Section 1: 8-K (FORM 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): October 1, 2018

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

(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))

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 7 – Regulation FD

Item 7.01 Regulation FD Disclosure.

On October 1, 2018, Miragen Therapeutics, Inc., a Delaware corporation ("Miragen"), issued a press release announcing the presentation of data from preclinical studies of its product candidate, remlarsen (also known as MRG-201), which is a microRNA-29 mimic, demonstrating the potential anti-fibrotic effect of remlarsen in the cornea of rats at the 2018 Oligonucleotide Therapeutics Society annual OLIGO meeting in Seattle, Washington. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. The information contained in this Item 7.01, including Exhibit 99.1, shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Miragen whether made before or after the date hereof, 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 October 1, 2018.

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.

Dated: October 1, 2018

By: /s/ Jason A. Leverone
Jason A. Leverone
Chief Financial Officer

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Section 2: EX-99.1 (EX-99.1)

Exhibit 99.1

MIRAGEN THERAPEUTICS ANNOUNCES THE PRESENTATION OF DATA FROM PRECLINICAL STUDIES DEMONSTRATING THE POTENTIAL ANTI-FIBROTIC EFFECT OF REMLARSEN IN THE CORNEA AT THE 2018 OLIGO MEETING IN SEATTLE, WA

- Remlarsen treatment increased corneal re-epithelialization, decreased corneal scar formation, and repressed the expression of several pro-fibrotic genes when compared to placebo treated eyes in a preclinical model of corneal ulceration.
- miRagen believes these results can support evaluation of remlarsen in human clinical trials to evaluate reduction of scarring following corneal ulceration.

BOULDER, CO, October 1, 2018 — miRagen Therapeutics, Inc. (NASDAQ: MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of RNA-targeted therapies, today announced data from its preclinical study of remlarsen, a microRNA-29 replacement, exploring the anti-fibrotic activity of remlarsen when administered topically to the eye after corneal ulceration. These data will be presented today in the oral session at the 2018 Oligonucleotide Therapeutics Society (OTS) annual OLIGO meeting, which is being held in Seattle, WA from September 30 – October 3, 2018.

The preclinical study investigated the anti-fibrotic effects of remlarsen in the cornea of rats. Remlarsen or a fluorescently labeled version of the product candidate were administered topically to the rat cornea in the context of a corneal ulcer. Highlights from the study observations include:

- Topically applied remlarsen penetrated into the cornea, without obvious local toxicity following corneal injury;
- Remlarsen treatment resulted in a decrease in corneal scarring and hazing as assessed by clinical evaluation and histopathology;
- Remlarsen treatment increased the corneal epithelial thickness, decreased the stromal thickness, and reduced the number of alpha-smooth muscle actin positive myofibroblasts in the corneal stroma; and
- Remlarsen treatment resulted in a reduction of pro-fibrotic gene expression from day 7-14 post-injury, indicating that target engagement was achieved in keratocytes and myofibroblasts in the corneal stroma.

“We believe these results support the conclusion that remlarsen was anti-fibrotic in a well established preclinical model and suggest that remlarsen might be an effective therapeutic in preventing corneal fibrosis and scarring following corneal injury, trauma, infection, ulceration or degenerative disease,” stated miRagen Executive Vice President, R&D, Paul Rubin.

“We are pleased with the data from this preclinical study of remlarsen, which support our belief that topical application may be an effective treatment to inhibit corneal fibrosis and scarring. We believe these results support our plans to advance remlarsen into human clinical studies for opthalmalogical indications,” said William S. Marshall, Ph.D., President and Chief Executive Officer of miRagen Therapeutics.

Corneal fibrosis and scarring can lead to hazing and vision loss following corneal surgery (e.g., photorefractive keratectomy, LASIK), chemical or thermal burn, trauma or ulceration due to viral or bacterial keratitis, or as a result of progressive disease (e.g., Fuch’s Endothelial Corneal Dystrophy). Corneal scarring remains one of the leading causes of blindness worldwide. No pharmacological therapies are currently available to prevent or treat corneal fibrosis and this is therefore an area of high medical need.

microRNA-29 is a potent anti-fibrotic microRNA that inhibits the expression of a host of genes that are important in the deposition of extracellular matrix. microRNA-29 is expressed at abnormally low levels in numerous pathological fibrotic conditions. Remlarsen, a synthetic oligonucleotide replacement of microRNA-29, has been previously shown to be pharmacodynamically active as measured by both target gene regulation and inhibition of fibrosis in skin wounds in a double-masked, placebo-controlled Phase 1 human clinical trial.

miRagen is also conducting a Phase 2 clinical trial for remlarsen assessing the safety, tolerability and activity of remlarsen in the prevention or reduction of keloid formation in subjects with a history of keloid scars, a persistent form of hypertrophic scarring.

About miRagen Therapeutics, Inc.

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 (MRG-106), remlarsen (MRG-201), 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, as well as certain cells involved in inflammation. 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 systemic sclerosis. MRG-110, an inhibitor of microRNA-92, is being developed under a license and collaboration agreement with Servier 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, 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; remlarsen may not be effective in the treatment of opthalmalogical indications; remlarsen may not advance into additional human clinical trials; and the results of miRagen's preclinical and 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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