

# REPLIMUNE GROUP INC.

## CASE OVERVIEW

**Lead Plaintiff Deadline:** 10/05/2026

**Status:** Investigating

**Company Name:** Replimune Group Inc.

**Court:** District of Massachusetts

**Case Number:** 1:26cv13612

**Class Period:** 10/20/2025 - 04/10/2026

**Ticker:** REPL

**Related Attorneys:** Thomas W. Elrod

**Related Practices:** Securities

The lawsuit alleges that Replimune made materially false and/or misleading statements and failed to disclose to investors that: (i) in connection with the Biologics License Application (“BLA”) for the Company’s lead product candidate, RP1, the study design concerns previously communicated by the FDA were not addressed; (ii) the Company had submitted data from an early unplanned analysis from RP1-104, which included only 40 patients (10% of the planned enrollment of 400 patients); and (iii) as a result, RPL-0001-16 and RP1-104 had deficiencies, which were likely to cause the FDA to reject the BLA.

On April 10, 2026, the FDA published a Complete Release Letter rejecting Replimune’s BLA for RP1 in combination with nivolumab. The FDA identified several deficiencies in the studies—RPL-0001-16 (IGNYTE) and RP1-104 (IGNYTE-3)—submitted by Replimune and found that “the evidence as presented does not meet the evidentiary standards required for regulatory approval, and the results of the additional exploratory analyses of the RPL-001-16 data do not alter our initial conclusion that the RPL-001-16 trial is not an adequate and well-controlled clinical investigation that demonstrates substantial evidence of effectiveness.” Additionally, the FDA asserted that Replimune “submitted data from an early unplanned analysis from RP1-104 representing 10% of the planned enrollment.” The FDA stated it had “clearly communicated” its “concerns with the study design in multiple FDA interactions throughout [Replimune’s] development program,” but “the study design concerns previously communicated were not addressed.” On this news, Replimune’s stock price fell \$1.15, or 19.46%, to close at \$4.76 per share on April 10, 2026.

After the market closed on April 10, 2026, the Company issued a press release, stating that “a randomized controlled trial was preferred” by the FDA but claiming that the FDA communicated that “if the data was sufficiently compelling, a single arm trial could be acceptable for consideration under accelerated approval.” On this news, Replimune’s stock price fell a further \$3.60, or 64.29%, to close at \$1.70 per share on April 13, 2026.