

MIRNA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 11/10/16 for the Period Ending 11/10/16

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| Address | 3711 SOUTH MOPAC EXPRESSWAY, STE 100 AUSTIN, TX 78746 |
| Telephone | 512-901-0900 |
| CIK | 0001527599 |
| Symbol | MIRN |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Pharmaceuticals |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

**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): November 10, 2016**

Mirna Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37566
(Commission
File Number)

26-1824804
(IRS Employer
Identification Number)

3711 South Mopac Expressway

Austin, TX 78735

(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (512) 901-0900

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation 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))
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Item 2.02 Results of Operations and Financial Condition.

On November 10, 2016, Mirna Therapeutics, Inc. (“Mirna”) issued a press release announcing its financial results for the three and nine months ended September 30, 2016 . The press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), or incorporated by reference in any filing of Mirna under the Securities Act or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|----------------|--|
| 99.1 | Press release dated November 10, 2016. |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MIRNA THERAPEUTICS, INC.

Date: November 10, 2016

By: /s/ Alan Fuhrman

Alan Fuhrman

Chief Financial Officer

Mirna Therapeutics Reports Third Quarter 2016 Financial Results and MRX34 Clinical Program Updates

Austin, TX—November 10, 2016— Mirna Therapeutics, Inc. (Nasdaq: MIRN), a biopharmaceutical company focused on microRNA-based oncology therapeutics, today reported financial results for the third quarter of 2016 and provided an update on recent developments.

MRX34 CLINICAL PROGRAM

In September 2016, the Company voluntarily halted the ongoing Phase 1 trial of its first product candidate, MRX34, following multiple immune-related serious adverse events (SAEs) observed in patients dosed with MRX34 over the course of the trial. Three of these immune-related events resulted in the patient's death. Subsequently, the U.S. Food and Drug Administration (FDA) notified the Company that the Investigational New Drug (IND) Application for MRX34 has been placed on full clinical hold. Among other comments, the FDA requested a final clinical study report be submitted and noted that a risk-benefit summary with sufficient justification for the continued development of MRX34 would be necessary if the Company requested removal of the clinical hold.

"We were disappointed with the outcome of our Phase 1 study, however, our first priority in developing innovative therapeutics is the safety of patients," said President and CEO Paul Lammers, M.D., M.Sc. "Based on our assessment of both potential therapeutic benefit and risk, we have decided to discontinue development of MRX34 and suspend our pipeline R&D programs."

The Company has initiated a plan to reduce personnel and expenses in order to preserve capital and streamline operations, and it plans to focus on meeting regulatory requirements related to closure of the Phase 1 trial as well as other operating activities consistent with the decision to discontinue development of MRX34. The Company also expects to explore and evaluate strategic alternatives with the goal of enhancing stockholder value.

THIRD QUARTER 2016 FINANCIAL RESULTS

- **Cash Position and Guidance:** Cash, cash equivalents, and marketable securities totaled \$66.7 million as of September 30, 2016, compared to \$89.7 million as of December 31, 2015. The Company has no debt.

Beginning in the first quarter of 2017, after giving effect to the personnel and expense reductions, the Company expects its quarterly cash burn rate will range from \$2.1 million to \$2.3 million. This 2017 quarterly guidance includes contractual commitments and obligations, but excludes any one-time charges related to a strategic transaction should one be concluded.

- **Research and development expenses:** Research and development expenses were \$3.4 million and \$11.6 million for the three and nine months ended September 30, 2016, respectively, compared to \$4.7 million and \$12.6 million during the comparable periods in 2015. The decrease for the three and nine months ended September 30, 2016 compared to the same period in 2015 was primarily attributable to higher costs incurred in 2015 associated with our Phase 1 clinical trial for MRX34, specifically adding additional sites and upfront drug manufacturing costs. The decrease in 2016 was partially offset by an increase in employee compensation, benefits and stock compensation.
- **General and Administrative Expenses:** General and administrative expenses were \$2.0 million and \$6.1 million for the three and nine months ended September 30, 2016, respectively, compared to \$1.6 million and \$3.6 million during the comparable periods in 2015. The increase in general and administrative expenses was primarily attributable to increased employee compensation expense due to a higher headcount and higher outside professional and consulting costs, the majority of which were costs to comply with public company operating and reporting requirements.
- **Net Loss:** Net loss was approximately \$5.4 million and \$17.6 million for the three and nine months ended September 30, 2016, compared to a net loss of \$6.2 million and \$16.2 million for the comparable periods in 2015. The results included non-cash, stock-based related compensation charges of \$513,000 and \$1,202,000 for the three and nine months ended September 30, 2016, respectively, and \$210,000 and \$561,000 for the comparable periods in 2015.

About Mirna Therapeutics, Inc.

Mirna is a biopharmaceutical company focused on the development of microRNA-based oncology therapeutics. Mirna's first product candidate, MRX34, the first microRNA mimic to enter clinical development in oncology, was studied as a single agent in a multicenter Phase 1 clinical trial, which included patients with primary liver cancer, other solid cancers, and hematological malignancies. In September 2016, Mirna voluntarily halted enrollment and dosing in the clinical study following multiple immune-related serious adverse events (SAEs) observed in patients dosed with MRX34 over the course of the trial. The Company is currently evaluating opportunities to enhance stockholder value.

Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Mirna, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding whether we will meet regulatory requirements related to closure of the Phase 1 trial, our exploration and evaluation of strategic alternatives with the goal of enhancing stockholder value and our expectations regarding our quarterly cash burn rate. Such forward-looking statements involve substantial risks and uncertainties that could cause our future results, performance or achievements to differ significantly from those

expressed or implied by the forward-looking statements. We undertake no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to our business in general, see our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 30, 2016 and our Quarterly Report on Form 10-Q, expected to be filed with the SEC on or about November 10, 2016 .

Mirna Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share data)

| | September 30, 2016 (Unaudited) | December 31, 2015 |
|---|--------------------------------------|----------------------|
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 26,958 | \$ 89,713 |
| Short-term marketable securities | 39,300 | — |
| Prepaid expenses and other current assets | 818 | 829 |
| Total current assets | 67,076 | 90,542 |
| Property and equipment, net | 1,834 | 375 |
| Long-term marketable securities | 400 | — |
| Restricted cash | 2,431 | — |
| Total assets | \$ 71,741 | \$ 90,917 |
| Liabilities and Stockholders' Equity (Deficit) | | |
| Current Liabilities: | | |
| Accounts payable | \$ 1,153 | \$ 3,687 |
| Accrued expenses | 1,943 | 2,214 |
| Total liabilities | 3,096 | 5,901 |
| Stockholders' Equity (Deficit): | | |
| Preferred stock, \$0.001 par value, 5,000,000 shares authorized at September 30, 2016 and December 31, 2015; 0 shares outstanding at September 30, 2016 and December 31, 2015 | — | — |
| Common stock, \$0.001 par value; 250,000,000 shares authorized at September 30, 2016 and December 31, 2015; 20,835,868 and 20,830,555 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively | 21 | 21 |
| Additional paid in capital | 162,729 | 161,518 |
| Accumulated other comprehensive loss | (8) | — |
| Accumulated deficit | (94,097) | (76,523) |
| Total stockholders' equity | 68,645 | 85,016 |
| Total liabilities and stockholders' equity | \$ 71,741 | \$ 90,917 |

Mirna Therapeutics, Inc.
Condensed Statement of Operations and Comprehensive Loss (unaudited)
(in thousands)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|------------|------------------------------------|-------------|
| | 2016 | 2015 | 2016 | 2015 |
| Operating expenses: | | | | |
| Research and development | \$ 3,384 | \$ 4,683 | \$ 11,589 | \$ 12,584 |
| General and administrative | 1,940 | 1,556 | 6,119 | 3,618 |
| Total operating expenses | 5,324 | 6,239 | 17,708 | 16,202 |
| Other income (expense): | | | | |
| Interest income | 97 | 8 | 272 | 8 |
| Loss on disposal of assets | (138) | — | (138) | — |
| Total other income (expense) | (41) | 8 | 134 | 8 |
| Net loss | \$ (5,365) | \$ (6,231) | \$ (17,574) | \$ (16,194) |
| Less: Accretion and dividends on convertible preferred stock | — | (1,554) | — | (4,217) |
| Net loss attributable to common stockholders | \$ (5,365) | \$ (7,785) | \$ (17,574) | \$ (20,411) |

Investors

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