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): May 9, 2018 (May 9, 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 2 – Financial Information

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2018, Miragen Therapeutics, Inc., a Delaware corporation, or the Company, issued a press release reporting financial results for the three-month period ended March 31, 2018.

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, or 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.

Section 8 – Other Events

Item 8.01 Other Events.

On May 9, 2018, the Company announced that it recently filed an investigational new drug application for MRG-201. MRG-201, one of the Company's product candidates, is a replacement for, or mimic of, 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.

Section 9 – Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press release, dated May 9, 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: May 9, 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 REPORTS FIRST QUARTER 2018 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

- MRG-110 advanced into clinical development with the initiation of two Phase 1 clinical trials in collaboration with Servier
- Preclinical data released in two separate ophthalmology programs targeting microRNA-29 and the microRNA-183/96/182 cluster
- Cobomarsen and MRG-201 to advance into Phase 2 clinical trials this year
- $78.1 million in cash and cash equivalents as of March 31, 2018 after completing a $37.9 million common stock offering in February 2018
- Conference call and webcast today at 4:30 p.m. ET

BOULDER, CO, May 9, 2018 (GLOBE NEWSWIRE) — miRagen Therapeutics, Inc. (NASDAQ: MGEN), a clinical-stage biopharmaceutical company focused on the discovery and development of RNA-targeted therapies, today reported first quarter 2018 financial results and provided a corporate update.

“With three product candidates now in clinical development and additional preclinical programs targeting multiple indications, we are continuing to advance, de-risk and build confidence in our pipeline of potential microRNA targeted therapies,” said William S. Marshall, Ph.D., President and Chief Executive Officer of miRagen Therapeutics. “Cobomarsen and MRG-201 remain on track to advance into Phase 2 clinical trials later this year, and we were pleased to have recently initiated two Phase 1 clinical trials for MRG-110 in collaboration with our partner, Servier. We also continued to expand the potential of our innovative microRNA technologies by unveiling a new preclinical program evaluating microRNA mimics of the microRNA-183/96/182 cluster involved in retinal degeneration.”

Marshall continued, “We are encouraged by the advancement of our pipeline of microRNA therapeutic candidates and excited about the opportunities that our microRNA focused discovery and development platform could provide as our clinical programs continue to show promising efficacy and safety profiles.”

Recent Achievements and Anticipated Progress

Cobomarsen

- miRagen closed enrollment in its Phase 1 cutaneous T-cell lymphoma (CTCL) trial and plans to release additional data from this study, including response rates from longer-term duration of treatment, in the first half of 2018.
- miRagen continued to evaluate patients in its Phase 1 clinical trial of cobomarsen for other oncology indications and plans to release interim Phase 1 data in at least one of these potential expansion indications in the second half of 2018.

- With enrollment in the Phase 1 CTCL trial now closed, miRagen plans to initiate a Phase 2 clinical trial, evaluating cobomarsen in patients with CTCL in the second half of 2018 which, based on discussions with the U.S. Food and Drug Administration, could allow us to apply for accelerated approval.

MRG-201

- miRagen recently filed an Investigational New Drug Application, or IND, for MRG-201 and plans to initiate a Phase 2 clinical trial to evaluate MRG-201 in subjects with a predisposition for keloid formation in the second quarter of 2018.
- In May, miRagen presented preclinical data demonstrating the potential of MRG-201 to inhibit the expression of multiple factors responsible for fibrosis in disease models in both the cornea and retina.
- In the second half of 2018, miRagen anticipates releasing preclinical in vivo data from its lung fibrosis studies.

MRG-110

- In March, Servier and miRagen initiated a Phase 1 clinical trial to evaluate the safety and tolerability of MRG-110 in a systemic dosing protocol to support additional clinical studies for the potential treatment of heart failure. The dosing of the first patient in this trial triggered a €3.0 million milestone to miRagen under the terms of its agreement with Servier.
- In May, miRagen announced that it had initiated a separate Phase 1 trial designed to evaluate the safety and tolerability of MRG-110 after intradermal administration for potential use in indications such as surgical incisions, severe lacerations or chronic wounds.
- miRagen also recently released preclinical data showing administration of MRG-110 improved tissue perfusion and wound healing. Results from these studies in a preclinical model which closely reflects human wound healing helped to inform the joint decision by miRagen and Servier to move MRG-110 into human clinical evaluation for potential use in dermal revascularization.

Preclinical Pipeline

- miRagen unveiled a new program to evaluate microRNA mimics of the microRNA-183/96/182 cluster for potential use in progressive vision loss. Mimics of this microRNA cluster have been shown to play an important role in the establishment and maintenance of neurosensory cells, including photoreceptors and hair cells (cells associated with hearing).
- In May, miRagen presented data showing mimics of the microRNA cluster were able to cause functional improvement of photoreceptors and vision in a preclinical model of retinal degeneration.

First Quarter 2018 Financial Results

Cash and Cash Equivalents

- Cash and cash equivalents at March 31, 2018 were $78.1 million, compared to $47.4 million at December 31, 2017. Total net cash used in operations was approximately $7.4 million for the quarter ended March 31, 2018.

- In February 2018, miRagen completed an underwritten public offering of 7,414,996 shares of its common stock. Proceeds to miRagen from the offering were $37.9 million after deducting underwriting discounts, commissions and other offering expenses.
- miRagen expects that the cash and cash equivalents as of March 31, 2018 will be sufficient to fund its operations into early 2020.

Revenue

- Revenue was $4.8 million for the first quarter of 2018, as compared to $0.5 million for the first quarter of 2017. The increase in revenue was due primarily to a €3.0 million (or $3.7 million) milestone payment earned under the Servier collaboration upon the initiation of the first Phase 1 trial of MRG-110 in March 2018, as well as an increase in research and development activity reimbursable under the Servier collaboration.

Operating Expenses

- Research and development expenses were $6.4 million for the first quarter of 2018, as compared to $4.1 million for the first quarter of 2017. The increase in research and development expenses was driven primarily by increased personnel-related costs as miRagen added to its research and development team in 2018, as well as higher technology license fees and clinical development expenses to support expanded development stage programs.
- General and administrative expenses were $3.0 million for the first quarter of 2018, as compared to $3.3 million for the first quarter of 2017. The decrease in general and administrative expenses was due primarily to lower professional fees, which were partially offset by higher personnel related costs, as miRagen added to its general and administrative team in 2018.

Net Loss

- Net loss available to common stockholders for the first quarter of 2018 was $4.7 million, or $0.18 per share, as compared to a net loss of $7.0 million, or $0.60 per share, for the first quarter of 2017.

Conference Call Information

miRagen will host a conference call today at 4:30 p.m. ET to discuss its financial results for the first quarter 2018. Participants may access the call by dialing (888) 394-8218 in the U.S. or (323) 701-0225 outside the U.S. and providing the conference ID number 8152157. 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 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.

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

	Three Months Ended March 31,	
	2018	**2017**
Revenue:		
Collaboration revenue	$ 4,756	$ 10
Grant revenue	28	452
Total revenue	4,784	462
Operating expenses:		
Research and development	6,413	4,120
General and administrative	2,990	3,281
Total operating expenses	9,403	7,401
Loss from operations	(4,619)	(6,939)
Other income (expense):		
Interest and other income	167	30
Interest and other expense	(209)	(71)
Net loss	(4,661)	(6,980)
Accretion of redeemable convertible preferred stock to redemption value	—	(5)
Net loss available to common stockholders	$ (4,661)	$ (6,985)
Net loss per share, basic and diluted	$ (0.18)	$ (0.60)
Weighted-average shares used to compute basic and diluted net loss per share	26,483,112	11,555,286

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

	March 31, 2018	**December 31, 2017**
Cash and cash equivalents	$ 78,099	$ 47,441
Total assets	$ 86,992	$ 52,481
Notes payable	$ 10,018	$ 9,922
Total liabilities	$ 14,286	$ 13,971
Total stockholders' equity	$ 72,706	$ 38,510

Investor/Media Contact:
Adam Levy
Chief Business Officer
(720) 407-4595
alevy@miragen.com
(Back To Top)