UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K/A

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): June 28, 2023

Roivant Sciences Ltd.

(Exact Name of Registrant as Specified in Charter)

Bermuda	**001-40782**	**98-1173944**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

7th Floor
50 Broadway
London SW1H 0DB
United Kingdom
(Address of Principal Executive Offices, and Zip Code)

+44 207 400-3347
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 communication 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 Shares, $0.0000000341740141 per share	**ROIV**	**The Nasdaq Global Market**
Redeemable warrants, each whole warrant exercisable for one Common Share	**ROIVW**	**The Nasdaq Global 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 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 June 28, 2023, Roivant Sciences Ltd. (the "Company") issued an updated press release announcing its financial results for the fiscal quarter and year ended March 31, 2023. The updated release confirms previously announced timing for topline data from Immunovant's Phase 3 trials in thyroid eye disease as the first half of calendar year 2025 that was inadvertently misstated in a prior version of the release. A copy of the updated press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth under this "Item 2.02. Results of Operations and Financial Condition" (including the exhibit thereto) shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing made by the Company pursuant to the Securities Act of 1933, as amended, other than to the extent that such filing incorporates by reference any or all of such information by express reference thereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Roivant Sciences Ltd. Press Release, dated June 28, 2023
104	Cover Page Interactive Data File (embedded with 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.

ROIVANT SCIENCES LTD.

By: /s/ Matt Maisak
Name: Matt Maisak
Title: Authorized Signatory

Dated: June 28, 2023

Exhibit 99.1

Roivant Reports Financial Results for the Fourth Quarter and Fiscal Year Ended March 31, 2023, and Provides Business Update

- RVT-3101 demonstrated improved efficacy results from the induction to chronic period in the TUSCANY-2 Phase 2b study in ulcerative colitis and was well tolerated with a favorable safety profile across all doses
- A Phase 2 study of RVT-3101 in Crohn's disease has been initiated with topline data expected in the fourth quarter of calendar year 2024
- VTAMA® (tapinarof) net product revenue was $13.7M for the quarter and $28.0M for the fiscal year ended March 31, 2023, with over 170,000 prescriptions written by approximately 11,000 unique prescribers since launch
- VTAMA® gross-to-net yield was 25% for the quarter ended March 31, 2023, and as of June 2023, coverage has been expanded to 125 million US commercial lives or 76% of total US commercial lives
- VTAMA® met the primary and all secondary endpoints in two Phase 3 studies ADORING 1 and 2, marking Roivant's ninth and tenth consecutive positive Phase 3 trials since 2019
- ADORING 1 and 2 evaluated 813 patients with moderate-to-severe atopic dermatitis – no new safety or tolerability signals were observed in this population, which included children as young as 2 years old
- Phase 1 trial initiated for IMVT-1402, a subcutaneously administered, next-generation FcRn inhibitor with initial data expected in August / September 2023
- Roivant reported $1.7B in cash and cash equivalents

BASEL, LONDON, and NEW YORK, June 28, 2023 – Roivant (Nasdaq: ROIV) today reported its financial results for the fourth quarter and fiscal year ended March 31, 2023, and provided an update on the business.

Roivant's Chief Executive Officer, Matt Gline, noted: "I'm incredibly pleased with the progress we've made in recent months. Last week, we reported RVT-3101 data from the chronic period of TUSCANY-2, our Phase 2b study in ulcerative colitis. These data surpassed our expectations, demonstrating improvement from the induction period at week 14 to the chronic period at week 56 across all key efficacy endpoints for patients treated with the expected Phase 3 dose. In addition, earlier this spring we announced positive topline results for VTAMA's ADORING 1 and ADORING 2 Phase 3 trials in atopic dermatitis. The results reported across both studies showed efficacy comparable to that of many systemic products, and we feel VTAMA has the potential to be a safe and efficacious topical option for adults and children as young as 2 years old. Finally, we reported strong growth in VTAMA revenue this past quarter in psoriasis with over 75% of US commercial lives now covered. These recent developments, combined with our strong balance sheet, continue to support Roivant's growing leadership in the treatment of immunological and inflammatory disease, and we are proud of our continued track record in clinical execution."

Recent Developments

- **Dermavant:** For the quarter and fiscal year ended March 31, 2023, Roivant reported VTAMA net product revenue of $13.7 million and $28.0 million, respectively, representing a 25% gross-to-net yield for the quarter. As of June 2023, over 170,000 VTAMA prescriptions have been written by approximately 11,000 unique prescribers for psoriasis, based on IQVIA data. Coverage has been expanded to 125 million US commercial lives, representing 76% of the total. VTAMA met the primary and all secondary endpoints in two Phase 3 studies, evaluating 813 moderate-to-severe atopic dermatitis patients. Importantly, no new safety or tolerability signals were observed in this population, which included children as young as 2 years old.

- **Immunovant:** In May 2023, Immunovant announced its Investigational New Drug (IND) application and Clinical Trial Application (CTA) for IMVT-1402 were cleared by the FDA and MEDSAFE, respectively, and its Phase 1 clinical trial in healthy subjects was initiated in New Zealand. Additionally, a Phase 2 proof-of-concept clinical trial of batoclimab in Graves' disease (GD) was initiated.

- **Telavant:** In June 2023, Telavant reported positive data from the chronic period of TUSCANY-2, a large, global Phase 2b study evaluating RVT-3101 for the treatment of ulcerative colitis. Outcomes were measured at week 56 for the chronic period (vs. week 14 from the previously reported induction period). At the expected Phase 3 dose in the overall population and in the biomarker positive populations, RVT-3101 treatment produced clinically meaningful efficacy results with improved Clinical Remission, Endoscopic Improvement, and Endoscopic Remission at week 56.

- **Roivant:** Roivant reported its consolidated cash, cash equivalents and restricted cash of $1.7B at March 31, 2023, supporting cash runway into the second half of calendar year 2025.

Major Upcoming Milestones

- **Dermavant** plans to submit its sNDA for VTAMA in atopic dermatitis to the FDA in the first quarter of calendar year 2024.

- **Immunovant** expects IMVT-1402 Phase 1 initial data from single-ascending dose cohorts in August/September 2023 and initial data from multiple-ascending dose cohorts in October/November 2023. Additionally, for batoclimab: top-line results from the ongoing myasthenia gravis (MG) trial are expected in the second half of calendar year 2024. Top-line results from the Phase 3 thyroid eye disease (TED) program, consisting of two Phase 3 clinical trials, are expected in the first half of calendar year 2025. Initial data from period 1 of the Phase 2B trial in chronic inflammatory demyelinating polyneuropathy (CIDP) is expected to be available in the first half of calendar year 2024. Initial results from the Phase 2 proof-of-concept trial in GD are expected in the fourth quarter of calendar year 2023.

- **Telavant** has initiated a Phase 2 dose-ranging study of RVT-3101 in Crohn's disease with data expected in the fourth quarter of calendar year 2024.

- **Priovant** plans to announce topline results from the potentially registrational trial evaluating brepocitinib for the treatment of patients with systemic lupus erythematosus (SLE) in the fourth quarter of calendar year 2023. Priovant also expects to announce topline results from the Phase 3 trial in dermatomyositis (DM) in calendar year 2025.

- **Hemavant** plans to announce data from the ongoing open-label Phase 1/2 trial evaluating RVT-2001 for the treatment of transfusion-dependent anemia in lower-risk myelodysplastic syndromes (MDS) patients in the second half of calendar year 2023.

- **Kinevant** plans to report topline data from the ongoing Phase 2 trial of namilumab for the treatment of sarcoidosis in the second half of calendar year 2024.

Matt Gline added: “I am incredibly pleased to welcome Meghan FitzGerald to our Board of Directors. Meghan’s deep expertise in healthcare and her extraordinary commitment to patients will be invaluable to Roivant’s mission to accelerate the development and commercialization of medicines that matter.”

Fourth Quarter and Fiscal Year Ended March 31, 2023, Financial Summary

Cash Position

As of March 31, 2023, the company had cash, cash equivalents and restricted cash of approximately $1.7 billion.

Research and Development Expenses

Research and development (R&D) expenses decreased by $3.2 million to $131.9 million for the three months ended March 31, 2023, compared to $135.1 million for the year ended March 31, 2022, primarily due to decreases in share-based compensation of $11.9 million and other expenses of $3.7 million, partially offset by an increase in program specific costs of $12.3 million, largely driven by the anti-FcRn franchise.

Non-GAAP R&D expenses were $126.0 million for the three months ended March 31, 2023, compared to $117.8 million for the three months ended March 31, 2022.

R&D expenses increased by $42.2 million to $525.2 million for the year ended March 31, 2023, compared to $483.0 million for the year ended March 31, 2022, primarily due to increases in program-specific costs of $45.8 million and personnel-related expenses of $28.1 million, partially offset by a decrease in share-based compensation of $32.8 million. The increase of $45.8 million in program-specific costs largely reflects the progression of our programs and drug discovery, including the anti-FcRn franchise, RVT-2001, brepocitinib, and RVT-3101. The asset acquisitions of brepocitinib, RVT-2001, and RVT-3101 were completed in September 2021, November 2021, and November 2022, respectively. Increases in program-specific costs were partially offset by certain decreases, including $19.3 million for tapinarof, which was primarily due to the completion of ADORING 1 and ADORING 2 phase 3 atopic dermatitis clinical trials during the year ended March 31, 2023. The increase of $28.1 million in personnel-related expenses largely reflects the progression of our programs, particularly the anti-FcRn franchise. The decrease of $32.8 million in share-based compensation expense was primarily due to the achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination in September 2021, resulting in the recognition of a one-time catch-up expense of $22.9 million relating to cumulative service rendered between the grant date of the respective awards and completion of the Business Combination and continued recognition of expense over the requisite service periods.

Non-GAAP R&D expenses were $489.2 million for the year ended March 31, 2023, compared to $416.1 million for the year ended March 31, 2022.

Acquired In-Process Research and Development Expenses

There was no acquired in-process research and development (IPR&D) expense for the three months ended March 31, 2023. Acquired IPR&D expenses were $1.5 million for the three months ended March 31, 2022.

Acquired IPR&D expenses decreased by $42.1 million to $97.7 million for the year ended March 31, 2023, compared to $139.9 million for the year ended March 31, 2022. The decrease was primarily due to higher consideration for the purchase of IPR&D during the year ended March 31, 2022 as a result of consideration for the purchase of IPR&D of $82.1 million relating to the acquisition of brepocitinib, a one-time milestone expense of approximately $39 million due to the achievement of a development milestone related to tapinarof, and consideration for the purchase of IPR&D of $14.1 million relating to the acquisition of RVT-2001. Acquired IPR&D expenses for the year ended March 31, 2023, was driven by consideration for the purchase of IPR&D of $87.7 million relating to the acquisition of RVT-3101 and the achievement of a development milestone relating to batoclimab, which resulted in a one-time milestone expense of $10.0 million.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses decreased by $13.5 million to $125.5 million for the three months ended March 31, 2023, compared to $139.0 million for the three months ended March 31, 2022. The decrease was primarily due to a decrease in share-based compensation of $40.0 million, partially offset by higher SG&A expenses at Dermavant as a result of the commercial launch of VTAMA.

Non-GAAP SG&A expenses were $102.6 million for the three months ended March 31, 2023, compared to $77.3 million for the three months ended March 31, 2022.

SG&A expenses decreased by $174.5 million to $600.5 million for the year ended March 31, 2023, compared to $775.0 million for the year ended March 31, 2022. The decrease was primarily due to a decrease in share-based compensation expense of $314.6 million, partially offset by higher SG&A expenses at Dermavant as a result of the commercial launch of VTAMA. The decrease in share-based compensation resulted from the achievement of the liquidity event vesting condition for certain equity instruments upon the closing of the Business Combination in September 2021, resulting in the recognition of a one-time catch-up expense of $350.0 million for the year ended March 31, 2022, for cumulative service rendered between the grant date of the respective awards and completion of the Business Combination.

Non-GAAP SG&A expenses were $407.6 million for the year ended March 31, 2023, compared to $271.1 million for the year ended March 31, 2022.

Loss from Continuing Operations

Loss from continuing operations was $175.4 million for the three months ended March 31, 2023, compared to $291.3 million for the three months ended March 31, 2022. On a per common share basis, loss from continuing operations was $0.20 for the three months ended March 31, 2023, and $0.39 for the three months ended March 31, 2022. Non-GAAP loss from continuing operations was $189.4 million for the three months ended March 31, 2023, compared to $187.7 million for the three months ended March 31, 2022.

Loss from continuing operations was approximately $1.2 billion for the year ended March 31, 2023, compared to $924.1 million for the year ended March 31, 2022. On a per common share basis, loss from continuing operations was $1.58 for the year ended March 31, 2023, and $1.26 for the year ended March 31, 2022. Non-GAAP loss from continuing operations was $924.3 million for the year ended March 31, 2023, compared to $784.2 million for the year ended March 31, 2022.

ROIVANT SCIENCES LTD.
Selected Balance Sheet Data
(in thousands)

	March 31, 2023	March 31, 2022
Cash, cash equivalents and restricted cash	$ 1,692,115	$ 2,074,034
Total assets	2,389,604	2,585,129
Total liabilities	782,017	523,695
Total shareholders' equity	1,607,587	2,038,943
Total liabilities, redeemable noncontrolling interest and shareholders' equity	2,389,604	2,585,129

ROIVANT SCIENCES LTD.

Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Three Months Ended March 31,		Years Ended March 31,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)		
Revenues:				
Product revenue, net	$ 13,657	$ —	$ 28,011	$ —
License, milestone and other revenue	13,719	9,223	33,269	55,286
Revenue, net	27,376	9,223	61,280	55,286
Operating expenses:				
Cost of revenues	4,175	459	13,128	8,966
Research and development (includes $4,366 and $16,294 of share-based compensation expense for the three months ended March 31, 2023 and 2022, respectively, and $30,914 and $63,735 of share-based compensation expense for the years ended March 31, 2023 and 2022, respectively)	131,857	135,077	525,215	483,035
Acquired in-process research and development	—	1,517	97,749	139,894
Selling, general and administrative (includes $20,832 and $60,865 of share-based compensation expense for the three months ended March 31, 2023 and 2022, respectively, and $186,603 and $501,221 of share-based compensation expense for the years ended March 31, 2023 and 2022, respectively)	125,510	138,973	600,506	775,033
Total operating expenses	261,542	276,026	1,236,598	1,406,928
Loss from operations	(234,166)	(266,803)	(1,175,318)	(1,351,642)
Change in fair value of investments	(32,462)	72,909	20,815	87,291
Gain on sale of investment	—	—	—	(443,754)
Change in fair value of debt and liability instruments	(12,031)	(44,101)	78,001	(3,354)
Gain on termination of Sumitomo Options	—	—	—	(66,472)
Gain on deconsolidation of subsidiaries	—	(5,041)	(29,276)	(5,041)
Interest income	(14,284)	(170)	(32,184)	(369)
Interest expense	8,575	1,475	27,968	7,041
Other income, net	(4,748)	(399)	(15,808)	(3,237)
Loss from continuing operations before income taxes	(179,216)	(291,476)	(1,224,834)	(923,747)
Income tax expense	(3,793)	(163)	5,190	369
Loss from continuing operations, net of tax	(175,423)	(291,313)	(1,230,024)	(924,116)
Income from discontinued operations, net of tax	114,561	—	114,561	—
Net loss	(60,862)	(291,313)	(1,115,463)	(924,116)
Net loss attributable to noncontrolling interests	(27,245)	(21,251)	(106,433)	(78,854)
Net loss attributable to Roivant Sciences Ltd.	$ (33,617)	$ (270,062)	$ (1,009,030)	$ (845,262)
Amounts attributable to Roivant Sciences Ltd.:				
Loss from continuing operations, net of tax	$ (148,178)	$ (270,062)	$ (1,123,591)	$ (845,262)
Income from discontinued operations, net of tax	114,561	—	114,561	—
Net loss attributable to Roivant Sciences Ltd.	$ (33,617)	$ (270,062)	$ (1,009,030)	$ (845,262)
Basic and diluted net (loss) income per common share:				
Basic and diluted loss from continuing operations	$ (0.20)	$ (0.39)	$ (1.58)	$ (1.26)
Basic and diluted income from discontinued operations	$ 0.15	$ —	$ 0.16	$ —
Basic and diluted net loss per common share	$ (0.05)	$ (0.39)	$ (1.42)	$ (1.26)
Basic and diluted weighted average shares outstanding:				
Basic	742,541,052	692,623,282	712,791,115	669,753,458
Diluted	742,541,052	692,623,282	712,791,115	669,753,458

ROIVANT SCIENCES LTD.

Reconciliation of GAAP to Non-GAAP Financial Measures
(unaudited, in thousands)

	Note	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Years Ended March 31, 2023	Years Ended March 31, 2022
Loss from continuing operations, net of tax		**$ (175,423)**	**$ (291,313)**	**$ (1,230,024)**	**$ (924,116)**
Adjustments:					
Cost of revenues					
Amortization of intangibles	(1)	2,298	—	7,468	—
Share-based compensation	(2)	37	—	95	—
Research and development:					
Share-based compensation	(2)	4,366	16,294	30,914	63,735
Depreciation and amortization	(3)	1,539	943	5,097	3,244
Selling, general and administrative:					
Share-based compensation	(2)	20,832	60,865	186,603	501,221
Depreciation and amortization	(3)	2,116	763	6,292	2,688
Other:					
Change in fair value of investments	(4)	(32,462)	72,909	20,815	87,291
Gain on sale of investment	(5)	—	—	—	(443,754)
Change in fair value of debt and liability instruments	(6)	(12,031)	(44,101)	78,001	(3,354)
Gain on termination of Sumitomo Options	(7)	—	—	—	(66,472)
Gain on deconsolidation of subsidiaries	(8)	—	(5,041)	(29,276)	(5,041)
Estimated income tax impact from adjustments	(9)	(704)	942	(294)	313
Adjusted loss from continuing operations, net of tax (Non-GAAP)		**$ (189,432)**	**$ (187,739)**	**$ (924,309)**	**$ (784,245)**

	Note	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Years Ended March 31, 2023	Years Ended March 31, 2022
Research and development expenses		**$ 131,857**	**$ 135,077**	**$ 525,215**	**$ 483,035**
Adjustments:					
Share-based compensation	(2)	4,366	16,294	30,914	63,735
Depreciation and amortization	(3)	1,539	943	5,097	3,244
Adjusted research and development expenses (Non-GAAP)		**$ 125,952**	**$ 117,840**	**$ 489,204**	**$ 416,056**

	Note	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Years Ended March 31, 2023	Years Ended March 31, 2022
Selling, general and administrative expenses		**$ 125,510**	**$ 138,973**	**$ 600,506**	**$ 775,033**
Adjustments:					
Share-based compensation	(2)	20,832	60,865	186,603	501,221
Depreciation and amortization	(3)	2,116	763	6,292	2,688
Adjusted selling, general and administrative expenses (Non-GAAP)		**$ 102,562**	**$ 77,345**	**$ 407,611**	**$ 271,124**

Notes to non-GAAP financial measures:

(1) Represents non-cash amortization of intangible assets associated with milestone payments made in connection with regulatory approvals.

(2) Represents non-cash share-based compensation expense.

(3) Represents non-cash depreciation and amortization expense, other than amortization of intangible assets associated with milestone payments made in connection with regulatory approvals.

(4) Represents the unrealized loss (gain) on equity investments in unconsolidated entities that are accounted for at fair value with changes in value reported in earnings.

(5) Represents a one-time gain on sale of investment resulting from the merger of Datavant and CIOX Health in July 2021.

(6) Represents the change in fair value of debt and liability instruments, which is non-cash and primarily includes the unrealized loss relating to the measurement and recognition of fair value on a recurring basis of certain liabilities.

(7) Represents the one-time gain on termination of the options held by Sumitomo Pharma Co., Ltd. to purchase Roivant's ownership interest in certain Vants (the "Sumitomo Options").

(8) Represents the one-time gain on deconsolidation of subsidiaries.

(9) Represents the estimated tax effect of the adjustments.

Investor Conference Call Information

Roivant will host a live conference call and webcast at 8:00 a.m. EST on Wednesday, June 28, 2023, to report its financial results for the fourth quarter and fiscal year ended March 31, 2023, and provide a business update.

To access the conference call by phone, please register online using this registration link. A webcast of the call will also be available under "Events & Presentations" in the Investors section of the Roivant website at https://investor.roivant.com/news-events/events. The archived webcast will be available on Roivant's website after the conference call.

About Roivant

Roivant is a commercial-stage biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Today, Roivant's pipeline is concentrated in inflammation and immunology and includes VTAMA, a novel topical approved for the treatment of psoriasis and in development for the treatment of atopic dermatitis; batoclimab and IMVT-1402, fully human monoclonal antibodies targeting the neonatal Fc receptor ("FcRn") in development across several IgG-mediated autoimmune indications; and RVT-3101, an anti-TL1A antibody in development for ulcerative colitis and Crohn's disease, in addition to several other therapies in various stages of clinical development. We advance our pipeline by creating nimble subsidiaries or "Vants" to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business. For more information, visit www.roivant.com.

Roivant Forward-Looking Statements

This press release contains forward-looking statements. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are usually identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and variations of such words or similar expressions. The words may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act.

Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, and statements that are not historical facts, including statements about the clinical and therapeutic potential of our products and product candidates, the availability and success of topline results from our ongoing clinical trials and any commercial potential of our products and product candidates. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements.

Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, those risks set forth in the Risk Factors section of our filings with the U.S. Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this press release, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Contacts:

Investors

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Media

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