

**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 10, 2021

Rain Therapeutics Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40356
(Commission
File Number)

81-1130967
(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 August 10, 2021, Rain Therapeutics Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 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 June 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release, dated August 10, 2021</u>

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 10, 2021

Rain Therapeutics Inc.

By: /s/ Avanish Vellanki

Avanish Vellanki

Chairman and Chief Executive Officer

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

First patient dosed in Phase 3 registrational trial (MANTRA) evaluating milademetan (RAIN-32) in patients with dedifferentiated (“DD”) liposarcoma (“LPS”)

Quarter-end cash position of \$164.6 million provides runway through late 2024

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

NEWARK, Calif., August 10, 2021 (GLOBE NEWSWIRE) — Rain Therapeutics Inc. (“Rain”), a late-stage company developing precision oncology therapeutics, today reports financial results for the second quarter and six months ended June 30, 2021, along with an update on the company’s key developments, business operations and upcoming milestones.

“Rain has made strong progress in the second quarter and six months ended 2021,” said Avanish Vellanki, co-founder and chief executive officer of Rain. “Patients with dedifferentiated liposarcoma are in desperate need of new therapies, and we are proud to have been able to dose the first patient in a pivotal Phase 3 trial in under 12 months from acquiring the program. As we move forward with the milademetan clinical strategy, we look to commence our second trial, MANTRA-2, in patients with MDM2-amplified solid tumors, in the second half of 2021.”

Key Developments and Operational Updates

- **First Patient Dosed in Phase 3 MANTRA Clinical Trial of Milademetan (RAIN-32) for DD LPS**
 - In July 2021, Rain announced that the first patient was randomized in the multicenter, open-label, Phase 3 registrational trial (MANTRA) evaluating milademetan, an oral mouse double minute 2 (“MDM2”) inhibitor, for the treatment of DD LPS.
 - Rain anticipates data from this trial in 2023.
- **MDM2-Amplified Phase 2 Basket Trial (MANTRA-2) to commence shortly**
 - Rain anticipates enrolling the first patient in its basket study of patients with MDM2-amplified advanced solid tumors (MANTRA-2) in the second half of 2021. These patients will exhibit a degree of MDM2 amplification that Rain believes is oncogenic and sensitive to MDM2 inhibition.
 - Rain anticipates interim data in 2H 2022.
- **Collaborations with Tempus and Caris Life Sciences for the Milademetan MDM2-Amplified Phase 2 Basket Trial (MANTRA-2)**
 - In June 2021, Rain announced an agreement with Tempus, an artificial intelligence and precision medicine company, to use their comprehensive genomic profiling testing platform for the Phase 2, MANTRA-2 basket trial for milademetan. Under the terms of the agreement, Tempus will provide both centralized tumor testing and patient matching services using their Connect & TIME Trial® Network.

- In June 2021, Rain also announced a patient referral partnership with Caris Life Sciences (“Caris”). Under the terms of the partnership, Caris will provide patient referral services using their molecular intelligence trials platform for MANTRA-2.
- **Milademetan Non-Clinical Data Abstracts Submitted to Upcoming Conferences**
 - Rain, in collaboration with several research partners, intends to present non-clinical data at upcoming conferences relating to additional clinical opportunities for milademetan in the second half of 2021. Presentations for milademetan have been submitted and accepted to the 2021 World Conference of Lung Cancer (Sept. 8-14, 2021) and the 2021 EORTC-NCI-AACR International Conference on Molecular Targets and Cancer Therapeutics virtual conference (Oct. 7-10, 2021).

Anticipated Near-term Milestones

- **Milademetan MDM2-Amplified Phase 2 Basket Study (MANTRA-2)**
 - Phase 2 trial expected to commence in the second half of 2021
 - Rain anticipates interim data in 2H 2022
- **Milademetan Intimal Sarcoma Phase 2 Study**
 - Phase 2 trial expected to commence by early 2022
 - Rain anticipates interim data in late 2022
- **Milademetan DD LPS Phase 3 Study (MANTRA)**
 - Rain anticipates data from this trial in 2023
- **RAD52 Research Program**
 - Lead candidate selection expected in 2022

Second Quarter Financial Results

For the three and six months ended June 30, 2021, Rain reported a net loss of \$8.2 million and \$15.0 million, respectively, as compared to a net loss of \$2.6 million and \$5.2 million for the same periods in 2020, respectively. Net loss per share for the three and six months ended June 30, 2021, were \$0.39 and \$1.23, respectively, as compared to a net loss per share of \$0.78 and \$1.60 for the same periods in 2020, respectively.

Research and development (“R&D”) expenses were \$5.5 million and \$10.8 million for the three and six months ended June 30, 2021, respectively, as compared to \$1.5 million and \$3.2 million for the same periods in 2020, respectively. The increases were primarily driven by the clinical costs for Rain’s lead product candidate, milademetan, as Rain prepared to launch its Phase 3 pivotal trial in DD LPS in July 2021, as well as personnel costs. Non-cash stock-based compensation expenses included in R&D expenses were approximately \$0.6 million and \$0.8 million in the three and six months ended June 30, 2021, respectively, as compared to \$0.1 million and \$0.2 million in the same periods in 2020, respectively.

General and administrative (“G&A”) expenses were \$2.7 million and \$4.2 million for the three and six months ended June 30, 2021, respectively, as compared to \$1.1 million and \$1.8 million for the same periods in 2020, respectively. The increases were primarily due to increases in various third-party G&A costs, including legal, outside consulting, as well as accounting and audit fees. Non-cash stock-based compensation expense included in G&A expenses were approximately \$0.2 million in each of the three and six months ended June 30, 2021, 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 \$1.0 million in the three and six months ended June 30, 2021, respectively, as compared to \$0.2 million and \$0.4 million for the same periods in 2020, respectively.

As of June 30, 2021, Rain had \$164.6 million in cash, cash equivalents and short-term investments. This included the \$121.5 million in net proceeds from Rain’s initial public offering in April 2021. Rain’s quarter-end cash position adequately provides runway through late-2024.

As of June 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 \$50.0 million to \$60.0 million and a projected year end cash balance of approximately \$137.0 million to \$147.0 million in cash, cash equivalents and short-term investments.

Second 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, August 10, 2021, at 1:30 p.m. PT (4:30 p.m. ET). The conference call can be accessed by dialing 1 (800) 708-4539 (U.S. Toll Free) / 1 (847) 619-6396 (U.S. Toll). The passcode for the conference call is 50202648. 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 Well-Differentiated/Dedifferentiated Liposarcoma

Liposarcoma (“LPS”) is a rare cancer originating from fat cells located in the soft tissues of the body. It is a malignant cancer that can spread to other parts of the body. Well-differentiated (“WD”) LPS is less aggressive and tends to present as a large painless mass found in deeper tissues. Dedifferentiated (“DD”) LPS is more aggressive, arising from WD LPS, and is usually found in tissue behind the abdominal area (retroperitoneal) or the extremities. WD/DD LPS are the most frequent subtypes of LPS and share common genomic abnormalities, predominately MDM2 gene amplification. The incidence of LPS is estimated at approximately 3,000 patients annually in the U.S., of which two-thirds are of the DD and WD type, and for which there are few effective treatment options.

About MANTRA Trial

The MANTRA trial is a randomized, multicenter, open-label, Phase 3 registrational trial evaluating milademetan, an oral MDM2 inhibitor, for the treatment of DD LPS. The MANTRA trial is designed to evaluate the safety and efficacy of milademetan compared to trabectedin, a current standard of care, in patients with unresectable or metastatic DD LPS that progressed on one or more prior systemic therapies, including at least one anthracycline-based therapy. Approximately 160 patients will be randomly assigned in a 1:1 ratio to receive milademetan or trabectedin. The primary objective of the MANTRA trial is to compare progression-free survival as determined by blinded independent review between the milademetan treatment arm and trabectedin control arm, in patients with unresectable or metastatic DD LPS, with or without a well-differentiated LPS component. Overall survival, disease control rate, objective response rate, duration of response, safety and patient reported outcomes will also be evaluated.

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 (RAIN-32), 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 (RAIN-32), the tolerability and safety profile of milademetan, the timing for selection of a lead candidate for RAD52 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.

Media Contact:

Jordyn Temperato

LifeSci Communications

+1.646.876.5196

jtemperato@lifescicomms.com

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	5,489	1,473	10,817	3,235
Selling, general and administrative	2,700	1,119	4,180	1,787
Total costs and expenses	<u>8,189</u>	<u>2,592</u>	<u>14,997</u>	<u>5,022</u>
Loss from operations	(8,189)	(2,592)	(14,997)	(5,022)
Other income (expense)				
Interest income	6	6	14	26
Interest expense, related party	—	(33)	—	(64)
Change in fair value of convertible promissory notes, related party	—	(5)	—	(133)
Total other income (expense), net	<u>6</u>	<u>(32)</u>	<u>14</u>	<u>(171)</u>
Net loss	<u>\$ (8,183)</u>	<u>\$ (2,624)</u>	<u>\$ (14,983)</u>	<u>\$ (5,193)</u>
Net loss per share, basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.78)</u>	<u>\$ (1.23)</u>	<u>\$ (1.60)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>20,825,334</u>	<u>3,360,388</u>	<u>12,225,929</u>	<u>3,250,039</u>

SUMMARY BALANCE SHEET DATA
(in thousands)

	June 30, 2021 (unaudited)	December 31, 2020 (1)
Cash, cash equivalents and short-term investments	\$ 164,647	\$ 58,863
Total assets	174,553	61,080
Stockholders' equity (deficit)	164,834	(37,417)

(1) Derived from audited financial statements

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

	Three Months Ended March 31,	
	2021	2020
	(unaudited)	
Operating expenses:		
Research and development	5,328	1,762
Selling, general and administrative	1,480	668
Total costs and expenses	<u>6,808</u>	<u>2,430</u>
Loss from operations	(6,808)	(2,430)
Other income (expense)		
Interest income	8	20
Interest expense, related party	—	(31)
Change in fair value of convertible promissory notes, related party	—	(128)
Total other income (expense), net	<u>8</u>	<u>(139)</u>
Net loss	<u>\$ (6,800)</u>	<u>\$ (2,569)</u>
Net loss per share, basic and diluted	<u>\$ (1.93)</u>	<u>\$ (0.82)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>3,530,975</u>	<u>3,139,695</u>

SUMMARY BALANCE SHEET DATA
(in thousands)

	March 31, 2021 (unaudited)	December 31, 2020 (1)
Cash, cash equivalents and short-term investments	\$ 53,110	\$ 58,863
Total assets	56,497	61,080
Stockholders' deficit	(44,052)	(37,417)

(1) Derived from audited financial statements