,896)	$ (8,714)	$ (20,525)	$ (13,375)
Net loss per share, basic and diluted	$ (0.29)	$ (0.29)	$ (0.66)	$ (0.47)
Weighted-average shares used to compute basic and diluted net loss per share	30,983,918	30,295,200	30,935,272	28,399,687

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

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 24,007	$ 32,606
Short-term investments	$ 19,940	$ 29,875
Total assets	$ 48,782	$ 66,147
Note payable, inclusive of current portion	$ 10,151	$ 10,298
Total liabilities	$ 15,345	$ 14,803
Total stockholders' equity	$ 33,437	$ 51,344

(Back To Top)