

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

\_\_\_\_, Individually and on behalf of all  
others similarly situated,

Plaintiff,

vs.

SAREPTA THERAPEUTICS, INC.,  
DOUGLAS S. INGRAM, DALLAN  
MURRAY, and LOUISE RODINO-  
KLAPAC,

Defendants.

CIVIL ACTION NO.:

CLASS ACTION

DEMAND FOR A JURY TRIAL

**CLASS ACTION COMPLAINT  
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

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 Sarepta Therapeutics, Inc. (“Sarepta” or the “Company”), with the U.S. Securities and Exchange Commission (“SEC”); (b) review and analysis of press releases and media reports issued by and disseminated by Sarepta; and (c) review of other publicly available information concerning Sarepta.

**NATURE OF THE ACTION AND OVERVIEW**

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Sarepta securities between June 22, 2023, and June 24, 2025, inclusive (the “Class Period”). Plaintiff pursues claims against the Defendants (defined *infra*) under the Securities

Exchange Act of 1934 (the “Exchange Act”).

2. Sarepta is a commercial-stage biopharmaceutical company headquartered that focuses on RNA and gene therapies for the treatment of rare diseases. During the Class Period, Sarepta was engaged in the development of therapies to treat Duchenne muscular dystrophy (“Duchenne”), including ELEVIDYS. ELEVIDYS is a prescription gene therapy intended for a limited category of people with Duchenne.

3. Throughout the Class Period, Defendants made materially false and misleading statements that conditioned investors to believe ELEVIDYS was a safe therapy that could be expanded for wider application approval. Defendants also misled investors concerning ELEVIDYS’s revenue outlook. Defendants positioned ELEVIDYS as having no hindrances to broader use, which would in turn allow for a strong growth in prescriptions.

4. In truth, Defendants failed to disclose material adverse facts about the Company’s compliance, operations, and outlook. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) ELEVIDYS posed significant safety risks to patients; (ii) ELEVIDYS trial regimes and protocols failed to detect severe side effects; (iii) the severity of adverse events from ELEVIDYS treatment would cause the Company to halt recruitment and dosing in ELEVIDYS trials, attract regulatory scrutiny, and create greater risk around the therapy’s present and expanded approvals; and (iv) as a result of the foregoing, Defendants materially misled with, and/or lacked a reasonable basis for, their positive statements.

5. On March 18, 2025, Sarepta issued a safety update on ELEVIDYS announcing that a patient had died following treatment with ELEVIDYS. On this news, Sarepta’s stock price fell \$27.81 per share, or 27.44%, to close at \$73.54 per share on March 18, 2025.

6. Then, on April 4, 2025, Sarepta disclosed that European Union member country

authorities had requested that the independent data monitoring committee meet to review death announced on March 18, 2025. Sarepta simultaneously halted recruitment and dosing in some of the ELEVIDYS clinical studies. On this news, Sarepta's stock price fell \$4.18 per share, or 7.13%, to close at \$54.43 per share on April 4, 2025.

7. Next, on June 15, 2025, Sarepta disclosed a second patient had died of acute liver failure following treatment with ELEVIDYS. The Company announced it was suspending shipments of ELEVIDYS for non-ambulatory patients while Sarepta took time to evaluate trial regimens and discussed findings with regulatory authorities. Sarepta also revealed that it was pausing dosing in one of its ELEVIDYS clinical studies.

8. On this news, Sarepta's stock price fell \$15.24 per share, or 42.12%, to close at \$20.91 per share on June 15, 2025.

9. Finally, on June 24, 2025, the United States Food and Drug Administration ("FDA") issued a Safety Communication announcing it had received reports of two deaths and was investigating the risk of acute liver failure with serious outcomes following treatment with ELEVIDYS. The communication noted that the FDA was evaluating the need for further regulatory action.

10. On this news, Sarepta's stock price fell \$1.52 per share, or 8.01%, to close at \$17.46 per share on June 25, 2025.

11. 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**

12. 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).

13. 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).

14. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Sarepta securities trade on the NASDAQ Stock Market (“NASDAQ”), located within this Judicial District.

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

### **PARTIES**

16. Plaintiff, as set forth in the attached Certification, acquired Sarepta securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

17. Sarepta is a Delaware corporation with principal executive offices located at 215 First Street, Suite 415, Cambridge, MA. Sarepta securities trade in an efficient market on the NASDAQ under the ticker symbol “SRPT”.

18. Defendant Douglas S. Ingram (“Ingram”) has served as Sarepta’s President and Chief Executive Officer at all relevant times.

19. Defendant Dallon Murray (“Murray”) has served as Sarepta’s Senior Vice President & Chief Commercial Officer at all relevant times.

20. Defendant Louise Rodino-Klapac (“Rodino-Klapac”) has served as Sarepta’s

Executive Vice President, Chief Scientific Officer and Head of Research & Development at all relevant times.

21. Defendants Ingram, Murray and Rodino-Klapac are sometimes referred to herein collectively as the “Individual Defendants.”

22. The Individual Defendants possessed the power and authority to control the contents of Sarepta’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Sarepta’s SEC filings 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 to cause them to be corrected. Because of their positions with Sarepta, and their access to material information available to them but not to the public, 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 being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

23. Sarepta is a commercial-stage biopharmaceutical company headquartered in Cambridge, Massachusetts. The Company focuses on RNA and gene therapies for the treatment of rare diseases. For several years, Sarepta has been engaged in the development of therapies to treat Duchenne muscular dystrophy (“Duchenne”), including ELEVIDYS. ELEVIDYS is a prescription gene therapy intended to treat ambulatory and non-ambulatory people with Duchenne who are at least 4 years old and have a confirmed mutation in the dystrophin gene.

24. In June 2023, the FDA granted accelerated approval for ELEVIDYS, which

allowed the drug to be used for certain ambulatory patients. The FDA's accelerated program provides for an expedited approval process for therapies that treat serious conditions and fill an unmet medical need. Drugs can be approved based on a company's reported surrogate endpoints, even before their intended benefits are fully verified.

25. Throughout the Class Period, Sarepta began working with patients and healthcare providers to prescribe ELEVIDYS. During this time, the Company also conducted clinical trials for ELEVIDYS to show its purported efficacy and expand its application to a broader array of people with Duchenne. Accordingly, the Defendants projected that wider use of ELEVIDYS would grow and accelerate revenues for the Company.

**The Defendants' Materially False and  
Misleading Statements Issued During the Class Period**

26. The Class Period begins on June 22, 2023, when Sarepta issued a press release, pre-market trading, announcing the upcoming start of a clinical trial for ELEVIDYS (the "June 2023 Press Release"). The June 2023 Press Release contained the following statement from Defendant Ingram on the purported benefits experienced with ELEVIDYS:

As we prepare to launch ELEVIDYS, we should acknowledge and celebrate the decades of dedication and work from the patient community, families, clinicians, and our Sarepta colleagues that resulted in today's approval. Our confirmatory trial, EMBARK, should read out in the fourth quarter of this year. ***If EMBARK confirms the benefits seen in our prior trials***, Sarepta will move rapidly to submit a BLA supplement to expand the approved label as broadly as good science permits.

27. On August 2, 2023, Sarepta issued a press release announcing the Company's financial results for the second quarter of 2023, ending June 30, 2023 (the "2Q23 Press Release"). The 2Q23 Press Release included comments from Defendant Ingram on the status of the EMBARK trials stating, "The launch of ELEVIDYS is off to a great start, with our first reimbursed infusion today, ahead of plan. In addition to making this launch a success, our paramount goal is

to translate a positive result in our confirmatory trial, EMBARK, later this year to a broad label as rapidly as possible.”

28. On the same day, the Defendants held an investor conference call to discuss Sarepta’s latest financial results. In his opening remarks, Defendant Ingram commented on the progress of the ELEVIDYS trial, stating in part, “ELEVIDYS is our fourth approved Duchenne therapy, *and we have been very successful with all of our prior launches, consistent with our track record, the ELEVIDYS launch is going well.*”

29. On the same call, Defendant Rodino-Klapac commented on the Company’s assurance of transparency with the ELEVIDYS trial stating, “As we look forward to the weeks and months ahead, we remain firmly committed to our values to *follow the science and present objective evidence that supports an ELEVIDYS's ability to change the trajectory of Duchenne muscular dystrophy.*” In discussing the results of ELEVIDYS clinical trials, Defendant Rodino-Klapac additionally said:

*In clinical trials, ELEVIDYS demonstrated positive results at multiple time points, including one two and four years after treatment in addition to consistent safety profile.* The BLA for ELEVIDYS included efficacy and safety data from studies 101, 102, and 103 for ENDEAVOR, as well as an integrated analysis across these three clinical studies, comparing functional results to propensity score matched external control.

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The data from studies 101, 102 and 103 Cohort 1, which is ages four to seven have now been either published or accepted for publication in peer-reviewed journals. *When compared to appropriate control populations, ELEVIDYS has consistently shown a treatment effect as measured by change in MSA score at one year.*

30. Later on the same call, Defendant Murray commented on the demand for and efficacy of ELEVIDYS, stating:

And finally to touch on antibody testing, over 700 kits are in the hands of our key sites within a day or two of approval. Testing is currently underway, and the process is working smoothly. *We've seen very strong demand for ELEVIDYS and are encouraged by the discussions with KOLs, payers and the broader community.*

We began receiving enrollment forms within hours of approval, and we continue to see them come in on a daily basis.

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Launching the first gene therapy for Duchenne patients requires a multifaceted approach with a high level of communication not only with HCPs and sites, but also patients, families and payers to ensure patients have timely access to this groundbreaking therapy. *As a result of our preparation and diligent efforts, we are now at the point where patients can begin receiving ELEVIDYS with confidence.*

31. On November 1, 2023, Sarepta issued a press release announcing the Company's financial results for the third quarter of 2023, ending September 30, 2023 (the "3Q23 Press Release"). The 3Q23 Press Release announced that the EMBARK trial's topline results "support the conclusion that ELEVIDYS modifies the course of the disease in patients with Duchenne," and *"no new safety signals were observed."* The 3Q23 Press Release included comments from Defendant Ingram on the status of the EMBARK trial stating:

The third quarter was a defining moment for Sarepta. We launched ELEVIDYS, our fourth therapy and the first gene therapy for boys with Duchenne muscular dystrophy, we continued to drive great performance of our three PMOs and importantly, on a non-GAAP basis we have achieved profitability, placing us in ever more rarified territory in biotech.

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Reflecting a superb launch, ELEVIDYS net product revenue came in at \$69.1 million. Total net product revenue stands at \$309.3 million, growing 49 percent over the same quarter last year. And non-GAAP earnings stood at approximately \$38.0 million in the quarter, a major milestone for Sarepta.

32. On the same day, the Defendants held an investor conference call to discuss Sarepta's latest financial results. In his opening remarks, Defendant Ingram commented on the safety, efficacy and revenue of ELEVIDYS, stating:

First, taken as a whole, *the results of EMBARK confirm that ELEVIDYS stabilizes muscles, slows or entirely arrests decline, does so across the ages, and does so with a laudable safety profile not shared by other programs for*



**Duchenne.**

Second, the EMBARK results have not only satisfied the confirmatory requirements for our June approval, but ***have shown that ELEVIDYS benefits patients across age groups consistent with its mechanism of action.*** Hence, we will soon be submitting a BLA supplement to broaden the ELEVIDYS label to remove age and ambulation restrictions.

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Third quarter total revenue came in at \$332 million, and total net product revenue stands at \$309.32 million, growing 49% over the same quarter last year reflecting the team's ability to execute and serve Duchenne patients. ***ELEVIDYS net product revenue came in at \$69.11 million, nearly tripled mean external consensus.***

33. On the same call, Defendant Murray provided further comments on the marketability of ELEVIDYS stating:

[W]e generated just over \$69 million in net product revenues in the third quarter for ELEVIDYS. ***Notably, the team exceeded our own lofty site readiness expectations with nearly 70 sites ready to dose today. This helps us support the patients at risk of aging out today and also sets us up for longer term success going forward.***

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The team is working diligently as we speak, educating the payers on the robustness of the newly available EMBARK data. ***We're confident that this data sets the stage nicely for access to align with our label today, as well as when we gain a broader label.***

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So to summarize ELEVIDYS, it was a great first quarter for the launch because our team and our key stakeholders were prepared and they executed flawlessly to support the patients we serve. ***Driven in large part by the robust ELEVIDYS revenue in the third quarter, we grew overall net product revenue by roughly 30% over the prior quarter.*** Net product revenue in Q3 of 2023 was \$309.3 million.

34. Later on the same call, Bank of America Merrill Lynch analyst Tazeen Ahmad asked the Individual Defendants for color on when the Company would complete its BLA filing with the FDA. Defendant Ingram responded:

[T]he inquiry ... is focused, and that focus is on the fundamental question, *does the totality of the evidence, justify conclusion that ELEVIDYS is bringing a better life to these patients. And of course, we believe that it does. The standard for this is quite clear.*

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The statute says it's very clear. *Can one fairly and responsibly conclude that the therapy will have the effect it purports to have*, and the regulations are also particularly clear that for life-threatening and severely debilitating illnesses one's life can be shed especially where no satisfactory alternative therapy exists.

35. On February 28, 2024, Sarepta issued a press release announcing the Company's financial results for the four quarter and full year 2023, ending December 31, 2023 (the "4Q23 Press Release"). The 4Q23 Press Release reported that the FDA had accepted Sarepta's efficacy Biologics License Application ("BLA") supplement for ELEVIDYS, which could allow Sarepta to widen therapy applications. Specifically, the Company planned to expand the labeled indication for ELEVIDYS and convert the ELEVIDYS accelerated FDA approval to a traditional FDA approval.

36. On the same day, the Defendants held an investor conference call to discuss Sarepta's latest financial results. In his opening remarks, Defendant Ingram commented on ELEVIDYS' performance stating:

In addition to continuing strong performance among our three approved therapies, *ELEVIDYS' performance was particularly impressive, and reflects first-in-class launch excellence, notwithstanding, a label limited to four and five-year-olds, representing only about 3% or so of the total Duchenne population. ELEVIDYS net product revenue was \$131.2 million for the quarter, and over \$200 million for the full-year.* I'm exceptionally proud of the team's performance here, which speaks to our level of preparation and attention to detail, expert understanding of all aspects of launching innovative rare disease therapies, and, of course, our passion for bringing a better life to those living with Duchenne.

37. On the same call, Defendant Murray provided further comments on ELEVIDYS' revenues stating:

Turning to ELEVIDYS, we're extremely pleased with launch execution, exceeding

our own lofty expectations. In fact, the \$200 million in net product revenue surpassed the combined 2023 revenue of the other five gene therapy launches from the past 18 months. Remarkable, given the ELEVIDYS approval occurred just this past summer. ***The success of ELEVIDYS shows that gene therapy can be commercially viable***, providing hope for those patients with Duchenne, and for all those with genetic conditions with unmet need. While revenue is how we quantify the success of this launch externally, we measure ourselves on how we support patients.

38. Later in the call, Defendant Rodino-Klapac further commented on the projected pathway for the ELEVIDYS therapy stating:

In June 2023, the FDA granted accelerated approval to ELEVIDYS, [the] first gene therapy to treat Duchenne muscular dystrophy. ***Since that time, we've been successfully treating ambulatory pediatric patients aged four through five years with Duchenne, who have a confirmed mutation in the DMD gene***. And then, just about two weeks ago, and as Doug mentioned, we were thrilled to announce that the FDA accepted and filed our efficacy supplement for ELEVIDYS, whereby they will now evaluate broadening the approved indication of ELEVIDYS. By removing age and emulation restrictions and converting the ELEVIDYS accelerated approval to a traditional approval.

39. On May 1, 2024, Sarepta issued a press release announcing the Company's financial results for the first quarter of 2024, ending March 31, 2024 (the "1Q24 Press Release"). The 1Q24 Press Release reported that ELEVIDYS had generated net revenues of \$133.9 million for the quarter. The 1Q24 Press Release also included comments from Defendant Ingram on ELEVIDYS' revenue and outlook stating:

[O]ur recently approved gene therapy, ELEVIDYS, achieved nearly \$134.0 million in net product revenue in the quarter. Although its initial label is quite narrow, ***ELEVIDYS has posted cumulative sales of over \$334.0 million since its approval in June of last year, far exceeding performance of all other gene therapies approved in the last few years combined***. Working with the FDA, we continue to productively prosecute our BLA supplement to expand the ELEVIDYS addressable population, with a target action date of June 21, 2024. If successful, 2024 could be the most profound year yet in our fight against the effects of Duchenne muscular dystrophy and a bellwether for the transformative potential of gene therapy for rare disease.

40. On the same day, the Defendants held an investor conference call to discuss

Sarepta's latest financial results. In his opening remarks, Defendant Ingram reiterated ELEVIDYS' revenue outlook stating:

***[W]e have already posted over \$334 million since our [ELEVIDYS] approval last June, far exceeding all other gene therapies approved in the last few years combined. This says much about the opportunity in front of us.*** Physician and patient demand are significant. We are working well with public and private payers to facilitate access and our multiyear obsessive preparation in sight readiness, manufacturing, distribution, access and support is all paying off.

41. On the same call, Defendant Rodino-Klapac also commented that data supported wider approval of ELEVIDYS, stating:

As Doug mentioned in his opening remarks, the BLA supplements for ELEVIDYS was submitted in December of last year. We requested the removal of any age or ambulation restrictions in the label and conversion to traditional approval. ***The totality of data generated for ELEVIDYS supports but is a disease-modifying therapy that changes the trajectory of Duchenne, demonstrating a treatment benefit that is clinically meaningful and similar regardless of age.***

42. On June 20, 2024, Sarepta issued a press release announcing FDA Approval of ELEVIDYS to patients ages four and above, regardless of ambulatory status (the "June 2024 Press Release"). In the June 2024 Press Release, Defendant Ingram call the approval "a watershed occasion for the promise of gene therapy and a win for science."

43. On August 7, 2024, Sarepta issued a press release announcing the Company's financial results for the second quarter of 2024, ending June 30, 2024 (the "2Q24 Press Release"). The 2Q24 Press Release reiterated the FDA's broadened access of ELEVIDYS for all patients at least 4 years of age. Defendant Ingram also provided comments on the safety and efficacy of ELEVIDYS in the 2Q24 Press Release stating:

***We look forward to reviewing the comprehensive data supporting the safety and efficacy of ELEVIDYS*** at the 29th Annual Congress of the World Muscle Society taking place in October, including muscle and cardiac MRI data and other biomarker results showing improvement in muscle health of treated patients.

44. On the same day, the Defendants held an investor conference call to discuss Sarepta's latest financial results. In his opening remarks, Defendant Ingram bragged on the revenue outlook ELEVIDYS stating:

Anyone who has been watching over the last seven-plus years will realize that this is exactly what we are particularly good at. Certainly, we are great at developing therapies for rare disease, and we are great at managing the process to get them approved and we have become exceptional at managing complex manufacturing and distribution. But perhaps above all else, we are second to no one in the world at launching Duchenne therapies, working with payers and ensuring access.

As we have noted previously, with the broader label granted in June of this year, the opportunity to serve patients and in so doing reward committed investors will be enormous. ***Our early launch has exceeded even our optimistic expectations. All signals are currently positive from physician and patient demand to enrollment forms to assay kit ordering to positive payer interactions.***

45. On the same call, Defendant Murray touted the success of the ELEVIDYS trial launch stating:

Now turning to the ELEVIDYS launch. We're pleased with the launch progress date and are on track to realize the opportunity in front of us. To put the current situation into perspective, almost the entire Duchenne population became eligible for ELEVIDYS essentially overnight. What we're seeing right now is the key neuromuscular centers reacting to unprecedented demand from entirety of their Duchenne patient populations. The treating sites are rapidly working through and prioritizing patient demand. We're confident in their ability to manage this, given the fact that these are the same centers who navigated all of the recent Duchenne and SMA launches, including Zolgensma.

Your uptake assumptions should reflect the patient journey to obtain an infused gene therapy. We're only several weeks into this new launch. However, ***we have some exciting successes to report, which highlight the progress the team has made in the short time we've had with the ELEVIDYS label expansion.***

46. Later in the call, Defendant Rodino-Klapac commented on the purported wide efficacy of ELEVIDYS stating:

The mechanism of action of ELEVIDYS is universal, regardless of disease state as long as muscle is present. As a result, ***the ELEVIDYS dystrophin expressed by our therapy in non-ambulatory patients is reasonably likely to clinical benefit in this population.*** As a result, accelerated approval or AA has been granted for the treatment of non-ambulatory patients, ages 4 and older.

47. During the question-and-answer session of the call, Bank of America Merrill Lynch analyst Tazeen Ahmad asked the Individual Defendants what had changed with the enrollment to therapy process “from the time that you got approved for the four- to five-year roles, when did it start lengthening to what you're saying, what is it three to six months that it's going to take?” Defendant Ingram answered the question with:

Thank you very much for your question. The short answer is, there really is no bottleneck at all. Now, as I think we said in the last earnings call, it's clearly the case that with the four- to five-year-olds, we were all in. I mean all, not just us, physicians, families and the payers, we're all in kind of a crisis mode, prioritizing kids that were about to age out of the label, and we're able to do it more rapidly than is normal.

But the normal process is about three to five months. And I mean normal that's not atypical for these sorts of therapies, but it's very typical for EXONDYS, VYONDYS, AMONDYS, and now ELEVIDYS. ELEVIDYS has some additional requirements, including, for instance, the requirement that one test for and is negative for neutralizing antibodies. So, to be very clear, there is no bottleneck here. ***We're doing brilliantly. That start forms are great. Patient and physician demand is great. Manufacturing is great. Everything is going very, very well.***

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And then it's going to take three to five months. That means that we're going to have nice growth in Q3, but it will be moderated and then Q4 will be very strong growth, as we've mentioned, more than double the growth in Q4 of this year. And then ***as we model right now, based on everything we're seeing, we're going to do between \$2.9 billion and \$3.1 billion in revenue across the four therapies next year, which speaks to the success that we believe is happening with ELEVIDYS,*** and it speaks to the continuing success of our PMOs and the fact that we're seeing fairly modest cannibalization, and we imagine we'll see fairly modest cannibalization in the next year.

48. On November 6, 2024, Sarepta issued a press release announcing the Company's financial results for the third quarter of 2024, ending September 30, 2024 (the “3Q24 Press Release”). Defendant Ingram comments on outlook for ELEVIDYS in the 3Q24 Press Release stating: **“Reflecting our detailed preparation and track record of commercial execution, the**

**launch of ELEVIDYS is proceeding to plan.** ELEVIDYS net product revenue was \$181.0 million in the quarter, exceeding prior guidance.”

49. On the same day, the Defendants held an investor conference call to discuss Sarepta’s latest financial results. In his opening remarks, Defendant Ingram reiterated the earnings and outlook for ELEVIDYS’ stating:

We are tracking well to Q4 and 2025 performance consistent with prior guidance.

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Additionally, our program to move ELEVIDYS to suspension manufacturing is proceeding very well. We have had very encouraging interactions with the FDA, and we continue our engineering runs in anticipation of commencing a bridging study in 2025.

50. During the same call, Defendant Rodino-Klapac provided remarks on the safety of ELEVIDYS stating:

We continue to advance the ELEVIDYS clinical program and share new datasets as they become available. We recently published the primary one year EMBARK results in Nature Medicine, a high impact journal. In addition, we had multiple presentations at the World Muscle Society Congress in early October. This included additional EMBARK data, Muscle MRI and Cardiac MRI. ***Muscle MRI changes were consistent with functional outcomes from EMBARK Part 1, showing stabilization or slowing of disease progression with SRP-9001, while progression occurred in placebo treated patients evidenced by accumulation of fat and fibrosis.***

***In addition to the EMBARK data, we've also presented safety and expression data from Study 103 or ENDEAVOR, demonstrating consistent safety and expression data across ambulatory and non-ambulatory patients. As of the end of October 2024, we have dosed over 80 late ambulatory and non-ambulatory patients within our clinical program and continue to see a consistent safety profile.***

51. During the question-and-answer session of the call, Jeffries analyst Andrew Tsai asked the Individual Defendants to reconcile how Roche, Sarepta’s partner with the ELEVIDYS launch was reporting a different number of patients treated than what the Company was reporting. Defendant Ingram answered the question with:

I'm not going to comment or confirm that we haven't provided those numbers like that. We're going to use revenue as our metric, and we're -- as it stands today, standing on the guidance that we provided previously. I mean it certainly is the case qualitatively that we have dosed an enormous number of patients.

***We have an extraordinary amount of experience with ELEVIDYS.*** Louise will have mentioned to you that we have already dosed between clinicals and some commercial 80 or so, probably more than that by now. About 80 patients that are either late ambulatory or non-ambulatory, in addition to all of the other patients we dose. ***And as you know, we've not seen a difference in any safety metrics. So things that look great.*** The profile of the therapy looks great and the launch is going great. So that's where we are right now with it. And we're excited to give you an update after Q4.

52. On January 27, 2025, Sarepta issued a press release regarding test results for part two of the EMBARK study announcing sustained benefits were demonstrated, as well as disease stabilization, following treatment with ELEVIDYS (the “January 2025 Press Release”). The January 2025 Press Release included comments from Defendant Rodino-Klapac stating:

We're very encouraged to see the results from Part 2 of EMBARK as they further elucidate the impact ELEVIDYS has on disease progression in a blinded, controlled study. Skeletal muscle MRI demonstrates the importance of preserving muscle, ***and the functional outcome results show disease stabilization sustained through two years after treatment.***

Over time, we continue to observe a statistically significant difference favoring ELEVIDYS compared to a well-matched external control on NSAA and timed tests. ***The consistency and totality of evidence supporting a long-term and clinically meaningful treatment benefit with ELEVIDYS continues to grow.*** We look forward to sharing more details with the clinical community in upcoming scientific forums.

53. On February 26, 2025, Sarepta issued a press release announcing the Company's financial results for the fourth quarter and full year 2024, ending December 31, 2024 (the “4Q24 Press Release”). Defendant Ingram commented on the outlook for ELEVIDYS in the 4Q24 Press Release stating, “In 2025, we intend to capitalize on our 2024 achievements, in addition to 2025 net product revenue guidance of \$2.9 billion to \$3.1 billion, representing 70% year-over-year growth and 162% yearly growth for ELEVIDYS.”



54. On the same day, the Defendants held an investor conference call to discuss Sarepta's latest financial results. In his opening remarks, Defendant Ingram reiterated ELEVIDYS performance during 2024 stating:

Turning to ELEVIDYS, in 2024, we had by a wide margin the most successful launch of a gene therapy yet in history. For the fourth quarter, ELEVIDYS sales stood at \$385 million -- \$384 million, representing 112% increase over the prior sequential quarter. And while we have already achieved over \$1 billion in sales since our initial approval in 2023, this represents less than 5% of the on-label addressable opportunity, so clearly this is just the beginning.

As you know, we already met our important ELEVIDYS milestone in late January. We reported the two-year and one-year crossover results for ELEVIDYS. ***From our pivotal trial EMBARK and in all pre-specified measures, that includes all functional measures, muscle health, biomarkers, those on ELEVIDYS did strongly, statistically, significantly better than untreated natural history would have predicted.*** We have passed 600 patients now on therapy across a broad range of ages and weights. These data are further proof of the transformative potential of ELEVIDYS to change the future course of this disease for patients.

55. On the same call, Defendant Rodina-Klapac also commented on the success of ELEVIDYS stating:

Given what we know about ELEVIDYS, what the science and data have shown us, and what we have observed in the large population of patients that have been treated with ELEVIDYS, ***we were not surprised by such overwhelmingly positive data from the study, which demonstrated that ELEVIDYS impact the trajectory of Duchenne and offers an early treatment option intended to avoid unnecessary and unavoidable muscle damage.***

In summary and evidenced by the data, ELEVIDYS demonstrated a clinically meaningful response across all of Sarepta studies with increasing divergence from natural history over time that supports the durability of the therapy.

56. During the question-and-answer session of the call, RBC Capital Markets analyst Brian Abraham asked the Individual Defendants their thoughts about data results expectations for expanded application of therapies. Defendant Ingram answered:

We have a lot of conviction around this, as you can well imagine, first because we've already actually dosed patients with SRP-9003, but also because SRP-9003 stands on the shoulders of all of the work that we've done with 9001 now

***ELEVIDYS. We have dosed hundreds and hundreds and hundreds of patients with ELEVIDYS. We understand the law, the safety profile and we understand the power of our constructs and our promoter to get really good expression and get it safely. So that's sort of the bar and we're very confident about where we're going to go with that.***

57. The statements referenced in paragraphs 24-54 were materially false and/or misleading, as well as failed to disclose material adverse facts about the Company's compliance, operations, outlook. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) ELEVIDYS posed significant safety risks to patients; (ii) ELEVIDYS trial regimes and protocols failed to detect severe side effects; (iii) the severity of adverse events from ELEVIDYS treatment would cause the Company to halt recruitment and dosing in ELEVIDYS trials, attract regulatory scrutiny, and create greater risk around the therapy's present and expanded approvals; and (iv) as a result of the foregoing, Defendants materially misled with, and/or lacked a reasonable basis for, their positive statements about the Company's compliance, operations, outlook during the Class Period.

### **The Truth Begins to Emerge**

58. On March 18, 2025, Sarepta issued a safety update on ELEVIDYS announcing that a patient had died following treatment with ELEVIDYS. The Company disclosed that the patient suffered acute liver failure leading to death, which represented "a severity of acute liver injury not previously reported for ELEVIDYS." The Company maintained, however, that "benefit-risk of ELEVIDYS remains positive."

59. On this news, Sarepta's stock price fell \$27.81 per share, or 27.44%, to close at \$73.54 per share on March 18, 2025.

60. Then, on April 4, 2025, Sarepta issued a press release that provided an update on ELEVIDYS. The Company disclosed that European Union member country authorities had

requested that the independent data monitoring committee meet to review the death announced on March 18, 2025. As a result, Sarepta halted recruitment and dosing in some of the ELEVIDYS clinical studies (SRP-9001-302 (ENVOL), Study SRP-9001-303 (ENVISION) and Study SRP-9001-104). Nonetheless, Sarepta claimed the “temporary” pause should not have a material impact on the affected studies.

61. On this news, Sarepta’s stock price fell \$4.18 per share, or 7.13%, to close at \$54.43 per share on April 4, 2025.

62. Next, on June 15, 2025, Sarepta disclosed a second patient had died of acute liver failure following treatment with ELEVIDYS. The Company disclosed it was suspending shipments of ELEVIDYS for non-ambulatory patients while Sarepta took time to evaluate trial regimens and discussed findings with regulatory authorities. The Company also revealed that it was pausing dosing of ELEVIDYS in the ENVISION clinical study (Study SRP-9001-303) to evaluate the protocol in accordance with the FDA.

63. On this news, Sarepta’s stock price fell \$15.24 per share, or 42.12%, to close at \$20.91 per share on June 15, 2025.

64. Finally, on June 24, 2025, the FDA issued a Safety Communication announcing it had received reports of two deaths and was investigating the risk of acute liver failure with serious outcomes following treatment with ELEVIDYS. The communication noted that the FDA was evaluating the need for further regulatory action.

65. On this news, Sarepta’s stock price fell \$1.52 per share, or 8.01%, to close at \$17.46 per share on June 25, 2025.

66. 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.

### **CLASS ACTION ALLEGATIONS**

67. 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 Sarepta securities between June 22, 2023 and June 24, 2025, 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.

68. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Sarepta’s securities were 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 Sarepta securities 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 Sarepta or its transfer agent, and may be notified of the pendency of this action by mail or email, using a form of notice similar to that customarily used in securities class actions.

69. 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.

70. 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.

71. 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' actions 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 Sarepta; and
- (c) to what extent the members of the Class have sustained damages and the proper measure of damages.

72. 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**

73. The market for Sarepta'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, Sarepta's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class, relying upon the integrity of the market price of the Company's securities and market information relating to Sarepta, purchased or otherwise acquired Sarepta's securities and have been damaged thereby.

74. During the Class Period, Defendants materially misled the investing public, thereby

inflating the price of Sarepta'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 Sarepta's business, operations, and prospects as alleged herein.

75. 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 Sarepta's financial well-being and prospects. These material misstatements and/or omissions had the 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**

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

77. During the Class Period, Plaintiff and the Class purchased Sarepta'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**

78. 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, Defendants, by virtue of their receipt of information reflecting the true facts regarding Sarepta, and, as to the Management Defendants, their control over, and/or receipt and/or modification of Sarepta's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Sarepta, participated in the fraudulent scheme alleged herein.

### **APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)**

79. The market for Sarepta'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, Sarepta's securities traded at artificially inflated prices during the Class Period. On June 24, 2024, the Company's common stock price closed at a Class Period-high of \$163.85 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 Sarepta's securities and market information relating to Sarepta, and have been damaged thereby.

80. During the Class Period, the artificial inflation of Sarepta's securities 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 Sarepta's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Sarepta 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 securities. 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.

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

(a) Sarepta securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market.

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

(c) Sarepta 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) Sarepta 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.

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

83. 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' 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**

84. 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 Sarepta 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**

85. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 24-80 above as if fully set forth herein.

86. 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 Sarepta'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.

87. 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 Sarepta'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.

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

89. Defendants employed devices, schemes, and artifices to defraud, while in possession of material adverse nonpublic information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Sarepta'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 Sarepta 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.

90. Each of the Management Defendants' primary liability and controlling person liability arises from the following facts: (i) the Management 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.

91. 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. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Sarepta'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.

92. As a result of the dissemination of materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Sarepta's securities was artificially inflated during the Class Period. In ignorance of the fact that the 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 trade, 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 Sarepta's securities during

the Class Period at artificially high prices and were damaged thereby.

93. 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 Sarepta was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Sarepta 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.

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

95. 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 Management Defendants**

96. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 24-80 above as if fully set forth herein.

97. Management Defendants acted as controlling persons of Sarepta 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

98. Company with the SEC and disseminated to the investing public, Management 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. Management 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.

99. In particular, Management 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.

100. As set forth above, 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, Management Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

#### **PRAYER FOR RELIEF**

101. 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**

102. Plaintiff hereby demands a trial by jury.

DATED:

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