

**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): March 3, 2022

Rain Therapeutics Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40356
(Commission
File Number)

82-1130967
(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 March 3, 2022, Rain Therapeutics Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 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 year ended December 31, 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

<u>Exhibit No.</u>	Description
99.1	Press Release, dated March 3, 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: March 3, 2022

Rain Therapeutics Inc.

By: /s/ Avanish Vellanki

Avanish Vellanki

Chairman and Chief Executive Officer



Rain Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Highlights Recent Progress

- Quarter-end cash position of \$140.2 million provides runway to complete all ongoing and planned clinical trials of milademetan, including an ample cash cushion for the Phase 3 MANTRA trial in liposarcoma –
- Enrollment in both Phase 3 liposarcoma trial (MANTRA) and Phase 2 basket trial (MANTRA-2) are on schedule, all site activations anticipated by the end of the first quarter 2022 –
- Rain entered into a clinical supply agreement with Roche for the supply of atezolizumab for a planned Phase 1 trial (MANTRA-4) combination study of milademetan and atezolizumab in patients with CDKN2A loss and p53 wildtype advanced cancers –
- Management to host conference call and webcast today at 4:30 PM Eastern Time –

NEWARK, Calif., March 3, 2022 (GLOBE NEWSWIRE) — Rain Therapeutics Inc. (NasdaqGS: RAIN), (Rain), a late-stage company developing precision oncology therapeutics, today reports financial results for the fourth quarter and full year ended December 31, 2021, along with an update on the Company's key developments, business operations and upcoming milestones.

“Rain has achieved a number of important clinical milestones for milademetan including commencing two of the four planned trials in MDM2-dependent cancers. Rain dosed the first patient in the third quarter of last year and exceeded year-end 2021 targets for site activations for the pivotal, Phase 3 MANTRA trial in patients with liposarcoma and dosed the first patient in our Phase 2 MANTRA-2 basket trial in genetically selected patients with MDM2 gene amplification. We have also outlined two additional trials to start in the second half of this year, including the MANTRA-3 trial in patients with Merkel cell carcinoma, and our first combination trial MANTRA-4, with Roche's anti-PD-L1 antibody, atezolizumab, in patients with advanced cancers exhibiting loss of the CDKN2A gene,” said Avanish Vellanki, co-founder and chief executive officer of Rain.

Mr. Vellanki added, “We believe we have a strong capital position supporting completion of our ongoing and planned clinical trials, including an ample cash cushion for the Phase 3 MANTRA data timelines in liposarcoma. Further, considering the current capital markets picture in the biotech industry, we have taken steps to be even more prudent with capital to preserve the opportunity to generate data for milademetan across a diverse set of cancers.”

Key Developments and Operational Updates

- **Phase 3 Dedifferentiated Liposarcoma Trial (MANTRA) is enrolling on schedule**
 - Global site activations exceeded the target for year-end 2021, and all sites anticipated to be activated by the end of the first quarter of 2022. Enrollment in MANTRA trial on schedule.
- **Phase 2 Basket Trial (MANTRA-2) of Milademetan for MDM2-Amplified Advanced Solid Tumors**
 - Rain dosed the first patient in its multicenter, open-label Phase 2 basket trial (MANTRA-2) in November 2021, evaluating milademetan in MDM2-amplified advanced solid tumors. Enrollment in MANTRA-2 trial on schedule.
 - Rain made significant progress in site activations for MANTRA-2 and anticipates all sites will be activated by the end of the first quarter of 2022.

- **Phase 2 Trial for Milademetan in Merkel Cell Carcinoma (MANTRA-3)**
 - A Phase 2 clinical trial of milademetan as monotherapy in Merkel cell carcinoma (MCC) patients relapsed from first-line checkpoint inhibitors is anticipated to commence in the second half of 2022.
- **Rain Enters into Clinical Supply Agreement with Roche for the Supply of Atezolizumab in a Phase 1 Basket Trial in Advanced Solid Tumors Exhibiting Loss of the CDKN2A Gene (MANTRA-4)**
 - In January 2022, Rain announced a clinical supply agreement with Roche for the supply of the anti-Programmed Death Ligand-1 (PD-L1) monoclonal antibody, atezolizumab.
 - A Phase 1 trial (MANTRA-4) is planned to evaluate the safety, tolerability and efficacy of milademetan in combination with Roche's atezolizumab in patients with loss of CDKN2A and wild-type p53 advanced solid tumors and is anticipated to commence in the second half of 2022.
- **RAD52 Research Program**
 - Continues to progress, with Rain-generated compounds exhibiting improved potency and selectivity versus the initial licensed portfolio.

Key Upcoming Milestones

- Milademetan Dedifferentiated Liposarcoma Phase 3 Trial (MANTRA)
 - Top-line data anticipated in 2023
- Milademetan MDM2-Amplified Phase 2 Basket Trial (MANTRA-2)
 - Interim data anticipated in the second half of 2022
- Milademetan MCC Phase 2 Trial (MANTRA-3)
 - Phase 2 trial anticipated to commence in the second half of 2022
- Milademetan Phase 1 Combination Trial (MANTRA-4)
 - Phase 1 trial anticipated to commence in the second half of 2022

Fourth Quarter Financial Results

For the three months and year ended December 31, 2021, Rain reported a net loss of \$18.0 million and \$51.4 million, respectively, as compared to a net loss of \$5.4 million and \$21.1 million for the same periods in 2020, respectively. Net loss per share for the three months and year ended December 31, 2021, was \$0.68 and \$2.65, respectively, as compared to a net loss per share of \$1.56 and \$6.29 for the same periods in 2020, respectively.

R&D expenses were \$14.7 million and \$40.8 million for the three months and year ended December 31, 2021, respectively, as compared to \$4.2 million and \$15.4 million for the same periods in 2020, respectively. The increases were primarily driven by the ongoing Phase 3 pivotal trial in dedifferentiated liposarcoma (MANTRA) and Phase 2 tumor-agnostic basket trial (MANTRA-2), as well as personnel costs. Non-cash stock-based compensation expenses included in R&D expenses were approximately \$1.1 million and \$2.5 million in the three months and year ended December 31, 2021, respectively, as compared to \$0.2 million and \$0.6 million in the same periods in 2020, respectively.

General and administrative (G&A) expenses were \$3.4 million and \$10.7 million for the three months and year ended December 31, 2021, respectively, as compared to \$1.3 million and \$3.6 million for the same periods in 2020, respectively. The increases were primarily due to higher costs associated with Rain becoming a public company, including the costs of director and officer insurance, personnel, legal, outside consulting, and accounting and audit fees. Non-cash stock-based compensation expense included in G&A expenses were approximately \$0.2 million and \$0.6 million for the three months and year ended December 31, 2021, respectively, as compared to \$0.1 million and \$0.3 million for the same periods in 2020, respectively.

Total non-cash stock-based compensation expenses were approximately \$1.3 million and \$3.1 million for the three months and year ended December 31, 2021, respectively, as compared to \$0.3 million and \$0.9 million for the same periods in 2020, respectively.

As of December 31, 2021, Rain had \$140.2 million in cash, cash equivalents and short-term investments. Rain anticipates that its year-end cash position will provide runway into the first half of 2024, including completion of all its ongoing and planned clinical trials with an ample cash cushion for the Phase 3 MANTRA trial in liposarcoma.

As of December 31, 2021, Rain had approximately 26.5 million shares of common stock outstanding.

Fourth 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, March 3, 2022 at 1:30 pm PT (4:30 pm ET). A live webcast may be accessed here: <https://edge.media-server.com/mmc/p/c4ut4zai>. The conference call can be accessed by dialing (833) 562-0127. The passcode for the conference call is 4729972.

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 Milademetan

Milademetan (also known as RAIN-32) is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. Milademetan has already 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 therapeutic window of MDM2 inhibition. Milademetan is being evaluated in an ongoing Phase 3 clinical trial in patients with LPS (MANTRA), as well as a Phase 2 tumor-agnostic basket trial in certain solid tumors (MANTRA-2). Rain anticipates commencing a Phase 2 clinical trial of milademetan (MANTRA-3), for the treatment of patients with wildtype p53 Merkel cell carcinoma who are also refractory to immune checkpoint inhibition (ICI), in the second half of 2022, as well as a Phase 1 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 second half of 2022. Milademetan has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) 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, Rain's ongoing and planned studies for milademetan, including patient enrollment in the Phase 3 trial (MANTRA) and Phase 2 trial (MANTRA-2), timing for the commencement of the planned Phase 2 trial (MANTRA-3) and Phase 1 trial (MANTRA-4) and the timing for topline and interim data, and expectations regarding the sufficiency of capital resources. 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, difficulty enrolling patients in our clinical trials given the relatively small LPS patient population, Rain's reliance on third parties to conduct and support its preclinical studies and clinical trials, and the other risks 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 December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
	(unaudited)		(audited)	
Operating expenses:				
Research and development	\$ 14,672	\$ 4,172	\$ 40,773	\$ 15,367
General and administrative	3,405	1,280	10,739	3,591
Total costs and expenses	<u>18,077</u>	<u>5,452</u>	<u>51,512</u>	<u>18,958</u>
Loss from operations	(18,077)	(5,452)	(51,512)	(18,958)
Other income (expense)				
Interest income	94	9	119	32
Interest expense, related party	—	—	—	(135)
Change in fair value of convertible promissory notes, related party	—	—	—	(2,024)
Other income	—	—	1	2
Total other income (expense), net	<u>94</u>	<u>9</u>	<u>120</u>	<u>(2,125)</u>
Net loss before income tax expense	\$ (17,983)	\$ (5,443)	\$ (51,392)	\$ (21,083)
Income tax expense	(2)	—	(2)	—
Net loss	<u>\$ (17,985)</u>	<u>\$ (5,443)</u>	<u>\$ (51,394)</u>	<u>\$ (21,083)</u>
Net loss per share, basic and diluted	<u>\$ (0.68)</u>	<u>\$ (1.56)</u>	<u>\$ (2.65)</u>	<u>\$ (6.29)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>26,470,600</u>	<u>3,482,687</u>	<u>19,405,833</u>	<u>3,351,850</u>

SUMMARY BALANCE SHEET DATA
(in thousands)

	December 31, 2021	December 31, 2020
	(audited)	(audited)
Cash, cash equivalents and short-term investments	\$ 140,218	\$ 58,863
Total assets	147,140	61,080
Stockholders' equity (deficit)	130,504	(37,417)