



Replimune Reports Fiscal First Quarter 2027 Financial Results and Provides Corporate Update

August 14, 2026

TUDRIQEV™ in combination with nivolumab receives FDA accelerated approval and will launch within 60 days

Michelle DiNapoli appointed as Chief Commercial Officer

Recently completed financing extends cash runway to support commercial launch and confirmatory trial

WOBURN, Mass., Aug. 14, 2026 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (Nasdaq: REPL), a commercial stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced financial results for the fiscal first quarter ended June 30, 2026 and provided a business update.

On August 6, 2026, the Company announced the U.S. Food and Drug Administration (FDA) has approved TUDRIQEV (vusolimogene oderparepvec-wtpg), previously referred to as RP1, in combination with nivolumab for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression with a PD-1 antibody-based regimen. The Company has begun launch preparations in the U.S. and anticipates having product in the market within 60 days. Replimune also recently completed a \$150 million financing to support commercial launch and the ongoing IGYTE-3 confirmatory trial.

The Company also announced today the appointment of Michelle DiNapoli as Chief Commercial Officer, effective August 18, 2026. Ms. DiNapoli brings more than 25 years of biopharmaceutical experience commercializing innovative oncology therapies and building high-performing commercial organizations. She joins Replimune after a seven-year tenure at Deciphera Pharmaceuticals. At Deciphera, she built the U.S. sales force, led the U.S. Commercial organization, and scaled infrastructure to drive launch execution as the company grew from a single product to a multi-product organization. Prior to Deciphera, Ms. DiNapoli spent 16 years at Genentech in commercial leadership roles spanning breast, lung, and colorectal cancer franchises as well as cancer immunotherapy, developing deep expertise in market access, lifecycle management, and cross-functional execution.

"The FDA's approval of TUDRIQEV is a defining milestone for Replimune and, more importantly, for the patients facing advanced melanoma, where the need for safe and effective treatment options remains significant," said Sushil Patel, Ph.D., CEO of Replimune. "With this approval, we are now a fully integrated biotechnology company. We are completing the build out of our commercial infrastructure to enable a successful launch and bring TUDRIQEV to patients as quickly as possible."

Program Highlights & Milestones

RP1 (vusolimogene oderparepvec)

- **IGYTE-3 Confirmatory Study:** The global Phase 3 trial assessing RP1 in combination with nivolumab versus physician's choice in patients with advanced melanoma who have progressed on anti-PD-1 and anti-CTLA-4 therapies or are ineligible for anti-CTLA-4 treatment is actively enrolling. The primary endpoint, expected to readout in 2030, is overall survival, and key secondary endpoints are progression free survival and overall response rate.

RP2

- **REVEAL Study:** The registration-directed Phase 2/3 trial of RP2 in metastatic uveal melanoma is actively enrolling. The trial is evaluating RP2 in combination with nivolumab versus ipilimumab in combination with nivolumab in approximately 280 patients. The primary endpoints of the trial are overall survival and progression free survival, and key secondary endpoints are overall response rate and disease control rate. Phase 2/3 transition is expected in Q1 2027.

Financial Highlights

- **Cash Position:** As of June 30, 2026, cash, cash equivalents and short-term investments were \$195.3 million, as compared to \$268.9 million as of fiscal year ended March 31, 2026. The decrease in cash balance was a result of cash burn related to operating activities in advancing the company's clinical development plans.

Based on our current operating plan, we expect that our existing cash and cash equivalents and short-term investments, as of June 30, 2026, in addition to the \$141.0 million of net proceeds from the issuance of our common stock in August 2026, will enable us to fund operations for greater than twelve months from the issuance of the condensed consolidated financial statements, which includes scale up for the commercialization of TUDRIQEV in advanced melanoma and for working capital and general corporate purposes.

- **R&D Expenses:** Research and development expenses were \$49.3 million for the fiscal first quarter and \$57.8 million for the fiscal first quarter ended June 30, 2025. This decrease was primarily due to a decrease in personnel related and other

costs, as well as a decrease in direct research costs relating to the IGNYTE, ARTACUS and CERPASS studies. Research and development expenses included \$3.6 million in stock-based compensation expenses for the fiscal first quarter ended June 30, 2026.

- **S,G&A Expenses:** Selling, general and administrative expenses were \$19.0 million for the fiscal first quarter ended June 30, 2026, as compared to \$32.6 million for the fiscal first quarter ended June 30, 2025. Selling, general and administrative expenses included \$4.1 million in stock-based compensation expenses for the fiscal first quarter ended June 30, 2026.
- **Net Loss:** Net loss was \$69.8 million for the fiscal first quarter ended June 30, 2026 and \$86.7 million for the fiscal first quarter ended June 30, 2025.

About TUDRIQEV™ (vusolimogene oderparepvec-wtpg)

TUDRIQEV (vusolimogene oderparepvec-wtpg) is a genetically modified herpes simplex virus, type 1 (HSV-1) oncolytic viral therapy that encodes a fusogenic glycoprotein derived from gibbon ape leukemia virus with the R sequence deleted (GALV-GP-R-) and human granulocyte macrophage colony-stimulating factor (GM-CSF). The genes encoding the HSV-1 neurovirulence factor ICP34.5 and the transporter associated with antigen presentation inhibitor ICP47 are deleted from TUDRIQEV. TUDRIQEV preferentially replicates within the tumor leading to tumor lysis, release of tumor and viral antigens, proinflammatory molecules, and infiltration of T cells. The GALV-GP-R- expressed by TUDRIQEV increases direct tumor killing and the GM-CSF expressed by TUDRIQEV is intended to activate and mature dendritic cells and monocytes. In the anti-PD-1 resistant setting, TUDRIQEV and nivolumab in combination may promote anti-tumor immune response.

INDICATION

TUDRIQEV™ is indicated in combination with nivolumab for the treatment of adult patients with unresectable advanced cutaneous melanoma who experienced disease progression with a programmed death receptor-1 (PD-1)-blocking antibody-based regimen.

This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Accidental exposure of TUDRIQEV: Healthcare providers, caregivers, close contacts, pregnant women, newborns, and patients should avoid direct contact with injected tumors, dressings, or bodily fluids of patients.

Herpetic infection or reactivation: Patients with suspected herpetic infections should contact their healthcare provider for assessment and antiviral treatment of the suspected herpetic infection as clinically warranted.

Injection procedure complications: Complications related to injection procedure have occurred, including hemorrhage, infection, and visceral injury. Patients should be monitored for signs and symptoms of visceral injury (eg, pneumothorax) during and after TUDRIQEV administration and managed according to clinical practice.

Immune-mediated events: In clinical studies, immune-mediated events, including colitis, hepatitis, myocarditis, neuropathy, capillary leak syndrome, dermatitis, and vitiligo have been reported in patients treated with TUDRIQEV and nivolumab.

Adverse Reactions

Most common non-laboratory adverse reactions reported in more than 10% of patients were fatigue, pyrexia, infections, chills, musculoskeletal pain, nausea, diarrhea, injection site reaction, headache, cough, influenza like illness, rash, vomiting, pruritus, arthralgia, constipation, decreased appetite, dizziness, dyspnea, hemorrhage, edema, and abdominal pain.

Serious adverse reactions occurring in >1% patients include pleural effusion (n=3), acute kidney injury (n=2), arthralgia (n=2), atrial fibrillation (n=2), atrial flutter (n=2), cancer pain (n=2), hypophysitis (n=2), immune-mediated enterocolitis (n=2), pyrexia (n=2), sepsis (n=2), urinary tract infection (n=2), and myocardial infarction (n=2). Serious adverse reactions leading to death include myocardial infarction (n=1) and multiple organ dysfunction (n=1).

Drug Interactions

Patients receiving systemic antiviral treatment for herpetic infection should delay TUDRIQEV treatment for 72 hours after completion of antiviral therapy.

Special Populations

Advise females and males of reproductive potential to use effective contraception during treatment with TUDRIQEV and for 90 days after the last dose.

About RP1

RP1 (vusolimogene oderparepvec) is Replimune's lead product candidate and is based on a proprietary strain of herpes simplex virus engineered 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 RP2

RP2 is based on a proprietary strain of herpes simplex virus engineered 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. RP2 additionally expresses an anti-CTLA-4 antibody-like molecule, as well as GALV-GP R- and GM-CSF. RP2 is 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 oncolytic immunotherapies. Replimune's proprietary RPx platform is based on a potent HSV-1 backbone intended to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform is intended to ignite local activity 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 then activate a strong and durable systemic response. The RPx product candidates are expected to be synergistic with most established and experimental cancer treatment modalities, leading to 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 clinical trials, clinical studies and other clinical work (including the funding therefor, anticipated patient enrollment, safety data, study data, trial outcomes, timing or associated costs, sufficiency of any resulting data), regulatory applications and related submission contents and timelines, the timelines or outcomes related to litigation, including any rehearings or appeals of decisions in any such proceedings, and our ability to execute on our strategic or financial initiatives, our estimates regarding future expenses, capital requirements and needs for additional financing, and potential commercial viability, and potential reimbursement and utilization of TUDRIQEV involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Our ability to maintain TUDRIQEV's accelerated approval and to continue commercialization of TUDRIQEV may be contingent on verification of clinical benefit in a confirmatory trial(s). Other forward looking statements may be 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 experience in commercializing products for sale, our ability to successfully verify the clinical benefit of TUDRIQEV in our ongoing confirmatory Phase 3 trial, IGNYTE-3, our ability to meet our product manufacturing goal, the timing and scope of future regulatory approvals, the availability of combination therapies needed to conduct our clinical trials, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, the impact of political and global macro factors and military conflicts, 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.

Investor Inquiries

Chris Brinzey
ICR Healthcare
339.970.2843
chris.brinzey@icrhealthcare.com

Media Inquiries

Arleen Goldenberg
Replimune
917.548.1582
media@replimune.com

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

	Three Months Ended June 30,	
	2026	2025
Operating expenses:		
Research and development	\$ 49,277	\$ 57,843
Selling, general and administrative	18,970	32,579
Total operating expenses	68,247	90,422

Loss from operations	(68,247)	(90,422)
Other income (expense):		
Research and development incentives	296	420
Investment income	1,960	4,714
Interest expense on finance lease liability	(506)	(521)
Interest expense on debt obligations	(2,581)	(1,475)
Other (expense) income, net	(688)	591
Total other (expense) income, net	(1,519)	3,729
Net loss	<u>\$ (69,766)</u>	<u>\$ (86,693)</u>
Net loss per common share, basic and diluted	<u>\$ (0.72)</u>	<u>\$ (0.95)</u>
Weighted average common shares outstanding, basic and diluted	<u>96,864,452</u>	<u>91,516,199</u>

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

	June 30, 2026	March 31, 2026
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	\$ 195,328	\$ 268,889
Working capital	162,395	220,891
Total assets	252,447	332,388
Total stockholders' equity	105,645	166,160



Replimune, Inc.