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): **July 31, 2023**

REPLIMUNE GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38596**	**82-2082553**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

500 Unicorn Park Drive
Suite 303
Woburn, MA 01801
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(781) 222-9600**

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, par value $0.001 per share	REPL	The Nasdaq Stock Market LLC (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 (§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 August 3, 2023, Replimune Group, Inc. (the "Company") issued a news release announcing its financial results for the first quarter ended June 30, 2023 and certain corporate updates. A copy of the news release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly stated by specific reference in such filing.

Item 7.01 Regulation FD Disclosure

On July 31, 2023, the Company issued a news release announcing its entry into a clinical trial collaboration and supply agreement with Incyte Corporation. A copy of the news release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information contained in this Item 7.01 and in the accompanying Exhibit 99.2 shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Item 7.01 and the accompanying Exhibit 99.2 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	News Release dated August 3, 2023
99.2	News Release dated July 31, 2023
104	Cover page interactive data file (formatted as Inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REPLIMUNE GROUP, INC.

Date: August 3, 2023

By: /s/ Philip Astley-Sparke
Philip Astley-Sparke
Chief Executive Officer

Exhibit 99.1

Replimune Reports Fiscal First Quarter 2024 Financial Results and Provides Corporate Update

Topline data from the registration-directed CERPASS clinical trial of RP1 combined with Libtayo® (cemiplimab-rwlc) in cutaneous squamous cell carcinoma expected in early Q4 2023 and Biologics License Application submission anticipated in Q1/2 2024

Cost sharing collaboration in cutaneous squamous cell carcinoma in the neoadjuvant setting entered into with Incyte

Data snapshot for all 141 patients in the IGNYTE clinical trial cohort of RP1 in anti-PD1 failed melanoma expected Q4 2023

RP2 and RP3 Phase 2 programs; third-line colorectal cancer clinical trial initated, first- and second-line hepatocellular carcinoma trials expected to initiate this quarter; Phase 1 clinical trial update expected at year end

Strong balance sheet with cash runway into H2 2025

Woburn, MA, August 3, 2023 – Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel portfolio of tumor-directed oncolytic immunotherapies, today announced financial results for the fiscal first quarter ended June 30, 2023 and provided a business update.

"It was a productive quarter with positive updates for RP1 in anti-PD1 failed melanoma and RP2 in uveal melanoma presented at ASCO. The duration of responses are particularly impressive with all responding patients in the anti-PD1 failed melanoma 75 patient cohort presented late last year continuing without progression," said Philip Astley-Sparke, CEO of Replimune. "We now look forward to presenting the top-line data from our registration-directed CERPASS trial of RP1 in combination with Libtayo in cutaneous squamous cell carcinoma (CSCC) as well as sharing an initial snapshot from the full patient population in the IGNYTE clinical trial cohort of RP1 combined with Opdivo in anti-PD1 failed melanoma later in the year. Commercial preparations are progressing, and in line with our ambition of establishing a major skin cancer franchise, we are pleased to announce that we have entered a cost sharing collaboration with Incyte to conduct a clinical trial for the neoadjuvant treatment of CSCC with RP1 and the oral PD-L1 inhibitor, INCB99280."

Program Highlights & Milestones

RP1

- **CERPASS clinical trial of RP1 combined with Libtayo® in CSCC**
  - The trigger for the primary analysis from the registration-directed CERPASS clinical trial occurred in late June and data collection activities are nearly complete. Guidance for the top line data disclosure has been updated from Q3 to early Q4 2023 as a result of the independent review read rate tracking behind projections. Assuming positive data demonstrating overall clinical benefit, the Company plans to submit a biologics license application (BLA) for RP1 in Q1/2 2024, with the potential to combine the filings for both the CERPASS clinical trial and the IGNYTE anti-PD1 failed melanoma cohort.

- **Announced Clinical Trial Collaboration with Incyte to Evaluate RP1 and INCB099280 in CSCC**

  - Under the terms of the agreement, Incyte will initiate and sponsor a clinical trial of INCB99280 (oral PD-L1 inhibitor) and RP1 in approximately 40 patients with unresectable, high risk CSCC in the neoadjuvant setting. Replimune will supply Incyte with RP1 for the study and share costs.

- **RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed non-melanoma skin cancers**

  - Recruitment remains ongoing into the cohort of patients with anti-PD1 failed non-melanoma skin cancers, including CSCC, with a data update expected from the first 30 patients with at least six months follow up in early Q4 2023.

- **RP1 in solid organ transplant recipients with skin cancers**

  - Presented initial data from the ARTACUS clinical trial of RP1 monotherapy in solid organ transplant recipients with skin cancers at the American Transplant Congress (ATC) Meeting in June. These data included 11 evaluable patients with cutaneous squamous cell carcinoma (N=10) and Merkel cell carcinoma (N=1).

  - The data demonstrated an overall response rate (ORR) of 27.3%, with all responders achieving confirmed complete responses (CR).

  - RP1 monotherapy was well tolerated, and the safety profile was similar to non-immunocompromised patients with advanced skin cancers (IGNYTE study). No immune-mediated adverse events or evidence of allograft rejection were observed.

- **RP1 combined with Opdivo in anti-PD1 failed melanoma**

  - Presented updated data from the ongoing IGNYTE clinical trial at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in June. These data included the first 75 patients from the anti-PD1 failed melanoma cohort combined with the 16 anti-PD1 failed melanoma patients from the prior all comers 30 patient melanoma cohort (N=91 in total).

  - The data demonstrated an overall response rate (ORR) of 37.4%, with clinically meaningful activity across the range of anti-PD1 failed cutaneous melanoma settings enrolled, including in patients with moderate-high tumor burden and with visceral disease.

  - Systemic activity was seen in both injected and un-injected lesions, with both responding with similar durability and kinetics, including in un-injected visceral disease.

  - RP1 continues to be generally well tolerated with safety data showing predominantly ‘on target’ flu-like Grade 1-2 side effects indicative of systemic immune activation. Grade 3 treatment related events were rarely seen in the 91-patient group, with a range of Grade 3 events in one patient each, and two Grade 3 events of fatigue. There were two Grade 4 treatment related events (elevated lipase, and cytokine release syndrome) and no treatment related Grade 5 events.

  - The Company remains on track to announce snapshot data for all patients (N=141) in Q4 2023 by which point all patients will have had at least 6 months follow up, prior to the per protocol primary analysis at 12 months post the last patient enrolled.

RP2 and RP3

- **RP2 combined with nivolumab in uveal melanoma**

  - Presented updated data from an ongoing Phase 1b trial of RP2 at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in June. To date 17 patients have been treated with RP2 as monotherapy (N=3) or in combination with nivolumab (N=14) to date, with enrollment of uveal melanoma patients into this clinical trial now being complete.

  - In uveal melanoma, four of the 14 evaluable patients have thus far responded to treatment (28.6%), including metastatic tumors in the liver and bone. The final three of 17 patients remain on treatment, but currently have insufficient follow-up data to determine response outcome as of the cut-off date. Three of the four responses are ongoing at 9, 12 and 21 months, including for patients with liver and bone metastases, with the fourth patient having progressed at 15 months.

  - The safety profile as monotherapy and in combination with nivolumab was generally well tolerated with no additive adverse events observed.

- **RP2 and RP3 Phase 2 program**

  - RP2 and RP3 in combination with atezolizumab and bevacizumab in third-line colorectal cancer (CRC)

    - Two signal finding cohorts of 30 patients each will be enrolled in collaboration with Roche. The first cohort will enroll patients to be treated with atezolizumab combined with bevacizumab and RP2 and the second cohort with atezolizumab and bevacizumab and RP3. The Company believes that data with both RP2 and RP3 in CRC will allow the comparative efficacy of RP2 and RP3 to be evaluated in a particularly difficult to treat patient population. This clinical trial has now been initiated.

  - RP3 in combination with atezolizumab and bevacizumab in first (1L) and second-line (2L) hepatocellular carcinoma (HCC)

    - Two signal finding cohorts of 30 patients each will be enrolled in collaboration with Roche. The first cohort will enroll 1L patients treated with SOC atezolizumab combined with bevacizumab and RP3, and the second cohort will enroll patients who have progressed on 1L immunotherapy (including atezolizumab/bevacizumab), and will be treated with atezolizumab combined with bevacizumab and RP3. This clinical trial is expected to initiate this quarter.

  - RP3 in combination with standard of care therapy in squamous cell carcinoma of the head and neck (SCCHN)

    - A two-cohort clinical trial is planned, with the first cohort of 100 patients with locally advanced disease being randomized to receive either standard of care (SOC) cisplatin chemotherapy combined with radiation or RP3 combined with chemotherapy and radiation followed by adjuvant nivolumab therapy. The second, signal finding cohort, will enroll 30 patients with recurrent or metastatic SCCHN with low PDL1 levels (CPS<20) who will be treated with chemotherapy (carbopltin and paclitaxel), nivolumab and RP3. Due to the the global shortage of cisplatin and carboplatin, initiation of this study is currently on hold until sufficient supplies of these agents are available.

- **RP2 and RP3 Phase 1 program**

  - Accrual in the Phase 1 program is expected to materially complete in Q3 2023. Any additional Phase 2 development programs not already announced which are driven by data from the full Phase 1 data and other opportunistic considerations are expected to be disclosed by year end.

Corporate Update

- **Announced the appointment of new member to Board of Directors**

  - The Company appointed Veleka R. Peeples-Dyer, strategic enterprise leader and former Chair of the North American Food and Drug practice and Co-Chair of the Global Regulatory Group at Baker McKenzie, to the Company's Board of Directors effective June 1, 2023. The appointment strengthens the Company's board as it prepares for the anticipated commercialization of its leading pipeline of oncolytic immunotherapies, beginning with the potential 2024 commercial launch of RP1.

Financial Highlights

- **Cash Position:** As of June 30, 2023, cash, cash equivalents and short-term investments were $539.1 million, as compared to $583.4 million as of March 31, 2023. The decrease was primarily related to cash utilized in operating activities in advancing the Company's expended clinical development plans.

  Based on the current operating plan, the Company believes that existing cash, cash equivalents and short-term investments, as of June 30, 2023, will enable the Company to fund operations into the second half of calendar year 2025.

- **R&D Expenses:** Research and development expenses were $40.4 million for the first quarter ended June 30, 2023, as compared to $29.5 million for the first quarter ended June 30, 2022. This increase was primarily due to increased clinical and manufacturing expenses driven by the Company's lead programs and increased personnel expenses. Research and development expenses included $3.3 million in stock-based compensation expenses for the first quarter ended June 30, 2023.

- **S,G&A Expenses:** Selling, general and administrative expenses were $15.2 million for the first quarter ended June 30, 2023, as compared to $11.4 million for the first quarter ended June 30, 2022. The increase was primarily driven by personnel related costs, including sales and marketing personnel associated with pre-launch planning and build of the Company's commercial infrastructure. Selling, general and administrative expenses included $5.5 million in stock-based compensation expenses for the first quarter ended June 30, 2023.

- **Net Loss:** Net loss was $49.6 million for the first quarter ended June 30, 2023, as compared to a net loss of $42.3 million for the first quarter ended June 30, 2022.

About CERPASS

CERPASS is Replimune's registration-directed randomized, global Phase 2 clinical trial to compare the effects of Libtayo® (cemiplimab-rwlc) alone versus a combination of Libtayo and Replimune's investigational oncolytic immunotherapy RP1. The clinical trial recently completed enrollment and enrolled 211 patients with locally advanced or metastatic cutaneous squamous cell carcinoma who are naïve to anti-PD-1 therapy. The clinical trial will evaluate complete response rate and overall response rate as its two independent primary efficacy endpoints as assessed by independent review, as well as secondary endpoints including duration of response, progression-free survival, and overall survival. The clinical trial is being conducted under a clinical trial collaboration agreement with Regeneron and full commercial rights retained by Replimune. Libtayo is a registered trademark of Regeneron.

About IGNYTE

IGNYTE is Replimune's multi-cohort Phase 1/2 trial of RP1 plus nivolumab. There are 3 tumor specific cohorts currently enrolling in this clinical trial including a 125-patient cohort in anti-PD1 failed melanoma with registrational intent. This cohort was initiated after completing enrollment in a prior Phase 2 cohort in the same clinical trial of approximately 30 patients with melanoma. The additional cohorts are in non-melanoma skin cancers which includes both naïve and anti-PD1 failed CSCC, and in anti-PD1 failed microsatellite instability high, or MSI-H/dMMR tumors. This trial is being conducted under a collaboration and supply agreement with Bristol-Myers Squibb.

About RP1

RP1 is Replimune's lead product candidate and is based on a proprietary new strain of herpes simplex virus engineered and genetically armed with a fusogenic protein (GALV-GP R-) and GM-CSF to maximize tumor killing potency, the immunogenicity of tumor cell death, and the activation of a systemic anti-tumor immune response.

About RP2 & RP3

RP2 and RP3 are derivatives of RP1 that express additional immune-activating proteins. RP2 expresses an anti-CTLA-4 antibody-like molecule and RP3 additionally expresses the immune co-stimulatory pathway activating proteins CD40L and 4-1BBL, but does not express GM-CSF. RP2 and RP3 are intended to provide targeted and potent delivery of these proteins to the sites of immune response initiation in the tumor and draining lymph nodes, with the goal of focusing systemic immune-based efficacy on tumors and limiting off-target toxicity.

About Replimune

Replimune Group, Inc., headquartered in Woburn, MA, was founded in 2015 with the mission to transform cancer treatment by pioneering the development of novel tumor-directed oncolytic immunotherapies. Replimune's proprietary RPx platform is based on a potent HSV-1 backbone with payloads added to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform has a unique dual local and systemic mechanism of action consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens and altering of the tumor microenvironment to ignite a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities, and, with an attractive safety profile the RPx platform has the versatility to be developed alone or combined with a variety of other treatment options. For more information, please visit www.replimune.com.

Forward Looking Statements

This press release contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations about our cash runway, the design and advancement of our clinical trials, the timing and sufficiency of our clinical trial outcomes to support potential approval of any of our product candidates, our goals to develop and commercialize our product candidates, patient enrollments in our existing and planned clinical trials and the timing thereof, and other statements identified by words such as “could,” “expects,” “intends,” “may,” “plans,” “potential,” “should,” “will,” “would,” or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to generate positive clinical trial results for our product candidates, the costs and timing of operating our in-house manufacturing facility, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, political and global macro factors including the impact of the coronavirus as a global pandemic and related public health issues, and other risks as may be detailed from time to time in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other reports we file with the Securities and Exchange Commission. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

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Replimune Group, Inc.
Condensed Consolidated Statements of Operations
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,	
	2023	**2022**
Operating expenses:		
Research and development	$ 40,437	$ 29,478
General and administrative	15,211	11,398
Total operating expenses	55,648	40,876
Loss from operations	(55,648)	(40,876)
Other income (expense):		
Research and development incentives	393	851
Investment income	6,186	343
Interest expense on finance lease liability	(544)	(552)
Interest expense on debt obligations	(1,115)	-
Other income (expense)	1,374	(2,019)
Total other income (expense), net	6,294	(1,377)
Net loss attributable to common stockholders	$ (49,354)	$ (42,253)
Income tax provision	201	$ -
Net loss	$ (49,555)	$ (42,253)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.75)	$ (0.78)
Weighted average common shares outstanding, basic and diluted	66,367,702	54,211,446

Replimune Group, Inc.
Condensed Consolidated Balance Sheets
(Amounts In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2023	**March 31, 2023**
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 539,100	$ 583,386
Working capital	517,800	558,778
Total assets	603,891	646,591
Total stockholders' equity	514,029	555,292

Exhibit 99.2

FOR IMMEDIATE RELEASE

Replimune and Incyte Enter into Clinical Trial Collaboration and Supply Agreement to Evaluate RP1 and INCB099280 in Patients with Cutaneous Squamous Cell Carcinoma

Initial study in the neoadjuvant setting designed to assess RP1 in combination with the small molecule, oral PD-L1 inhibitor, INCB99280

WOBURN, Mass. and WILMINGTON, Del., July 31, 2023 – Replimune Group, Inc. (NASDAQ:REPL), a clinical stage biotechnology company pioneering the development of a novel portfolio of tumor-directed oncolytic immunotherapies, and Incyte (NASDAQ:INCY), a global biopharmaceutical company, today announced a clinical trial collaboration and supply agreement to study RP1, Replimune's lead product candidate, in combination with INCB99280, Incyte's small molecule oral PD-L1 inhibitor.

"We are excited to enter into this collaboration with Incyte to explore the use of RP1 prior to surgery as we believe that our tumor-directed oncolytic immunotherapies could have a great impact in the neoadjuvant setting both in cutaneous squamous cell carcinoma (CSCC) and in other cancer types, given the high rates of complete responses we've seen to date, and data indicating RP1 is generally very well tolerated" said Robert Coffin, Chief Research and Development Officer of Replimune. "The unique potential of the RPx platform to induce a patient-specific anti-tumor immune response with an off-the-shelf treatment speaks to the practicality and broad potential utility of the approach, and exploring its use with Incyte's oral PD-L1 inhibitor has the potential to improve the patient experience further."

"We look forward to collaborating with Replimune on this study evaluating INCB99280 and RP1 in patients with CSCC. Our oral PD-L1 program has shown promising safety and efficacy in early studies thus far, and we look forward to adding to the growing body of evidence for INCB99280 and learning more about its potential to improve clinical outcomes," said Lance Leopold, M.D., Group Vice President, Clinical Development Hematology and Oncology, Incyte.

Under the terms of the agreement, Incyte will initiate and sponsor the clinical trial of INCB99280 and RP1 in patients with high risk, resectable cutaneous squamous cell carcinoma (CSCC), with the clinical trial expected to initiate in early 2024. Replimune will supply Incyte with RP1 for the study and share equally in the costs of the study.

About RP1

RP1 is Replimune's lead oncolytic immunotherapy product candidate and is based on a proprietary new strain of herpes simplex virus engineered for robust tumor selective replication and genetically armed with a fusogenic protein (GALV-GP R-) and GM-CSF, intended to maximize tumor killing potency, the immunogenicity of tumor cell death, and the activation of a systemic anti-tumor immune response.

About INCB99280

INCB099280 is a potent and selective small molecule oral PD-L1 inhibitor, which has demonstrated promising clinical activity and safety in patients with solid tumors. INCB099280 is being evaluated in multiple Phase 2 studies as monotherapy and in combination with other antitumor agents.

About Replimune

Replimune Group, Inc., headquartered in Woburn, MA, was founded in 2015 with the mission to transform cancer treatment by pioneering the development of novel tumor-directed oncolytic immunotherapies. Replimune's proprietary RPx platform is based on a potent HSV-1 backbone with payloads added to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform has a unique dual local and systemic mechanism of action (MOA) consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens and altering of the tumor microenvironment (TME) to ignite a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities, and, with an attractive safety profile the RPx platform has the versatility to be developed alone or combined with a variety of other treatment options. For more information, please visit www.replimune.com.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

Replimune Forward-looking Statements

This press release contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations about the design and advancement of our clinical trials, those of our collaboration partners or the combined clinical trials with our collaboration partners, the timing and sufficiency of our clinical trial outcomes to support potential approval of any of our RPx product candidates or those of, or combined with, our collaboration partners, our goals to develop and commercialize our RPx product candidates alone or with our collaboration partners, patient enrollments in our planned clinical trials, alone or with our collaboration partners, and the timing thereof, and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to generate positive clinical trial results for our RPx product candidates, alone or with our collaboration partners, changes in laws and regulations to which we are subject, political and global macro factors, and other risks as may be detailed from time to time in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other reports we file with the Securities and Exchange Commission. Our actual results and the actual results of our collaboration partners and/or the combined results with our collaboration partners could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

Incyte Forward-looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the potential of INCB99280 and/or RP1 to treat patients with cuteaneous squamos carcinoma or for any other indication, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte‘s current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by regulatory authorities; Incyte‘s dependence on its relationships with its collaboration partners; the efficacy or safety of Incyte‘s products and the products of Incyte‘s collaboration partners; the acceptance of Incyte‘s products and the products of Incyte‘s collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte‘s reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended March 31, 2023. Incyte disclaims any intent or obligation to update these forward-looking statements.

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