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 13, 2023

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

Delaware	**001-41799**	**84-4388509**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5505 Morehouse Drive, Suite 300
San Diego, California 92121
(Address of principal executive offices)

Registrant's telephone number, including area code: (619) 937-2754

N/A
(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:

☐ 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))

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, $0.0001 par value per share	RYZB	Nasdaq Global Market

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

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 13, 2023, RayzeBio, Inc. (the "***Company***") issued a press release announcing its financial results for the quarter ended September 30, 2023. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

All of the information furnished in this Item 2.02 and Exhibit 99.1 of this Current Report on Form 8-K shall not be deemed to be "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, and shall not be incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 13, 2023
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.

RayzeBio, Inc.

Dated: November 13, 2023

By: /s/ Ken Song
Ken Song, M.D.
President and Chief Executive Officer

Exhibit 99.1

RayzeBio Reports Third Quarter 2023 Financial Results and Provides Corporate Update

SAN DIEGO, California, November 13, 2023 -- RayzeBio, Inc. (Nasdaq: RYZB), a targeted radiopharmaceutical company developing an innovative pipeline against validated solid tumor targets, today reported financial results for the third quarter ended September 30, 2023 and provided an update on key corporate initiatives.

“We have made significant progress in 2023 and achieved several clinical, discovery and corporate milestones as we continue to lead innovation in developing targeted radiopharmaceuticals for the benefit of patients with cancer,” said Ken Song, M.D., President and CEO of RayzeBio. “Our lead asset, RYZ101, is the first Actinium-225 based treatment in a Phase 3 clinical trial. We are on track to file an IND in the first half of 2024 for our next clinical drug candidate, which is focused on treating patients with liver cancer. Additionally, our oversubscribed IPO in September 2023 provides us with a strong balance sheet to fully invest in our initiatives.”

Recent Highlights and Upcoming Milestones

- ***Enrollment ongoing for the Phase 3 portion of the ACTION-1 clinical trial as well as follow-up of patients from the Phase 1b:*** Enrollment is ongoing in the registrational global Phase 3 portion of the ACTION-1 clinical trial of RYZ101 for patients with SSTR2 expressing GEP-NETs who have experienced progression of their cancer following treatment with Lu177 somatostatin analog therapy. RayzeBio expects to present the Phase 3 interim analysis in late 2025 / early 2026. As part of the IPO and subsequently at ESMO in October 2023, RayzeBio reported the interim results of the Phase 1b portion of the ACTION-1 clinical trial, where RayzeBio enrolled a total of 17 patients. As of the last data cut off on June 30, 2023, treatment has been well tolerated with no treatment-related serious adverse events or dose discontinuations due to any adverse event. Additionally, five patients have had a confirmed partial response, or PR, which is based on two consecutive evaluations showing PR, representing a confirmed objective response rate, or ORR, of 29%. RayzeBio is continuing to monitor the patients and expects to present updated Phase 1b data at a medical conference during the first half of 2024.

- ***RYZ801 and RYZ811 IND filing for HCC expected in 1H 2024:*** RYZ801 is a novel proprietary peptide which targets GPC3 for delivery of Ac225 for the treatment of HCC. Using Gallium 68, or Ga68, an imaging radioisotope, RayzeBio has already shown uptake of its novel proprietary peptide binder in patients with HCC via early human imaging studies conducted outside of the United States. RYZ801 is currently in IND enabling studies. Additionally, RayzeBio is developing RYZ811, which is a paired diagnostic imaging agent with the same peptide binder and chelator as RYZ801 but with Ga68 as the radioisotope. The Company plans to file an IND for each of RYZ801 and RYZ811 in the first half of 2024 followed by a Phase 1 clinical trial in HCC patients.

- ***Buildout of our state of the art manufacturing facility on track to be completed by the end of 2023:*** RayzeBio expects its in-house manufacturing facility in Indianapolis to be completed by the end of 2023 with GMP drug production starting in the first half of 2024. This facility will be an important milestone in creating vertical integration, which is essential to be a successful targeted radiopharmaceutical company.

- ***Completed $357 million upsized Initial Public Offering:*** In September, the Company completed its upsized IPO of 19,869,240 shares of common stock, at a price to the public of $18.00 per share. RayzeBio sold 18,706,240 shares of common stock and a selling stockholder sold 1,163,000 shares of common stock. The aggregate gross proceeds to RayzeBio from the offering, before deducting underwriting discounts and commissions and other offering expenses payable by RayzeBio, were approximately $336.7 million.

- ***Strengthened team with key Board of Director Appointments:*** RayzeBio added seasoned biotech executive Christy Oliger to its board of directors in August 2023 to provide commercial expertise. Additionally, in November 2023, RayzeBio added Tim Van Hauwermeiren, co-founder and CEO of argenx to its board of directors, further strengthening the board.

Third Quarter Financial Results

- **Cash Position**: As of September 30, 2023, RayzeBio had cash, cash equivalents and short-term investments of $540.2 million. RayzeBio projects its cash position is sufficient to fund operations through various milestones across its clinical programs.
- **Research and Development (R&D) Expenses:** R&D expenses for the third quarter of 2023 were $18.2 million, compared to $18.8 million for the third quarter of 2022. R&D expenses decreased primarily due to reduction in expenses related to license rights, offset by increases related to the clinical advancement of RYZ101 in GEP-NETs, pre-clinical efforts for RYZ801 and personnel costs, including share-based compensation expense associated with the growth of the Company's R&D team.
- **General and Administrative (G&A) Expenses:** G&A expenses for the third quarter of 2023 were $3.5 million, compared to $2.1 million for the third quarter of 2022. The increase of $1.4 million was primarily attributable to the increase in personnel costs associated with increased headcount and legal and other professional services conducted to support the growth of the business.
- **Net Loss:** Net loss for the third quarter of 2023 was $18.2 million, compared to the net loss for the third quarter of 2022 which was $20.4 million.

About RayzeBio
RayzeBio is building a vertically integrated radiopharmaceutical therapeutics (RPT) company to treat various cancers, with its lead program in a Phase 3 clinical trial. RayzeBio has created a pipeline of multiple drug candidates in therapeutic areas with significant market opportunities. Much like antibody drug conjugates emerged as a new and transformative treatment modality in certain cancers, the company sees an opportunity for innovative radiopharmaceutical therapeutics to follow a similar path. RayzeBio believes its strategic investments in building a robust product pipeline, development capabilities, and manufacturing infrastructure position the company to be an industry-leading pioneer in the broad application of RPT for cancer.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this press release that are not statements of historical fact are forward-looking statements. Such forward-looking statements include, without limitation, statements regarding the Company's ambition to become the leading targeted radiopharmaceutical company; the Company's expectations regarding plans for its current and future product candidates and programs; the potential therapeutic benefits of the Company's current and future product candidates; the planned clinical development of RYZ101, RYZ801 and the timing thereof, including anticipated timing of completion of enrollment of the ACTION-1 clinical trial and interim results thereof, as well as timing of IND submission for RYZ801; the expected timing of operationalizing the Company's manufacturing facility; and expectations regarding the time period over which the Company's capital resources will be sufficient to fund its anticipated operations. Words such as "believe," "anticipate," "plan," "expect," "intend," "will," "may," "goal," "potential" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. These forward-looking statements are based on the beliefs of the management of the Company as well as assumptions made by and information currently available to the Company. Such statements reflect the current views of the Company with respect to future events and are subject to known and unknown risks and uncertainties, including business, regulatory, economic and competitive risks and uncertainties about the Company, including, without limitation, risks inherent in developing drug candidates, future results from the Company's ongoing and planned clinical trials, the Company's ability to obtain adequate financing to fund its planned clinical trials and other expenses, risks that future clinical trial results may not be consistent with interim, initial or preliminary results or results from prior preclinical studies or clinical trials, trends in the industry, the legal and regulatory framework for the industry and future expenditures. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. The actual results may vary from the anticipated results and the variations may be material. Other factors that may cause the Company's actual results to differ from current expectations are discussed in the Company's filings with the Securities and Exchange Commission, including the section titled "Risk Factors" in the Company's Quarterly Report on From 10-Q for the quarter ended September 30, 2023. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date this press release is given. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Contact: Arvind Kush Email: info@rayzebio.com

RayzeBio, Inc.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating Expenses:				
Research and development	$ 18,170	$ 18,828	$ 48,759	$ 46,416
General and administrative	3,481	2,122	9,479	8,244
Total operating expenses	21,651	20,950	58,238	54,660
Loss from operations	(21,651)	(20,950)	(58,238)	(54,660)
Total other income, net	3,460	503	9,436	762
Net loss	(18,191)	(20,447)	(48,802)	(53,898)
Dividends	(1,209)	(4,550)	(1,209)	(4,550)
Net loss attributable to common stockholders	(19,400)	(24,997)	(50,011)	(58,448)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.26)	$ (6.55)	$ (5.99)	$ (17.14)
Weighted-average common shares outstanding, basic and diluted	15,399,901	3,817,307	8,350,628	3,409,940

RayzeBio, Inc.
Selected Condensed Balance Sheet Data
(in thousands)
(unaudited)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 251,964	$ 129,159
Short-term investments	288,205	167,087
Total assets	603,513	324,776
Total liabilities	28,191	20,812
Accumulated deficit	(180,127)	(130,116)