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, 2022

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, 2022, Rain Therapeutics Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. 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, 2022, 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, 2022
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 14, 2022

Rain Therapeutics Inc.

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

Exhibit 99.1

Rain Therapeutics Reports Third Quarter 2022 Financial Results and Highlights Recent Progress

– End of third quarter cash position of $90.7 million excludes the recent $50 million registered offering, and together, provide a cash runway into 2025 –

– Phase 3 pivotal MANTRA trial topline data now anticipated in first quarter of 2023 –

– Phase 2 MANTRA-2 trial preliminary interim data demonstrates encouraging monotherapy signal in ten evaluable patients; MANTRA-2 continues to enroll –

– Phase 2 MANTRA-3 trial deprioritized to rationalize use of financial resources –

– Phase 1/2 MANTRA-4 trial anticipated to commence in first quarter 2023 –

– Management to host conference call and webcast today at 5:00 PM Eastern Time –

NEWARK, Calif., November 10, 2022 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc. (NasdaqGS: RAIN), (Rain), a late-stage biotechnology company developing precision oncology therapeutics with a lead product candidate, milademetan, an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53, today reported financial results for the third quarter ended September 30, 2022, along with an update on the Company's key developments, business operations and upcoming milestones.

"Rain continues to execute on our milademetan franchise with encouraging early interim data from our Phase 2 MANTRA-2 trial and anticipated near-term topline data from our Phase 3 registrational MANTRA trial next quarter," said Avanish Vellanki, co-founder and chief executive officer of Rain. "The preliminary observations of monotherapy activity of milademetan in the MANTRA-2 trial demonstrates encouraging data in a novel biomarker-based tumor agnostic strategy and supporting potential in additional MDM2-dependent cancers."

Dr. Robert Doebele, MD, PhD, president and chief scientific officer of Rain continued, "Preliminary data from the MANTRA-2 trial exhibited activity with two unconfirmed partial responses (PRs) at their first scan and promising tumor regression activity in two additional patients following milademetan monotherapy. We are very encouraged to see proof of concept activity using a genetic selection strategy across a diverse set of solid tumor types in heavily pre-treated patients, and those that possess multiple genetic co-alterations including strong oncogenic driver mutations. We believe the early activity suggests reactivation of p53 in MDM2-dependent cancers and may represent a sound therapeutic strategy with single-agent milademetan, and possibly through combination regimens as well."

Dr. Richard Bryce, MBChB, chief medical officer of Rain continued, "We have also observed this promising activity from the MANTRA-2 trial in patients with MDM2 copy number above 8. Hence, we plan to revise the protocol to include patients tested locally for MDM2 copy number of 8 and greater and anticipate this will further enhance the pace of enrollment to expedite completion of the 65-patient trial. We plan to initiate the MANTRA-4 trial next quarter and remain very excited about this second tumor agnostic basket strategy."

Key Corporate Updates and Upcoming Milestones

- **$50.0 Million Registered Offering of Common Stock**
  - Completed a $50.0 million registered offering of common stock and non-voting common stock on November 8, 2022
  - End of third quarter cash balance of $90.7 million excludes the $50.0 million registered offering

- **Phase 3 MANTRA Trial of Milademetan in Dedifferentiated Liposarcoma**
  - Topline data now anticipated in the first quarter of 2023
- **Phase 2 Preliminary Interim Data for the MANTRA-2 Basket Trial of Milademetan for MDM2-Amplified Advanced Solid Tumors**
  - As of October 26, 2022, ten patients were efficacy-evaluable with CN ≥8 by central testing
    - Two unconfirmed PRs were observed with tumor regression of 34% and 30% (pancreatic and lung cancer, respectively)
      - The patient with pancreatic cancer is pending response confirmation and ongoing treatment
      - The patient with lung cancer is deceased due to COVID-19
    - Two patients exhibited promising activity with tumor regression of 29% and 27% (biliary tract and breast cancer, respectively) and the patients are continuing with the investigational therapy
  - Observed rapid anti-tumor effect of milademetan in heavily pretreated, refractory patients, with a median of four prior therapies
  - Safety profile to date is preliminarily consistent with prior Phase 1 milademetan trial
- **Phase 2 MANTRA-3 Trial in Merkel Cell Carcinoma Deprioritized**
  - MANTRA-3 is deprioritized to rationalize use of financial and personnel resources
- **Phase 1/2 MANTRA-4 Basket Trial in Advanced Solid Tumors Exhibiting Loss of the CDKN2A Gene**
  - Commencement of MANTRA-4, the trial to evaluate the combination of milademetan with Roche's FDA-approved IO therapy, atezolizumab, planned for first quarter of 2023
- **Recent addition to our Scientific Advisory Board, Nicholas A. Saccomano, Ph.D. in September 2022**
  - Dr. Saccomano is the former Chief Scientific Officer of Array Biopharma, and a seasoned leader and mentor with over 30 years of experience in pharmaceutical and biotechnology research and development

Our updated corporate presentation includes details of the preliminary interim data for MANTRA-2 and is available at the "Corporate Presentation" section of the Rain website.

Third Quarter Financial Results

For the three and nine months ended September 30, 2022, Rain reported a net loss of $18.0 million and $53.0 million, respectively, as compared to a net loss of $18.4 million and $33.4 million for the same periods in 2021, respectively.

Research and development (R&D) expenses were $14.5 million and $42.3 million for the three and nine months ended September 30, 2022, respectively, as compared to $15.3 million and $26.1 million for the same periods in 2021, respectively. The decrease for the three months ended September 30, 2022 as compared to the prior period was primarily due to the milestone fees to Daiichi Sankyo of $5.5 million incurred during the prior period, partially offset by various R&D costs for milademetan, as well as higher payroll-related costs for Rain's R&D personnel. The increase for the nine-months ended September 30, 2022 as compared to the prior period was primarily driven by the ongoing MANTRA Phase 3 trial in

liposarcoma and Phase 2 tumor-agnostic basket trial (MANTRA-2), as well as personnel costs and various other R&D costs for milademetan. Non-cash stock-based compensation expenses included in R&D expenses were approximately $0.7 million and $2.8 million in the three and nine months ended September 30, 2022, respectively, as compared to $0.7 million and $1.4 million in the same periods in 2021, respectively.

General and administrative (G&A) expenses were $3.9 million and $11.3 million for the three and nine months ended September 30, 2022, respectively, as compared to $3.2 million and $7.3 million for the same periods in 2021, respectively. The increases were primarily due to higher payroll-related costs for Rain's G&A personnel, outside consulting, legal costs and various third-party G&A costs. Non-cash stock-based compensation expense included in G&A expenses were approximately $0.2 million and $0.8 million for the three and nine months ended September 30, 2022, as compared to $0.2 million and $0.4 million for each of the same periods in 2021.

Total non-cash stock-based compensation expense were approximately $0.9 million and $3.6 million for the three and nine months ended September 30, 2022, respectively, as compared to $0.9 million and $1.8 million for the same periods in 2021, respectively.

As of September 30, 2022, Rain had $90.7 million in cash, cash equivalents and short-term investments as compared to $140.2 million at December 31, 2021. On November 8, 2022, Rain completed a $50.0 million registered offering of common stock and non-voting common stock, and together with the cash balance as of September 30, 2022 provides cash runway into 2025.

As of September 30, 2022, Rain had approximately 26.6 million shares of common stock outstanding.

Third Quarter 2022 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, 2022 at 2:00 pm PT (5:00 pm ET). A live webcast may be accessed here. The conference call can be accessed by dialing 1 (877) 704-4453 (U.S. Toll Free) / 1 (201) 389-0920 (International). The passcode for the conference call is 13733093.

Replay of the call will be available by visiting the "Events" section of the Rain website after the conclusion of the presentation and will be archived on the Rain website for 30 days.

About MANTRA-2

The MANTRA-2 trial is designed to evaluate the safety and efficacy of milademetan monotherapy in patients with advanced or metastatic solid tumors refractory or intolerant to standard-of-care therapy and that exhibit wild-type p53 and a prespecified minimum MDM2 gene copy number. Approximately 65 patients are anticipated to be enrolled to receive milademetan. As of the latest data cutoff on October 26, 2022, 17 patients have been enrolled. The primary endpoint of the trial is objective response rate as measured by RECIST criteria. Secondary endpoints include duration of response, disease control rate progression-free survival by investigator assessment, overall survival and growth modulation index.

About Milademetan

Milademetan (also known as RAIN-32) is an oral small molecule inhibitor of the MDM2-p53 complex that reactivates p53.Milademetan has demonstrated antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors in a Phase 1 clinical trial, supported by a rationally designed dosing schedule to mitigate safety concerns and widen the potential therapeutic window of MDM2 inhibition. Rain has completed enrollment in a Phase 3 trial of milademetan (MANTRA) in patients with LPS, and is evaluating milademetan in a Phase 2 tumor-agnostic basket trial in certain solid tumors (MANTRA-2). Rain anticipates commencing a Phase 1/2 clinical trial to evaluate the safety, tolerability and efficacy of milademetan in combination with Roche's atezolizumab in patients with loss of cyclin-dependent kinase inhibitor 2A (CDKN2A) and wildtype p53 advanced solid tumors (MANTRA-4), in the first quarter of 2023. Milademetan has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of LPS.

About Rain Therapeutics Inc.

Rain Therapeutics Inc. is a late-stage precision oncology company developing therapies that target oncogenic drivers 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-p53 complex that reactivates p53. 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, Rain's ongoing and planned trials for milademetan, including expected timing for the commencement of MANTRA-4, the efficacy and safety profile of milademetan, expected trial design, expected timing for topline data in MANTRA trial and the relationship between the results from the interim data from trial and results of future or ongoing clinical studies. 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," "expects" 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 and limited operating history, Rain's ability to execute on its strategy, Rain's reliance on third parties to conduct and support its preclinical studies and clinical trials, positive results from a clinical trial, or interim data from an ongoing clinical trial, may not necessarily be predictive of the results of future or ongoing clinical studies, the effect of the COVID-19 pandemic on Rain's clinical trials and business operations, the impact of general economic, health, industrial or political conditions in the United States or internationally, additional state and federal healthcare reform measures that could result in reduced demand for Rain's product candidates, the sufficiency of Rain's capital resources and its ability to raise additional capital, and the other risks described in Rain's Annual Report on Form 10-K for the year ended December 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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 14,510	$ 15,284	$ 42,322	$ 26,101
General and administrative	3,901	3,154	11,257	7,334
Total operating expenses	18,411	18,438	53,579	33,435
Loss from operations	(18,411)	(18,438)	(53,579)	(33,435)
Other income:				
Interest income	370	11	533	25
Other income	—	1	—	1
Total other income, net	370	12	533	26
Net loss	$ (18,041)	$ (18,426)	$ (53,046)	$ (33,409)
Net loss per share, basic and diluted	$ (0.68)	$ (0.70)	$ (2.00)	$ (1.96)
Weighted-average shares used to compute net loss per share, basic and diluted	26,564,615	26,466,746	26,535,474	17,025,032

SUMMARY BALANCE SHEET DATA
(in thousands)

	September 30, 2022 (unaudited)	December 31, 2021(1)
Cash, cash equivalents and short-term investments	$ 90,708	$ 140,218
Total assets	94,635	147,140
Stockholders' equity	81,409	130,504

(1) Derived from audited financial statements