
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): April 27, 2018 (April 27, 2018)

MIRAGEN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36483
(Commission
File Number)

47-1187261
(IRS Employer
Identification No.)

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

80301
(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 April 27, 2018, Miragen Therapeutics, Inc., a Delaware corporation, or the Company, issued a press release announcing new data showing administration of MRG-110, one of the Company's product candidates, improved tissue perfusion and wound healing in late stage preclinical studies. 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 April 27, 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: April 27, 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 New Data Showing Administration of MRG-110 Improved Tissue Perfusion and Wound Healing in Late Stage Preclinical Studies

- MRG-110 appeared to increase vascularization and reparative tissue formation in treated wounds; miRagen believes results support evaluation in human clinical trials
- MRG-110 treatment appeared to lead to more wounds undergoing complete closure at earlier timepoints compared to controls in healthy normal animals
- Data to be presented in oral and poster sessions at 2018 Wound Healing Society Annual Meeting

BOULDER, Colo., April 27, 2018 (GLOBE NEWSWIRE) – miRagen Therapeutics, Inc. (NASDAQ: MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of RNA-targeted therapies, announced new data from its preclinical studies of MRG-110, a miR-92 inhibitor, exploring the perfusion and healing benefits when administered by local injection to wounds. The data will be presented today, April 27, at the 2018 Wound Healing Society (WHS) Annual Meeting in Charlotte, North Carolina, by Rusty Montgomery, Ph.D., Director of Research, miRagen Therapeutics. MRG-110 is also the subject of a Phase 1 clinical trial assessing its safety and tolerability following systemic dosing in collaboration with Servier, an independent international pharmaceutical company headquartered in France.

“We continue to be encouraged by preclinical results reinforcing MRG-110 as a possible regulator of blood vessel formation and growth. The results presented today suggest that this leads to improved perfusion, or delivery of blood, to biological tissue,” said miRagen President and CEO William S. Marshall, Ph.D. “We believe this preclinical activity observed with MRG-110 demonstrates its potential to accelerate wound healing in healthy skin and in pathological conditions, providing support for its evaluation in future human clinical trials. We believe the data suggests that clinical investigation of this compound is warranted for potential use in indications such as surgical incisions, severe lacerations or chronic wounds.”

The data to be presented at the WHS Annual Meeting was gathered during multi-dose, randomized studies in a pig model of wound healing. Animals were dosed by intradermal injection around the periphery of excisional wounds with multiple dose levels of MRG-110 over a period of two weeks. Treatments were randomized across different wound sites on multiple animals. Control animals were treated with either standard of care (wound dressing changes only) or injection of vehicle control. Wound healing and perfusion were assessed by photography, physical measurements, laser Doppler imaging and histology over a seven-week period until complete wound closure was achieved. The results of these preclinical studies in a model system which mimics human wound healing informed miRagen and Servier’s joint decision to move MRG-110 into human clinical evaluation for potential use in dermal revascularization.

The results showed improved perfusion and benefits to the wound healing process including:

- MRG-110 increased vascularization within the wound bed ($p < 0.05$), which was associated with increased perfusion (delivery of blood) in drug treated wounds ($p < 0.05$) compared to controls.
- MRG-110 increased formation of new connective tissue and microscopic blood vessels that form on the surfaces of a wound during the healing process (granulation tissue) ($p < 0.01$) versus controls.
- At all doses tested there was evidence of accelerated wound healing in the majority of treated animals. The maximum difference in number of wounds with complete closure across all dose cohorts was shown at day 35. Improvements ranged from 25-58% (3-7/12) complete wound closure compared to 0% (0/8) treated with standard of care, and 12% (1/8) vehicle control treated animals.

MRG-110 is an inhibitor of microRNA-92, which has been shown in preclinical studies to be a regulator of new blood vessel creation. miRagen believes microRNA-92 inhibitors may accelerate and improve healing and thus potentially decrease complications of wounds in a variety of settings. MRG-110 is the third product candidate from miRagen to enter human clinical trials and is currently in a Phase 1 clinical trial in collaboration with Servier to evaluate its potential use in the treatment of heart failure. miRagen and Servier anticipate starting a second Phase 1 clinical trial evaluating intradermal administration of MRG-110 in the second quarter of this year for dermal revascularization.

Oral and Poster Presentation Details

Title: Improved Perfusion and Wound Healing in Healthy Pigs with MRG-110, an Inhibitor of MicroRNA-92A

- **Oral session:** Session K: Concurrent Oral Abstracts II
- **Date:** Friday, April 27, 2018, 2:45 p.m. – 2:55 p.m. ET
- **Location:** Room 203B, Charlotte Convention Center

- **Poster session:** WHS Poster Gala & Awards
- **Poster number:** P.IRD4
- **Date:** Friday, April 27, 2018, 7:15 p.m. – 8:45 p.m. ET
- **Location:** Hall C1, Charlotte Convention Center

For additional information, please visit the WHS Annual Meeting website: www.woundheal.org

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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