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): July 10, 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 8 – Other Events

Item 8.01 Other Events.

On July 10, 2018, Miragen Therapeutics, Inc., a Delaware corporation, issued a press release announcing the initiation of a Phase 2 clinical trial to evaluate MRG-201, its product candidate designed to treat fibrotic diseases, in subjects with a predisposition for keloid formation. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Section 9 – Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release, dated July 10, 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: July 10, 2018

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

(Back To Top)

Section 2: EX-99.1 (EX-99.1)

Exhibit 99.1

MIRAGEN THERAPEUTICS ANNOUNCES INITIATION OF PHASE 2 CLINICAL TRIAL OF MRG-201

BOULDER, Colo., July 10, 2018 (GLOBE NEWSWIRE) – miRagen Therapeutics, Inc. (NASDAQ: MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of RNA-targeted therapies, today announced the initiation of a Phase 2 clinical trial to evaluate MRG-201 in subjects with a predisposition for keloid formation. miRagen is developing MRG-201, a synthetic mimic of microRNA-29 for the potential treatment of patients with fibrotic diseases.

“We believe advancing MRG-201 into a Phase 2 clinical trial in subjects with a predisposition for keloid formation is an exciting opportunity to build on the Phase 1 data in induced cutaneous fibrosis, where MRG-201 reduced scar tissue deposition in healthy human volunteers,” said miRagen President and CEO William S. Marshall, Ph.D. “Keloids are benign growths that form when scar tissue grows excessively after skin is injured. The lesions can be disfiguring and are often itchy and painful which can lead to decreased quality of life for patients. We are encouraged by MRG-201’s potential to serve as a therapeutic option for those experiencing various types of pathological fibrosis.”

miRagen anticipates that the MRG-201 Phase 2 trial will enroll approximately 12 subjects that are historically predisposed to keloid formation after trauma to the skin at multiple clinical sites in the U.S. The study will be a double-blinded, randomized design. Subjects will receive small, matching excisional wounds that will be sutured and then injected with either MRG-201 or placebo. Thus, patients will serve as their own control, which will increase the statistical powering of the trial. The lesions will be observed for up to 12 months to determine presence or absence of keloid formation.

MRG-201 is designed to mimic the activity of microRNA-29 and decrease the expression of many proteins that are involved in fibrous scar formation. miRagen believes the results from its Phase 1 clinical trial of MRG-201 in induced cutaneous fibrosis, which demonstrated the ability of the product candidate to reduce fibrogenesis in humans after skin trauma when compared to untreated lesions, may provide support for the therapeutic approach in other pathological fibrotic conditions.

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), 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, MRG-201, 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; 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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(Back To Top)