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, 2021

Rain Therapeutics Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-40356**	**81-1130967**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

8000 Jarvis Avenue, Suite 204
Newark, CA 94560
(Address of Principal Executive Offices)

(510) 953-5559
(Registrant's telephone number, including area code)

Not Applicable
(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 obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

☐ 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 210.14d-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 Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**RAIN**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 10, 2021, Rain Therapeutics Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

This Item 2.02 and the Press Release attached hereto as Exhibit 99.1, insofar as they disclose information regarding the Company's results of operations and financial condition for the quarter ended September 30, 2021, are being furnished to the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits

(d) *Exhibits*. The following exhibit is being furnished herewith:

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated November 10, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: November 10, 2021

Rain Therapeutics Inc.

By: /s/ Avanish Vellanki
Avanish Vellanki
Chairman and Chief Executive Officer

Exhibit 99.1

Rain Therapeutics Reports Third Quarter 2021 Financial Results and Highlights Recent Progress

New Phase 2 clinical trial planned for milademetan in Merkel cell carcinoma (MCC), the MANTRA-3 trial, to start in mid-2022

Quarter-end cash position of $150.1 million provides runway to advance research and development (R&D) pipeline and complete all three planned clinical trials of milademetan

Management to host conference call and webcast today at 4:30PM Eastern Time

NEWARK, Calif., Nov. 10, 2021 (GLOBE NEWSWIRE) — Rain Therapeutics Inc. (NasdaqGS: RAIN), (Rain), a late-stage company developing precision oncology therapeutics, today reports financial results for the third quarter and nine months ended September 30, 2021, along with an update on the company's key developments, business operations and upcoming milestones.

"Rain has had a number of important recent accomplishments including data presentations at various medical conferences and announcement of plans to progress our lead candidate, milademetan, into a Phase 2 trial for patients with Merkel cell carcinoma," said Avanish Vellanki, co-founder and chief executive officer of Rain. "We continue to view milademetan as having a differentiated therapeutic index and will remain focused on strategies to further enhance its value for patients with MDM2-dependent cancers."

Key Developments and Operational Updates

- **Phase 2 Basket Trial (MANTRA-2) of Milademetan for MDM2-Amplified Advanced Solid Tumors**
  - Rain anticipates enrolling the first patient in its multicenter, open-label Phase 2 basket trial (MANTRA-2) this quarter, evaluating milademetan, an oral mouse double minute 2 (MDM2) inhibitor for the treatment of MDM2-amplified advanced solid tumors.
- **Non-Clinical Data on Milademetan Presented at IASLC 2021 (Sept. 8-14, 2021) and AACR-NCI-EORTC ("Triple Cancer Conference") 2021 (Oct. 7-10, 2021)**
  - Rain, in collaboration with certain research partners, presented non-clinical data on milademetan in MDM2-amplified tumors, Merkel cell carcinoma, GATA3-mutant ER+ breast cancer, and mesothelioma models.
- **Rain Highlights Plans for Phase 2 Trial for Milademetan in Merkel Cell Carcinoma (MANTRA-3)**
  - On the strength of recent non-clinical data from the Dana-Farber Cancer Institute presented at the Triple Cancer Conference, Rain is now prioritizing a Phase 2 clinical trial of milademetan as monotherapy in MCC patients failing first-line checkpoint inhibitors, with a trial start anticipated in mid-2022. The Phase 2 MCC clinical trial will replace the previously planned Phase 2 clinical trial of milademetan in intimal sarcoma.

- **Research and Development (R&D) Day**
  - Rain hosted a R&D Day webinar on November 9, 2021 which featured several key opinion leaders in oncology, along with members of Rain's management team, who discussed the Company's R&D program, as well as select clinical and preclinical data. A replay of the event is archived on the Company's corporate website here.

Anticipated Near-term Milestones

- **Milademetan MDM2-Amplified Phase 2 Basket Trial (MANTRA-2)**
  - Phase 2 trial anticipated to commence enrollment this quarter
  - Interim data anticipated in the second half of 2022
- **Milademetan MCC Phase 2 Trial (MANTRA-3)**
  - Phase 2 trial anticipated to commence in mid-2022
- **Milademetan Dedifferentiated Liposarcoma Phase 3 Trial (MANTRA)**
  - Data anticipated in 2023
- **RAD52 Research Program**
  - Lead candidate selection anticipated in 2022

Third Quarter Financial Results

For the three and nine months ended September 30, 2021, Rain reported a net loss of $18.4 million and $33.4 million, respectively, as compared to a net loss of $10.4 million and $15.6 million for the same periods in 2020, respectively. Net loss per share for the three and nine months ended September 30, 2021, was $0.70 and $1.96, respectively, as compared to a net loss per share of $3.05 and $4.73 for the same periods in 2020, respectively.

R&D expenses were $15.3 million and $26.1 million for the three and nine months ended September 30, 2021, respectively, as compared to $7.9 million and $11.2 million for the same periods in 2020, respectively. The increases were primarily driven by development milestone fees to Daiichi Sankyo Co., Ltd, R&D costs for Rain's lead candidate, milademetan, mainly for its on-going Phase 3 pivotal trial in dedifferentiated liposarcoma, as well as personnel costs. Non-cash stock-based compensation expenses included in R&D expenses were approximately $0.7 million and $1.4 million in the three and nine months ended September 30, 2021, respectively, as compared to $0.2 million and $0.4 million in the same periods in 2020, respectively.

General and administrative (G&A) expenses were $3.2 million and $7.3 million for the three and nine months ended September 30, 2021, respectively, as compared to $0.6 million and $2.3 million for the same periods in 2020, respectively. The increases were primarily due to increases in various third-party G&A costs, including legal costs, outside consulting fees and accounting and audit fees associated with maintaining compliance with exchange listing and SEC requirements as a public company, as well as personnel costs. Non-cash stock-based compensation expense included in G&A expenses were approximately $0.1 million and $0.4 million for the three and nine months ended September 30, 2021, respectively as compared to $0.1 million and $0.2 million for the same periods in 2020, respectively.

Total non-cash stock-based compensation expenses were approximately $0.8 million and $1.8 million in the three and nine months ended September 30, 2021, respectively, as compared to $0.3 million and $0.6 million for the same periods in 2020, respectively.

As of September 30, 2021, Rain had $150.1 million in cash, cash equivalents and short-term investments. Rain expects that its quarter-end cash position will provide runway to continue advancing its R&D pipeline and complete all three planned clinical trials of milademetan.

As of September 30, 2021, Rain had approximately 26.5 million shares of common stock outstanding.

The Company continues to expect its full year 2021 net cash used in operating activities to be approximately $50 million to $60 million and a projected year end cash balance of approximately $137 million to $147 million in cash, cash equivalents and short-term investments.

Third Quarter 2021 Results Conference Call and Webcast Details
The management of Rain Therapeutics will host a conference call and webcast for the investment community today, November 10, 2021, at 1:30 p.m. PT (4:30 p.m. ET). The conference call can be accessed by dialing 1 (833) 562-0127 (U.S. Toll Free) / 1 (661) 567-1105 (U.S. Toll). The passcode for the conference call is 1985710. A live webcast may be accessed by visiting the “Investors” section of the Rain Therapeutics’ website at www.rainthera.com. The call will be recorded and available for replay on the Company’s website for approximately 30 days after the call.

About Milademetan

Milademetan is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. Milademetan has already demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors in a Phase 1 clinical trial, validating a rationally-designed dosing schedule to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition. Milademetan is being evaluated in an ongoing Phase 3 clinical trial in patients with LPS (MANTRA) with a planned Phase 2 tumor-agnostic basket trial in certain solid tumors (MANTRA-2) anticipated to start in the fourth quarter of 2021. Rain Therapeutics also anticipates commencing a Phase 2 clinical trial of milademetan (MANTRA-3), for the treatment of patients with Merkel cell carcinoma refractory to immune checkpoint inhibition (ICI), in mid-2022. Milademetan has received U.S. Food and Drug Administration Orphan Drug Designation for patients with LPS.

About Rain Therapeutics Inc.

Rain Therapeutics Inc. is a late-stage precision oncology company developing therapies that target oncogenic drivers for which it is able to genetically select patients it believes will most likely benefit. This approach includes using a tumor-agnostic strategy to select patients based on their tumors’ underlying genetics rather than histology. Rain’s lead product candidate, milademetan, is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. In addition to milademetan, Rain is also developing a preclinical program that is focused on inducing synthetic lethality in cancer cells by inhibiting RAD52.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the results, conduct, progress and timing of Rain’s ongoing and planned trials for milademetan, the timing for data for Rain’s trials for milademetan, the potential for milademetan as a MDM2 inhibitor program and as a monotherapy for MCC, the timing for selection of a lead candidate for RAD52, the adequacy of Rain’s capital resources and the expected net cash used in operation activities and year end cash balance for full year 2021. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “plans,” “will,” “anticipates,” “goal,” “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Rain’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Rain’s business in general, our substantial dependence on the success of our lead product candidate, lack of success in our clinical trials, difficulties in enrolling patients, competition from competing products, the impact of the COVID-19 pandemic, and the other risks and uncertainties described in Rain’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 and subsequent filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. Rain undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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RAIN THERAPEUTICS INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	15,284	7,893	26,101	11,195
General and administrative	3,154	591	7,334	2,311
Total costs and expenses	18,438	8,484	33,435	13,506
Loss from operations	(18,438)	(8,484)	(33,435)	(13,506)
Other income (expense)				
Interest income	11	—	25	23
Interest expense, related party	—	(71)	—	(135)
Change in fair value of convertible promissory notes, related party	—	(1,891)	—	(2,024)
Other income	1	—	1	2
Total other income (expense), net	12	(1,962)	26	(2,134)
Net loss	$ (18,426)	$ (10,446)	$ (33,409)	$ (15,640)
Other comprehensive income:				
Unrealized gain on investments	$ 5	—	$ 5	—
Comprehensive loss	$ (18,421)	$ (10,446)	$ (33,404)	$ (15,640)
Net loss per share, basic and diluted	$ (0.70)	$ (3.05)	$ (1.96)	$ (4.73)
Weighted-average shares used in computing net loss per share, basic and diluted	26,466,746	3,422,458	17,025,032	3,307,932

SUMMARY BALANCE SHEET DATA
(in thousands)

	September 30 2021	December 31, 2020 (1)
	(unaudited)	
Cash, cash equivalents and short-term investments	$ 150,081	$ 58,863
Total assets	158,531	61,080
Stockholders' equity (deficit)	(147,275)	(37,417)

(1) Derived from audited financial statements