

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): October 16, 2019



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))

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 8 – Other Events

Item 8.01 Other Events.

On October 16, 2019, Miragen Therapeutics, Inc., a Delaware corporation, or the Company, issued a press release announcing data from two Phase 1 clinical trials of MRG-110, the Company's microRNA-92 inhibitor, showing that 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 show to correlate with activation of myofibroblasts. 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

<u>Exhibit Number</u>	<u>Exhibit Description</u>
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99.1	<u>Press release, dated October 16, 2019.</u>
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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: October 16, 2019

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

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Section 2: EX-99 (EX-99)

Exhibit 99.1



MIRAGEN ANNOUNCES NEW CLINICAL DATA SHOWING MRG-110 POSITIVELY IMPACTED TISSUE REPAIR AND NEW BLOOD VESSEL GROWTH

Data included in an oral presentation at the 15th annual meeting of the Oligonucleotide Therapeutics Society

Data supports advancing MRG-110 into additional clinical studies

BOULDER, CO, October 16, 2019 - miRagen Therapeutics, Inc. (NASDAQ: MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of RNA-targeted therapies, announced today new data from two Phase 1 clinical trials of MRG-110, miRagen's microRNA-92 inhibitor, in which 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. In addition, MRG-110 was safe and generally well-tolerated when given as a single intravenous dose or as three weekly intradermal doses.

"We believe these Phase 1 safety, tolerability, pharmacokinetics, and biomarker data may provide mechanistic proof-of-concept for use of MRG-110 in the treatment of cardiovascular disease and certain other conditions where vascular flow is compromised," said Paul Rubin, M.D., Executive Vice President, R&D, of miRagen Therapeutics. "When combined with the preclinical data that we have accumulated for MRG-110 in a variety of potential therapeutic settings, we believe these initial human data support advancing MRG-110 into additional clinical studies."

William S. Marshall, President and CEO of miRagen Therapeutics, added, "MRG-110 is our third product candidate to have observed proof-of-drug mechanism in humans with a good safety and tolerability profile. We believe this adds to the growing body of evidence that microRNA targeting may be a new avenue to treat complex diseases."

The two Phase 1 studies investigated MRG-110 in order to assess the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single and multiple local administrations of MRG-110 in excisional wounds. In addition, one of the studies was a systemic dosing study assessing safety and tolerability in healthy volunteers.

In small, acute wounds on normal healthy volunteers, single and multiple doses of MRG-110 appeared to:

- Increase angiogenesis as assessed by CD31 immunostaining, a marker of new blood vessel growth;
- Increase peri-wound perfusion, as assessed by non-invasive Laser Speckle Perfusion Imaging;
- Demonstrate pharmacodynamic target engagement by increasing CD49e (ITGA5) expression; and
- Reduce SMA expression, as assessed by immunostaining.

In the intradermal multiple ascending dose study, the mean granulation tissue, or new connective tissue, area was decreased in subjects treated with MRG-110 when compared to placebo treated subjects' wounds. miRagen believes that delayed granulation tissue formation may be related to the MRG-110 mediated decrease in α -SMA positive myofibroblasts, which are the predominant source of type I collagen and fibrogenic/inflammatory cytokines. The data also supported that delayed kinetics of granulation tissue formation was not detrimental to achieving full wound closure or appropriate collagen maturation.

miRagen believes that the data supports moving forward in cutaneous wounds of varying causes where increased perfusion may result in improved wound closure and reduced α -SMA expression may reduce scar formation and contracture. miRagen also believes that this mechanistic proof-of-concept study combined with the observed safety and tolerability of MRG-110 via systemic administration support additional clinical studies to evaluate the ability of the product candidate to enhance vascularization and function in the setting of heart failure.

These new data will be included in an oral presentation detailing the MRG-110 program provided by Dr. Rusty L. Montgomery, Director of Research, miRagen Therapeutics, today at the 15th annual meeting of the Oligonucleotide Therapeutics Society, which is being held in Munich, Germany. The presentation is titled, "Development of MRG-110, an LNA-AntimiR Targeting miR-92a For Use in Tissue Repair and Revascularization." The presentation will be available on the scientific publications page of the Company's website following the presentation at the 15th annual meeting of the Oligonucleotide Therapeutics Society.

In August 2019, miRagen announced that it had regained the rights to MRG-110 in all indications and all territories globally, including rights in the U.S. and Japan.

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, 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, 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 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 and scientific presentations, 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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