

MIRAGEN THERAPEUTICS, INC.
Form 8-K
August 11, 2017

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): August 11, 2017 (August 10, 2017)

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 2 Financial Information

Item 2.02 Results of Operations and Financial Condition.

On August 11, 2017, Miragen Therapeutics, Inc., a Delaware corporation (the *Company*), issued a press release reporting financial results for the three-month period ended June 30, 2017.

The press release is attached hereto as Exhibit 99.1, which is furnished under Item 2.02 of this report and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 (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 Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Section 5 Corporate Governance and Management

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangement of Certain Officers.

(b)

On August 10, 2017, Kyle A. Lefkoff and John W. Creecy each resigned from the Company's Board of Directors (the *Board*) and all committees of the Board of which each was a member immediately before such resignations. Neither Mr. Lefkoff's nor Mr. Creecy's resignation resulted from a disagreement on any matter relating to the Company's operations, policies or practices.

(d)

On August 10, 2017, the Board unanimously voted to elect Jeffrey S. Hatfield and Christopher Bowden, M.D. to the Board, effective immediately. The appointments of Mr. Hatfield and Dr. Bowden were made to fill the vacancies on the Board created by the resignations of Kyle A. Lefkoff and John W. Creecy.

Mr. Hatfield and Dr. Bowden were appointed to the Board to serve until their successors are duly appointed and qualified or their earlier death, resignation or removal. The Board has determined that each of Mr. Hatfield and Dr. Bowden is an independent director as defined in the listing rules of The NASDAQ Capital Market.

Jeffrey S. Hatfield

Mr. Hatfield has been appointed to serve as a member of the Audit Committee of the Board (the *Audit Committee*). There were no arrangements or understandings between Mr. Hatfield and any other persons pursuant to which he was selected as a director, and there are no related person transactions within the meaning of Item 404(a) of Regulation S-K promulgated by the U.S. Securities and Exchange Commission (the *SEC*) between Mr. Hatfield and the Company required to be disclosed herein.

Mr. Hatfield brings relevant industry experience and a breadth of expertise to the Board. From March 2004 through October 2016, Mr. Hatfield served as President and Chief Executive Officer of Vitae Pharmaceuticals, Inc. (*Vitae*), until its acquisition by Allergan in 2016. Prior to working at Vitae, Mr. Hatfield was with Bristol-Myers Squibb Company (*Bristol-Myers*) serving in numerous executive capacities, including as Senior Vice President of Bristol-Myers's Immunology and Virology divisions. Mr. Hatfield currently serves as a director on the boards of aTyr Pharma, Inc., a publicly traded biotechnology company, and InVivo Therapeutics Corp., a publicly traded medical therapeutic company, and has previously served as a director of Ambit Biosciences Corporation before it was acquired by Daiichi Sankyo Company, Ltd. He is an adjunct professor and is a dean's advisory board member for Purdue

University's College of Pharmacy. He earned a bachelor's degree in pharmacy from Purdue University's School of Pharmacy and a Master of Business Administration degree from The Wharton School at the University of Pennsylvania.

Pursuant to the Company's Amended and Restated Non-Employee Director Compensation Policy (the ***Policy***), Mr. Hatfield will receive annual cash compensation in the amount \$35,000 for his Board service and \$7,500 for his Audit Committee service. Under the Policy, Mr. Hatfield has the right to elect to receive all or a portion of his annual cash compensation under the Policy in the form of either cash, restricted common stock based on the closing price of the Company's common stock on The NASDAQ Capital Market on the date of grant, or stock options to purchase common stock based on the Black-Scholes option-pricing model as of the date of grant. Under the Policy, Mr. Hatfield will receive a one-time, initial option grant to

purchase 24,000 shares of the Company's common stock with an exercise price equal to the fair market value of a shares of the Company's common stock on August 10, 2017. This option will vest in 36 equal monthly installments. In accordance with the Policy, Mr. Hatfield will also be eligible to receive an annual option award to purchase shares of the Company's common stock, subject to Mr. Hatfield's continued service on the Board.

In connection with his appointment to the Board, Mr. Hatfield entered into the Company's standard form of Indemnity Agreement, a copy of which was filed as Exhibit 10.32 to the Company's Registration Statement on Form S-4 (File No. 333-214893) filed with the SEC on December 2, 2016.

Christopher Bowden, M.D.

Dr. Bowden has been appointed to the Compensation Committee of the Board (the *Compensation Committee*). There were no arrangements or understandings between Dr. Bowden and any other persons pursuant to which he was selected as a director, and there are no related person transactions within the meaning of Item 404(a) of Regulation S-K promulgated by the SEC between Dr. Bowden and the Company required to be disclosed herein.

Dr. Bowden brings substantial experience in clinical drug development to the Board. He currently serves as the Chief Medical Officer of Agios Pharmaceuticals, Inc. (*Agios*). Prior to joining Agios, he served as vice president, product development oncology, franchise lead (Signaling Group) at Genentech, Inc., a member of the Roche Group. Dr. Bowden received his medical degree from Hahnemann University School of Medicine in Philadelphia followed by internal medicine training at Roger Williams Medical Center and Providence VA Medical Center, Rhode Island. He completed his medical oncology fellowship at the National Cancer Institute Medicine Branch and is board certified in internal medicine and medical oncology.

Pursuant to the Policy, Dr. Bowden will receive annual cash compensation in the amount \$35,000 for his Board service and \$5,000 for his Compensation Committee service. Under the Policy, Dr. Bowden has the right to elect to receive all or a portion of his annual cash compensation under the Policy in the form of either cash, restricted common stock based on the closing price of the Company's common stock on The NASDAQ Capital Market on the date of grant, or stock options to purchase common stock based on the Black-Scholes option-pricing model as of the date of grant. Under the Policy, Dr. Bowden will receive a one-time, initial option grant to purchase 24,000 shares of the Company's common stock with an exercise price equal to the fair market value of a shares of the Company's common stock on August 10, 2017. This option will vest in 36 equal monthly installments. In accordance with the Policy, Dr. Bowden will also be eligible to receive an annual option award to purchase shares of the Company's common stock, subject to Dr. Bowden's continued service on the Board.

In connection with his appointment to the Board, Dr. Bowden entered into the Company's standard form of Indemnity Agreement, a copy of which was filed as Exhibit 10.32 to the Company's Registration Statement on Form S-4 (File No. 333-214893) filed with the SEC on December 2, 2016.

Section 8 Other Events

Item 8.01 Other Events.

MRG-106

On August 11, 2017, the Company announced new interim results from the Company's ongoing Phase 1 clinical trial of MRG-106 in subjects with the mycosis fungoides form of cutaneous T-cell lymphoma. MRG-106 is the Company's product candidate for treatment of certain cancers and is an inhibitor of microRNA-155, which is found at abnormally high levels in several blood cancers.

The new interim results of the Phase 1 clinical trial indicated that enrolled subjects continued to show improvement in total skin disease as measured by maximal change in the subject's modified Severity Weighted Assessment Tool (*mSWAT*) score. As of July 26, seventeen of eighteen subjects treated systemically with MRG-106 showed mSWAT score improvement, and the magnitude of mSWAT improvements generally correlated with the amount of time the subject received MRG-106 treatment. As of July 26, seven of nine subjects receiving more than one month of dosing of MRG-106 showed a 50% or greater improvement in mSWAT scores. Additionally, subjects receiving the treatment via intravenous infusion appear to have improved at a higher rate than those receiving MRG-106 treatment via subcutaneous injection. MRG-106 has been generally safe and well-tolerated at all dose levels evaluated to date.

The Company also announced that it has initiated rapid intravenous dosing in patients after discussing the plan with the U.S.

Food and Drug Administration during a meeting in June 2017. This route of administration may allow for higher maximal blood concentration and could provide additional convenience to patients.

The Company announced that it plans to evaluate MRG-106 in additional oncology indications within the current Phase 1 trial, including in T-cell leukemia/lymphoma, diffuse large B-cell lymphoma and chronic lymphocytic leukemia, as in each case the disease process appears to be related to an increase in miR-155 levels.

MRG-201

The Company also announced that the double-blind, placebo-controlled, single and multiple dose-escalation Phase 1 trial evaluating MRG-201 in induced cutaneous fibrosis has been completed. The Company plans to present final clinical trial results at a scientific conference before the end of this year. In 2018, the Company intends to initiate a Phase 2a trial to evaluate MRG-201 in subjects with a predisposition for keloid formation. Future indications to be studied for miR-29 replacements could include other fibrotic diseases of the eye and the lung.

Section 9 Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit Number | Exhibit Description |
|---------------------------|----------------------------|
|---------------------------|----------------------------|

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|------|--------------------------------------|
| 99.1 | Press Release, dated August 11, 2017 |
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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.

Dated: August 11, 2017

Miragen Therapeutics, Inc.

By: /s/ William S. Marshall
William S. Marshall, Ph.D.
President and Chief Executive Officer

EXHIBIT INDEX

| Exhibit Number | Exhibit Description |
|---------------------------|--------------------------------------|
| 99.1 | Press Release, dated August 11, 2017 |