UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

_____, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. REPLIMUNE GROUP, INC., SUSHIL PATEL, and EMILY HILL, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Replimune Group, Inc. ("Replimune" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Replimune; and (c) review of other publicly available information concerning Replimune.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Replimune securities between October 20, 2025 and July 28, 2026, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Replimune is a clinical-stage biotechnology company. Replimine's lead drug candidate is RP1 (or as its known by its generic name, *vusolimogene oderparepvec*). RP1 is a genetically modified herpes simplex virus designed to kill cancer cells and trigger a systemic immune response. RP1 is being evaluated in clinical trials, primarily the IGNYTE study, which is studying RP1 dosed in conjunction with nivolumab (Opdivo) for the treatment of advanced melanoma and other solid tumors. IGNYTE is a single-arm study, meaning every participant in the trial receives the exact same experimental treatment combination, as opposed to some participants receiving a placebo or other control treatment.

3. The US Food and Drug Administration ("FDA") has previously treated the Company's use of a single-arm study to support RP1 with skepticism. For example, in July 2025,

the FDA rejected the Company's initial Biologics License Application for RP1. In the Complete Response Letter explaining its rejection, the FDA has indicated that the IGNYTE trial is not considered to be an adequate and well-controlled clinical investigation that provides substantial evidence of effectiveness.

4. In October 2025, the Company announced that, following conversations with the FDA, the FDA had accepted its resubmission of RP1 for the treatment of advanced melanoma, which the Company said included expanded data from the IGNYTE trial to demonstrate the drug's efficacy.

5. On April 10, 2026, before the market opened, the FDA published a Complete Response Letter ("CRL") rejecting Replimune's Biologics License Application ("BLA") for RP1 in combination with nivolumab. The FDA noted that, during its September 2025 meeting, it had given the Company "recommendations regarding use of data from the ongoing Phase 3 trial to potentially support Accelerated Approval." However,[1] "***instead, [the Company] submitted data from an early unplanned analysis***" and "***[t]his data is insufficient to support an efficacy claim.***" The FDA noted that because the Phase II IGNYTE trial was a single-arm study, it was impossible to isolate RP1's specific clinical contribution from that of nivolumab (Opdivo). The FDA also flagged the ongoing Phase III IGNYTE-3 confirmatory trial, stating its similar single-arm design was still insufficient to definitively isolate the individual therapeutic contribution of RP1.

6. On this news, the Company's share price fell $1.15 or 19.46%, to close at $4.76 per share on April 10, 2026, on unusually heavy trading volume.

[1] Unless otherwise stated, all emphasis in bold and italics hereinafter is added, and all footnotes are omitted.

7. On April 10, 2026, after the market closed, the Company issued a press release discussing the FDA's response letter for the RP1 BLA. The press release stated "Replimune disagrees with the FDA about whether the data set, upon which breakthrough therapy designation was awarded, is sufficient to allow this promising medicine to be made available to advanced cancer patients." The Company further stated that "[p]rior to the original BLA submission, standard regulatory meetings were conducted to discuss trial design, patient population, and the BLA package requirements." The Company revealed that, during those meetings, it learned "***a randomized controlled trial was preferred***." The Company nonetheless maintained that "[i]n the CRL, the agency appears to have contradicted their positions expressed at the September 2025 Type A meeting."

8. On this news, the Company's share price fell $3.06 or 64.29%, to close at $1.70 per share on April 13, 2026, on unusually heavy trading volume.

9. The Company nonetheless resubmitted its BLA for RP1 once again, claiming to its resubmission was designed to address the FDA's concerns about the single-arm study design.

10. On July 28, 2026, before the market opened, the FDA released briefing documents ahead of its anticipated advisory committee meeting to review the third BLA for RP1. In its briefing documents, the FDA once again took issue with the Company's single-arm trial. The briefing documents stated the FDA deemed the single-arm mid-stage study submitted by Replimune to support the approval of the drug as "***not interpretable.***" The briefing documents state the assessment used in the study "***confounds interpretation of the reported efficacy results and limits FDA's ability to verify the reported results***."

11. On this news, Replimune's stock price fell $3.28, or 38.01%, to close at $5.35 per share on July 28, 2026, on unusually heavy trading volume.

12. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company had not reached an agreement with the FDA to permit the use of the single-arm study trial design used to support RP1's BLA; (2) that, as a result, there was a significant risk that the INGTYE clinical trail results did not demonstrate that the benefits of RP1 outweighed the risks; (3) that, as a result of the foregoing, there was a substantial risk to regulatory approval of RP1 for the treatment of advanced melanoma and other solid tumors; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

13. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

14. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

16. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in

substantial part in this Judicial District. In addition, the Company's principal executive offices are in this District.

17. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

18. Plaintiff ____, as set forth in the accompanying certification, incorporated by reference herein, purchased Replimune securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

19. Defendant Replimune is incorporated under the laws of Delaware with its principal executive offices located in Woburn, Massachusetts. Replimune's common stock trades on the NASDAQ exchange under the symbol "REPL."

20. Defendant Sushil Patel ("Patel") was the Company's Chief Executive Officer ("CEO") at all relevant times.

21. Defendant Emily Hill ("Hill") was the Company's Chief Financial Officer ("CFO") at all relevant times.

22. Defendants Patel and Hill (together, the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance

or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

23. Replimune is a clinical-stage biotechnology company. Replimune's lead drug candidate is RP1 (or as its known by its generic name, *vusolimogene oderparepvec*). RP1 is a genetically modified herpes simplex virus designed to kill cancer cells and trigger a systemic immune response. RP1 is being evaluated in clinical trials, primarily the IGNYTE study, which is studying RP1 dosed in conjunction with nivolumab (Opdivo) for the treatment of advanced melanoma and other solid tumors. IGNYTE is a single-arm study, meaning every participant in the trial receives the exact same experimental treatment combination, as opposed to some participants receiving a placebo or other control treatment.

24. The FDA has previously treated the Company's use of a single-arm study to support RP1 with skepticism. For example, in July 2025, the FDA rejected the Company's initial Biologics License Application for RP1. In the Complete Response Letter explaining its rejection, the FDA has indicated that the IGNYTE trial is not considered to be an adequate and well-controlled clinical investigation that provides substantial evidence of effectiveness.

Materially False and Misleading

Statements Issued During the Class Period

25. The Class Period begins on October 20, 2025. On that day, Replimune issued a press release, announcing the FDA's acceptance of the Company's BLA Resubmission of RP1 for

the Treatment of Advanced Melanoma. The press release stated, among other things, that "***[d]uring the past few months, Replimune has been working to address agency feedback. Additional information, data and analyses were included in the resubmission which will be part of the BLA review.***" Specifically, the press release stated as follows, in relevant part:

> Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has accepted the resubmission of the Biologics License Application (BLA) for RP1 in combination with nivolumab for the treatment of advanced melanoma in patients who progress on an anti-PD-1 containing regimen. The PDUFA date set by the FDA is April 10, 2026 based on a Class II resubmission timeline.
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> "We are pleased the agency has accepted the resubmission of our BLA for RP1," said Sushil Patel, Ph.D., CEO of Replimune. "RP1 plus nivolumab offers a strong risk benefit profile where there are few options for patients with advanced melanoma, who have progressed on PD-1 based therapy. We look forward to working closely with the agency to expedite this review as much as possible for patients' benefit."
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> ***During the past few months, Replimune has been working to address agency feedback. Additional information, data and analyses were included in the resubmission which will be part of the BLA review.*** The FDA indicated this resubmission is considered to be a complete response to the complete response letter received in July 2025.

26. On November 6, 2025, the Company issued a press release which announced earnings for the quarter ended September 30, 2025. The press release alleged that "***the FDA indicated that the IGNYTE-3 trial could potentially support approval***." The press release further reported the Company's financial results, in including its financial highlights. Specifically, the press release stated as follows, in relevant part:

> The Company announced on October 20, 2025, that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) resubmission of RP1 for the treatment of advanced melanoma with a Prescription Drug User Fee Act (PDUFA) target action date set for April 10, 2026. The resubmission is considered by the FDA to be a complete response to the complete response letter received on July 21, 2025. ***In the Type A meeting minutes, the FDA indicated that the IGNYTE-3 trial could potentially support approval.***

> "After a collaborative dialogue and productive engagement with the FDA we are encouraged by the acceptance of our BLA resubmission for RP1 in combination with nivolumab," said Sushil Patel, Ph.D., CEO of Replimune. "We are currently partnering with the agency on the ongoing review to bring this important therapy to patients."
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> Net loss was $83.1 million for the fiscal second quarter ended September 30, 2025 and $53.1 million for the fiscal second quarter ended September 30, 2024.

27. On November 6, 2025, the Company submitted its quarterly report for the period ended September 30, 2025 on a Form 10-Q filed with the SEC, affirming the previously reported financial results. The report stated the following regarding the Company's progress with its BLA for RP1, in relevant part:

> On October 20, 2025, the Company announced that the FDA had accepted the resubmission of the BLA for RP1 in combination with nivolumab for the treatment of advanced melanoma in patients who progress on anti-PD-1 containing regimen. The PDUFA date set by the FDA is April 10, 2026 based on a Class II resubmission timeline.
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> Our leading clinical trial of RP1 is referred to as the IGNYTE trial, which is a multi-cohort clinical trial being conducted in collaboration with Bristol Myers Squibb Company, or BMS, under which BMS has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1.
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> On September 2, 2025 we announced a type A meeting with the FDA had been scheduled to discuss the CRL following our submission of a briefing book addressing the points raised in the CRL, highlighting prior agreements related to the patient population, criteria for PD-1 resistance, and use of literature to support contribution of components. The briefing book also included an additional analysis of data from the BLA and addressed comments about the phase 3 confirmatory trial design raised by the FDA in the CRL. On September 18, 2025 we announced that, following the type A meeting with the FDA to discuss the CRL, which was conducted on September 16, 2025, we were evaluating feedback received during the meeting to determine our next steps and that, at that time, a path forward under the accelerated approval pathway had not been determined. ***Following the evaluation of FDA feedback and minutes from the type A meeting, we resubmitted***

the BLA on October 9, 2025. On October 20, 2025 we announced that the FDA had accepted the resubmission of the BLA for RP1 in combination with nivolumab for the treatment of advanced melanoma in patients who progress on an anti-PD-1 containing regimen. The resubmission included additional information, data and analyses that will be part of the BLA review. The FDA indicated that the resubmission is considered to be a complete response to the CRL and set a PDUFA date of April 10, 2026 based on a Class II resubmission timeline.

We plan to interact with the FDA during the review of the resubmitted BLA and, if approved, intend to bring RP1 to adult patients with advanced melanoma who have previously received an anti-PD-1 containing regimen who otherwise have limited treatment options.

28. On February 3, 2026, the Company issued a press release which announced earnings for the quarter ended December 31, 2025. The press release alleged that ***"[w]e have been engaged with the FDA in the review of the BLA resubmission for RP1."*** The press release further reported the Company's financial results, in including its financial highlights. Specifically, the press release stated as follows, in relevant part:

> The Company's Biologics License Application (BLA) resubmission for RP1 (vusolimogene oderparepvec) in anti-PD-1 failed melanoma was accepted by the FDA in October 2025 with a Prescription Drug User Fee Act (PDUFA) target action date of April 10, 2026. Commercial readiness activities are well underway to support a potential launch, if approved.
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> ***"We have been engaged with the FDA in the review of the BLA resubmission for RP1,"*** said Sushil Patel, Ph.D., CEO of Replimune. "Advanced melanoma patients can progress quickly and are in urgent need of safe and effective treatment options. Our team remains ready to launch RP1 with commercial supply produced and the commercial organization prepared to engage with our target accounts rapidly, assuming FDA approval."
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> Net loss was $70.9 million for the fiscal third quarter ended December 31, 2025 and $66.3 million for the fiscal third quarter ended December 31, 2024.

29. On February 3, 2026, the Company submitted its quarterly report for the period ended December 31, 2025 on a Form 10-Q filed with the SEC, affirming the previously reported

financial results. The report stated the following regarding the Company's progress with its BLA for RP1, in relevant part:

> Our leading clinical trial of RP1 is referred to as the IGNYTE trial, which is a multi-cohort clinical trial being conducted in collaboration with Bristol Myers Squibb Company, or BMS, under which BMS has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1.
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> On September 2, 2025 we announced a type A meeting with the FDA had been scheduled to discuss the CRL following our submission of a briefing book addressing the points raised in the CRL, highlighting prior agreements related to the patient population, criteria for PD-1 resistance, and use of literature to support contribution of components. The briefing book also included an additional analysis of data from the BLA and addressed comments about the phase 3 confirmatory trial design raised by the FDA in the CRL. On September 18, 2025 we announced that, following the type A meeting with the FDA to discuss the CRL, which was conducted on September 16, 2025, we were evaluating feedback received during the meeting to determine our next steps and that, at that time, a path forward under the accelerated approval pathway had not been determined. ***Following the evaluation of FDA feedback and minutes from the type A meeting, we resubmitted the BLA on October 9, 2025.*** On October 20, 2025 we announced that the FDA had accepted the resubmission of the BLA for RP1 in combination with nivolumab for the treatment of advanced melanoma in patients who progress on an anti-PD-1 containing regimen. ***The resubmission included additional information, data and analyses that will be part of the BLA review.*** The FDA indicated that the resubmission is considered to be a complete response to the CRL and set a PDUFA date of April 10, 2026 based on a Class II resubmission timeline.
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> ***We are interacting with the FDA during the review of the resubmitted BLA*** and, if approved, intend to bring RP1 to adult patients with advanced melanoma who have previously received an anti-PD-1 containing regimen who otherwise have limited treatment options. Without an approval of RP1 from this resubmitted BLA we might not be able to continue the development of RP1 for this indication, if at all, and we may be required to implement a restructuring plan and review our priorities across the RPx portfolio.

30. The above statements identified in ¶¶25-29 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company had not reached an agreement with the FDA to permit the use of the single-arm study trial design used

to support RP1's BLA; (2) that, as a result, there was a significant risk that the INGTYE clinical trail results did not demonstrate that the benefits of RP1 outweighed the risks; (3) that, as a result of the foregoing, there was a substantial risk to regulatory approval of RP1 for the treatment of advanced melanoma and other solid tumors; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

31. On April 10, 2026, before the market opened, the FDA published a CRL rejecting Replimune's BLA for RP1 in combination with nivolumab. The FDA noted that, during its September 2025 meeting, it had given the Company "recommendations regarding use of data from the ongoing Phase 3 trial to potentially support Accelerated Approval." However, "***instead, [the Company] submitted data from an early unplanned analysis***" and "***[t]his data is insufficient to support an efficacy claim.***" The FDA noted that because the Phase II IGNYTE trial was a single-arm study, it was impossible to isolate RP1's specific clinical contribution from that of nivolumab (Opdivo). The FDA also flagged the ongoing Phase III IGNYTE-3 confirmatory trial, stating its similar single-arm design was still insufficient to definitively isolate the individual therapeutic contribution of RP1. Specifically, the CRL stated as follows, in relevant part:

> ***In the Type A meeting dated September 16, 2025, FDA also communicated that the response criteria used in RPL-001-16 were not consistent with RECIST v1.1 and may not be comparable to response rates reported in the historical literature. FDA provided recommendations regarding use of data from the ongoing Phase 3 trial to potentially support Accelerated Approval.***
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> ***Instead, you submitted data from an early unplanned analysis from RP1-104, representing 10% of the planned enrollment, as well as additional exploratory analyses of the RPL-001-16 data, to support BLA resubmission. This data is insufficient to support an efficacy claim.***
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> FDA review identified several issues in the assessment of the reported response rate and duration of response in RPL-001-16, which include application of response

criteria that affect the ***reliability of the reported results and their clinical meaningfulness.***

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Trial design inadequate to establish contribution of effect

RPL-001-16 was not designed to isolate the contribution of vusolimogene oderparepvec when administered in combination with nivolumab.

The heterogeneity in the patient population enrolled in RPL-001-16 and lack of a well-established historical control benchmark for response rate and duration of response in a similar patient population (as discussed under FDA Comment 2) do not allow for a comparative analysis to be conducted between RPL-001-16 and the historical literature for the purposes of ascertaining nivolumab's expected monotherapy activity in this population.

As noted under FDA Comment #1, because the response rate and duration of response were not reliably assessed in RPL-001-16, challenges in comparing these data to external, historical control data for the purposes establishing contribution of effect of vusolimogene oderparepvec to the combination of vusolimogene oderparepvec and nivolumab are further confounded. Thus, it remains unclear whether the observed responses in RPL-001-16 are due to nivolumab alone.

Therefore, RPL-001-16 is not considered to be an adequate and well controlled clinical investigation that provides substantial evidence of effectiveness as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act) Section 505(d), 21 Code of Federal Regulations (CFR) § 314.126, and Section 351 of the Public Health Service Act (PHS Act).

32. On this news, the Company's share price fell $1.15 or 19.46%, to close at $4.76 per share on April 10, 2026, on unusually heavy trading volume.

33. On April 10, 2026, after the market closed, the Company issued a press release discussing the FDA's response letter for the RP1 BLA. The press release stated "Replimune disagrees with the FDA about whether the data set, upon which breakthrough therapy designation was awarded, is sufficient to allow this promising medicine to be made available to advanced cancer patients." The Company further stated that "[p]rior to the original BLA submission, standard regulatory meetings were conducted to discuss trial design, patient population, and the BLA package requirements." The Company revealed that, during those meetings, it learned "***a***

randomized controlled trial was preferred." The Company nonetheless maintained that "[i]n the CRL, the agency appears to have contradicted their positions expressed at the September 2025 Type A meeting."

34. On this news, the Company's share price fell $3.06 or 64.29%, to close at $1.70 per share on April 13, 2026, on unusually heavy trading volume.

35. On May 29, 2026, the Company issued a press release announcing a "Planned RP1 BLA Resubmission Following Productive Discussion with FDA." The press release asserted "***the Company and the FDA have aligned on a path forward for resubmission and reconsideration of the Biologics License Application (BLA) for RP1*** (vusolimogene oderparepvec) in combination with nivolumab for the treatment of advanced melanoma." Specifically, the press release stated as follows, in relevant part:

> Replimune Group, Inc. (NASDAQ: REPL), a clinical-stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that f***ollowing collaborative communications with the U.S. Food and Drug Administration (FDA), the Company and the FDA have aligned on a path forward for resubmission and reconsideration of the Biologics License Application (BLA) for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of advanced melanoma.***
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> The company will resubmit the RP1 BLA in the coming days. The FDA has indicated it will treat the BLA resubmission as an urgent matter upon receipt and will prioritize its review in recognition of the significant unmet need for patients in the advanced melanoma community. This constructive dialogue represents an important step forward for the thousands of patients living with advanced melanoma who have progressed on prior anti-PD-1 based therapy and have limited treatment options available to them.
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> The BLA is supported by data from the IGNYTE clinical trial, which evaluated RP1 combined with nivolumab in patients with confirmed progression on an anti-PD-1 containing regimen. Approximately 8,500 Americans with advanced melanoma die each year, and standard of care checkpoint inhibitor therapy fails approximately half of all patients who receive it, underscoring the urgent need for new treatment options.

36. On June 26, 2026, the Company issued a press release announcing the FDA acceptance of the RP1 BLA application resubmission, stating in part that "***[t]he resubmission seeks accelerated approval of RP1 in advanced melanoma based on data from the IGNYTE clinical trial***." Specifically, the press release stated as follows, in relevant part:

> Replimune Group, Inc. (NASDAQ: REPL), a clinical-stage biotechnology company pioneering the development of novel oncolytic immunotherapies, announced today that ***the U.S. Food and Drug Administration (FDA) has accepted for review the resubmission of the Biologics License Application (BLA) for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of advanced melanoma.*** The FDA considers this a complete, class 1 response with a goal date of August 2, 2026, and has notified the company to expect an advisory committee meeting in late July.
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> "We are pleased that the FDA has demonstrated urgency in reconsidering the RP1 BLA with an expeditious action date in recognition of the significant unmet need for advanced melanoma patients and support from the broader melanoma community," said Sushil Patel, Ph.D., CEO of Replimune. "We look forward to a productive scientific and clinical discussion on the risk/benefit profile of RP1 in this difficult to treat setting."
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> ***The resubmission seeks accelerated approval of RP1 in advanced melanoma based on data from the IGNYTE clinical trial, which evaluated RP1 combined with nivolumab in patients with confirmed progression on an anti-PD-1 containing regimen.***

37. On June 29, 2026, the Company issued a press release which announced earnings for the fourth quarter and fiscal year ended March 31, 2026. The press release alleged that "***[t]he FDA's acceptance of our RP1 BLA resubmission marks a pivotal milestone in our mission to bring this important therapy to patients.***" The press release further reported the Company's financial results, in including its financial highlights. Specifically, the press release stated as follows, in relevant part:

> The Company recently announced that the U.S. Food and Drug Administration (FDA) has accepted for review the resubmission of the Biologics License Application (BLA) for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of advanced melanoma. The FDA considers this a complete, class 1 response with a goal date of August 2, 2026, and has notified the company to expect an advisory committee meeting in late July.

> ***"The FDA's acceptance of our RP1 BLA resubmission marks a pivotal milestone in our mission to bring this important therapy to patients facing advanced melanoma, where the need for durable, effective treatment options remains significant,"*** said Sushil Patel, Ph.D., CEO of Replimune. "We are working hard to ensure we can provide access to RP1 as soon as possible pending an approval.["]
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> Net loss was $73.7 million for the fiscal fourth quarter and $313.9 million for the fiscal year ended March 31, 2026, as compared to a net loss of $74.1 million for the fiscal fourth quarter and $247.3 million for the fiscal year ended March 31, 2025.

38. On June 29, 2026, the Company submitted its annual report for the fiscal year ended March 31, 2026 on a Form 10-K filed with the SEC (the "FY25 10-K"). The FY25 10-K affirmed the previously reported financial results. The FY25 10-K stated the following regarding the Company's progress with its BLA for RP1, in relevant part:

> Our leading clinical trial of RP1 is referred to as the IGNYTE trial, which is a multi-cohort clinical trial being conducted in collaboration with Bristol Myers Squibb Company, or BMS, under which BMS has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1.
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> On September 2, 2025 we announced that a type A meeting with the FDA had been scheduled to discuss the CRL following our submission of a briefing book addressing the points raised in the CRL, highlighting prior agreements related to the patient population, criteria for PD-1 resistance, and use of literature to support contribution of components. The briefing book also included an additional analysis of data from the BLA and addressed comments about the Phase 3 confirmatory trial design raised by the FDA in the CRL. On September 18, 2025 we announced that, following the type A meeting with the FDA to discuss the CRL, which was conducted on September 16, 2025, we were evaluating feedback received during the type A meeting to determine our next steps and that, at that time, a path forward under the accelerated approval pathway had not been determined. ***Following the evaluation of FDA feedback and minutes from the type A meeting, we resubmitted the BLA on October 9, 2025.*** On October 20, 2025 we announced that the FDA had accepted the resubmission of the BLA for RP1 in combination with nivolumab for the treatment of advanced melanoma in patients who progress on an anti-PD-1 containing regimen. ***The resubmission of the BLA included additional information, data and analyses that will be part of the BLA review. The FDA indicated that the resubmission is considered to be a complete response to the***

CRL and set a target action date of April 10, 2026 based on a Class 2 resubmission timeline.

> On April 10, 2026, the FDA issued a second CRL for the RP1 BLA for the treatment of advanced melanoma. The second CRL reiterated points made in the first CRL that were presumably addressed by the FDA accepting the BLA for resubmission indicating the resubmission was a complete response to the initial CRL. The second CRL also reverses on points the FDA made in the September 2025 Type A meeting following the initial CRL. ***We announced on May 29, 2026, that following collaborative communications with the FDA, the Company and the FDA aligned on a path forward for resubmission and reconsideration of the BLA for RP1 in combination with nivolumab for the treatment of advanced melanoma.*** In that announcement, we reported that the FDA indicated that it will treat the BLA resubmission as an urgent matter upon receipt and will prioritize its review in recognition of the significant unmet need for patients in the advanced melanoma community. Without an accelerated approval of the BLA for RP1 in combination with nivolumab for the treatment of advanced melanoma from this resubmitted BLA we might not be able to continue the development of RP1 for this indication, if at all, and we may be required to implement a restructuring plan and review our priorities across the RPx portfolio and the company as a whole. On June 26, 2026 we announced the FDA accepted the BLA resubmission as a Class 1 resubmission with an action date of August 2, 2026. The FDA also stated that they would convene an advisory committee meeting in late July 2026.

39. The FY25 10-K further stated the following regarding the risks which "***could***" or "***may***" negatively impact the Company, including that the Company ***"cannot be certain that [it] will be able to successfully develop our product candidates or obtain regulatory approval for our product candidates, including following the CRLs we received for our BLA of RP1***." Specifically, the FY25 10-K stated as follows, in relevant part:

> ***Our product candidates are in various stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable. We cannot be certain that we will be able to successfully develop our product candidates or obtain regulatory approval for our product candidates, including following the CRLs we received for our BLA of RP1 in combination with nivolumab for the treatment of advanced melanoma. We have never generated any revenue from product sales and may never be profitable.***
>
> All of our product candidates are in various stages of research or clinical development. We have not generated any revenue from the sale of any product to date. Our lead product candidate, RP1, and any other product candidates require extensive preclinical and/or clinical testing and regulatory review from the FDA prior to approval and commercial use. It is possible that the FDA will not approve

an application that we may submit, or our product candidates may not obtain appropriate regulatory approvals necessary for us to commence clinical trials for our product candidates. Any delay or failure in obtaining required approvals could have a material adverse effect on our business. For example, in July 2025, we received a CRL from the FDA in connection with our BLA for RP1 in combination with nivolumab for the treatment of advanced melanoma. Following discussions with the agency, in October 2025, the FDA accepted our resubmission of the BLA for RP1. On April 10, 2026, the FDA issued a second CRL in connection with our BLA for RP1 for the treatment of advanced melanoma. On May 29, 2026, we announced that following collaborative communications with the FDA, we will resubmit our BLA for RP1 in combination with nivolumab for the treatment of advanced melanoma. On June 26, 2026 we announced the FDA accepted the BLA resubmission as a Class 1 resubmission with an action date of August 2, 2026. The FDA also stated that they would convene an advisory committee meeting in late July 2026. There is no assurance that following the FDAs acceptance of our resubmission of our BLA for RP1 in combination with nivolumab, we will be able to satisfy the FDA's concerns.

* * *

In addition, any of our other research and development efforts may not be successful. Furthermore, even if our clinical development efforts result in what we believe to be positive data, our product candidates, including RP1, may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably.

40. The above statements identified in ¶¶31, 33, 35-39 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company had not reached an agreement with the FDA to permit the use of the single-arm study trial design used to support RP1's BLA; (2) that, as a result, there was a significant risk that the INGTYE clinical trail results did not demonstrate that the benefits of RP1 outweighed the risks; (3) that, as a result of the foregoing, there was a substantial risk to regulatory approval of RP1 for the treatment of advanced melanoma and other solid tumors; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

41. On July 28, 2026, before the market opened, the FDA released briefing documents ahead of its anticipated advisory committee meeting to review the third BLA for RP1. In its briefing documents, the FDA once again took issue with the Company's single-arm trial. The briefing documents stated the FDA deemed the single-arm mid-stage study submitted by Replimune to support the approval of the drug as "***not interpretable.***" The briefing documents state the assessment used in the study "***confounds interpretation of the reported efficacy results and limits FDA's ability to verify the reported results***." Specifically, the briefing documents stated as follows, in relevant part:

> The key FDA review issues include the following:
>
> • ***In the IGNYTE study, the Applicant's application of Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) criteria for response assessment confounds interpretation of the reported efficacy results and limits FDA's ability to verify the reported results.***
>
> • The objective response data from the single-arm IGNYTE study are not of sufficient magnitude to overcome concerns about the contribution of effect, particularly in the absence of a reliable historical control, and therefore it cannot be determined whether RP1 contributes to any observed effect when administered in combination with nivolumab.
>
> • ***The overall survival analysis from the single-arm IGNYTE study is not interpretable.***

42. On this news, Replimune's stock price fell $3.28, or 38.01%, to close at $5.35 per share on July 28, 2026, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

43. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Replimune securities between October 20, 2025 and July 28, 2026, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants,

the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

44. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Replimune's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Replimune shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Replimune or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

45. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

46. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

47. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Replimune; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

48. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

49. The market for Replimune's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Replimune's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Replimune's securities relying upon the integrity of the market price of the Company's securities and market information relating to Replimune, and have been damaged thereby.

50. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Replimune's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Replimune's business, operations, and prospects as alleged herein.

51. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Replimune's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

52. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

53. During the Class Period, Plaintiff and the Class purchased Replimune's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

54. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced

in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Replimune, their control over, and/or receipt and/or modification of Replimune's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Replimune, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE

(FRAUD-ON-THE-MARKET DOCTRINE)

55. The market for Replimune's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Replimune's securities traded at artificially inflated prices during the Class Period. On June 26, 2026, the Company's share price closed at a Class Period high of $11.63 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Replimune's securities and market information relating to Replimune, and have been damaged thereby.

56. During the Class Period, the artificial inflation of Replimune's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Replimune's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Replimune and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted

in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

57. At all relevant times, the market for Replimune's securities was an efficient market for the following reasons, among others:

(a) Replimune shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Replimune filed periodic public reports with the SEC and/or the NASDAQ;

(c) Replimune regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Replimune was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

58. As a result of the foregoing, the market for Replimune's securities promptly digested current information regarding Replimune from all publicly available sources and reflected such information in Replimune's share price. Under these circumstances, all purchasers of Replimune's securities during the Class Period suffered similar injury through their purchase of Replimune's securities at artificially inflated prices and a presumption of reliance applies.

59. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972),

because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

60. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Replimune who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and

Rule 10b-5 Promulgated Thereunder

Against All Defendants

61. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

62. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Replimune's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

63. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Replimune's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

64. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Replimune's financial well-being and prospects, as specified herein.

65. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Replimune's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Replimune and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

66. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

67. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to

ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Replimune's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

68. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Replimune's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Replimune's securities during the Class Period at artificially high prices and were damaged thereby.

69. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Replimune was experiencing, which were not disclosed by Defendants, Plaintiff and other

members of the Class would not have purchased or otherwise acquired their Replimune securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

70. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

71. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

72. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

73. Individual Defendants acted as controlling persons of Replimune within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were

issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

74. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

75. As set forth above, Replimune and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: July ___, 2026

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By: _____
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