UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THOMAS OLDROYD, Individually and on behalf of all others similarly situated, Plaintiff, v. VERVE THERAPEUTICS, INC., SEKAR KATHIRESAN, and ALLISON DORVAL, Defendants.	**Case No:** **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff Thomas Oldroyd ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, among other things, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants' public documents, public filings, wire and press releases published by and regarding Verve Therapeutics, Inc. ("Verve Therapeutics" or the "Company"), and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired publicly traded Verve Therapeutics securities between August 9, 2022 and April 1, 2024, inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by

Defendants' violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to 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).

3. 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).

4. 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)) as the alleged misstatements entered and the subsequent damages took place in this judicial district.

5. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants (defined below), directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

6. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Verve Therapeutics securities during the Class Period and was economically damaged thereby.

7. Defendant Verve Therapeutics describes itself as a "clinical-stage genetic medicines company pioneering a new approach to the care of cardiovascular disease, transforming treatment from chronic management to single-course gene editing medicines."

8. Pertinent to this action is the Heart-1 Phase 1b clinical trial (the "Heart-1 Trial") of VERVE-101. The Company describes VERVE-101 as follows:

> VERVE-101 is a novel, investigational gene editing medicine designed to be a single course treatment that permanently turns off the *PCSK9* gene in the liver to reduce disease-driving low-density lipoprotein cholesterol (LDL-C). VERVE-101 is being developed initially as a treatment for patients with heterozygous familial hypercholesterolemia (HeFH), a prevalent and potentially life-threatening subtype of atherosclerotic cardiovascular disease (ASCVD). VERVE-101 consists of messenger RNA expressing an adenine base editor and an optimized guide RNA targeting the *PCSK9* gene packaged in an engineered lipid nanoparticle.

9. The Company described the Heart 1 Trial as follows:

> Heart-1 is an open-label Phase 1b clinical trial designed to enroll adult patients with heterozygous familial hypercholesterolemia (HEFH), established atherosclerotic cardiovascular disease (ASCVD) and uncontrolled hypercholesterolemia to evaluate the safety and tolerability of VERVE-101 administration, with additional analyses for pharmacokinetics and changes in blood PCSK9 protein and low-density lipoprotein cholesterol (LDL-C) levels. The single ascending dose portion of the trial has consisted of four dose levels: 0.1 mg/kg [n=3], 0.3 mg/kg [n=3], 0.45 mg/kg [n=6], and 0.6 mg/kg [n=1].

10. Defendant Verve Therapeutics is located at 201 Brookline Avenue, Suite 601, Boston, Massachusetts, 02215.

11. Verve Therapeutics' common stock trades on the NASDAQ exchange under the ticker symbol "VERV."

12. Defendant Sekar Kathiresan ("Kathiresan") co-founded the Company and served as its Chief Executive Officer ("CEO") at all relevant times.

13. Defendant Allison Dorval ("Dorval") served as the Company's Chief Financial Officer ("CFO") at all relevant times.

14. Defendants Kathiresan and Dorval are collectively referred to herein as the "Individual Defendants."

15. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

16. Verve Therapeutics is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

17. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Verve Therapeutics under *respondeat superior* and agency principles.

18. Defendant Verve Therapeutics and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS
Materially False and Misleading
Statements Issued During the Class Period

19. On August 9, 2022, before the market opened, the Company filed with the SEC its quarterly report on Form 10-Q for the period ending June 30, 2022 (the "2Q22 Report"). Attached to the 2Q22 Report were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Kathiresan and Dorval attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting, and the disclosure of all fraud.

20. The 2Q22 Report contained the following risk disclosure:

> ***If any of the product candidates we may develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidates, limit the commercial potential or result in significant negative consequences following any potential marketing approval.***
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> ***We only recently initiated our heart-1 clinical trial for VERVE-101***. Moreover, there have been only a limited number of clinical trials involving the use of gene editing technologies and none involving base editing technology similar to our technology. Furthermore, there has not been any gene editing product candidate that has received regulatory approval for use in humans. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that gene editing technologies will not cause undesirable side effects, as improper editing of a patient's DNA could lead to lymphoma, leukemia or other cancers or other aberrantly functioning cells.
>
> A significant risk in any gene editing product candidate is that "off-target" edits may occur, which could cause serious adverse events, undesirable side effects or unexpected characteristics. We cannot be certain that off-target editing will not occur in any of our ongoing or future clinical studies, and the lack of observed side effects in preclinical studies does not guarantee that such side effects will not occur in human clinical studies. ***There is also the potential risk of delayed or late presentation of adverse events following exposure to gene editors due to the potential permanence of edits to DNA or due to other components of product candidates used to carry the genetic material***. Further, because gene editing makes a permanent change, the therapy cannot be withdrawn, even after a side effect is observed.

We intend to use LNPs to deliver our gene editors to the liver. LNPs have recently been used to deliver mRNA in humans, including the COVID-19 vaccines developed by Pfizer Inc., or Pfizer, and BioNTech SE and by Moderna, Inc., and LNPs are being used to deliver mRNA for therapeutic use in clinical trials. LNPs have the potential to induce liver injury and/or initiate a systemic inflammatory response, either of which could potentially be fatal. ***While we aim to continue to optimize our LNPs, there can be no assurance that our LNPs will not have undesired effects. Our LNPs could contribute, in whole or in part, to one or more of the following: liver injury, immune reactions, infusion reactions, complement reactions, opsonization reactions, antibody reactions including IgA, IgM, IgE or IgG or some combination thereof, or reactions to the polyethylene glycol, or PEG, from some lipids or PEG otherwise associated with the LNP***. Certain aspects of our investigational medicines may induce immune reactions from either the mRNA or the lipid as well as adverse reactions within liver pathways or degradation of the mRNA or the LNP, any of which could lead to significant adverse events in one or more of our ongoing or future clinical trials. Some of these types of adverse effects have been observed for other LNPs. There may be uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in ongoing or future clinical trials and would result in significant delays in our programs.

Our GalNAc-LNPs are a novel delivery mechanism for delivery of gene editors to the liver and have not yet been studied in humans.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If in the future we are unable to demonstrate that any of the above adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we are able to develop for any or all targeted indications. They could also revoke a marketing authorization if a serious safety concern is identified in any post-marketing follow up studies. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate we may develop, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify

and develop product candidates, and may harm our business, financial condition, result of operations, and prospects significantly.

(Emphasis added).

21. The statement in ¶ 20 was materially false and misleading because it omitted that a single adverse event in the Heart-1 Trial, even an asymptomatic one where abnormalities were resolved within a few days, could cause the Company to halt enrollment in the Heart-1 trial.

22. On November 7, 2022, the Company filed with the SEC its quarterly report on Form 10-Q for the period ending September 30, 2022 (the "3Q22 Report"). Attached to the 3Q22 Report were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Kathiresan and Dorval attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting, and the disclosure of all fraud.

23. The 3Q22 Report contained the following risk disclosure:

If any of the product candidates we may develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidates, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

We only recently initiated our heart-1 clinical trial for VERVE-101. Moreover, there have been only a limited number of clinical trials involving the use of gene editing technologies and none involving base editing technology similar to our technology. Furthermore, there has not been any gene editing product candidate that has received regulatory approval for use in humans. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that gene editing technologies will not cause undesirable side effects, as improper editing of a patient's DNA could lead to lymphoma, leukemia or other cancers or other aberrantly functioning cells.

A significant risk in any gene editing product candidate is that "off-target" edits may occur, which could cause serious adverse events, undesirable side effects or unexpected characteristics. We cannot be certain that off-target editing will not occur in any of our ongoing or future clinical studies, and the lack of observed

side effects in preclinical studies does not guarantee that such side effects will not occur in human clinical studies. There is also the potential risk of delayed or late presentation of adverse events following exposure to gene editors due to the potential permanence of edits to DNA or due to other components of product candidates used to carry the genetic material. Further, because gene editing makes a permanent change, the therapy cannot be withdrawn, even after a side effect is observed.

We are using LNPs to deliver our gene editors to the liver. LNPs have recently been used to deliver mRNA in humans, including the COVID-19 vaccines developed by Pfizer Inc., or Pfizer, and BioNTech SE and by Moderna, Inc., and LNPs are being used to deliver mRNA for therapeutic use in clinical trials. LNPs have the potential to induce liver injury and/or initiate a systemic inflammatory response, either of which could potentially be fatal. While we aim to continue to optimize our LNPs, there can be no assurance that our LNPs will not have undesired effects. Our LNPs could contribute, in whole or in part, to one or more of the following: liver injury, immune reactions, infusion reactions, complement reactions, opsonization reactions, antibody reactions including IgA, IgM, IgE or IgG or some combination thereof, or reactions to the polyethylene glycol, or PEG, from some lipids or PEG otherwise associated with the LNP. ***Certain aspects of our investigational medicines may induce immune reactions from either the mRNA or the lipid as well as adverse reactions within liver pathways or degradation of the mRNA or the LNP, any of which could lead to significant adverse events in one or more of our ongoing or future clinical trials***. Some of these types of adverse effects have been observed for other LNPs. There may be uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in ongoing or future clinical trials and would result in significant delays in our programs.

Our GalNAc-LNPs, which we plan to use in VERVE-201, are a novel delivery mechanism for delivery of gene editors to the liver and have not yet been studied in humans.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If in the future we are unable to demonstrate that any of the above adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we are able to develop for any or all targeted indications. They could also revoke a marketing authorization if a serious

> safety concern is identified in any post-marketing follow up studies. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate we may develop, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations, and prospects significantly.
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> (Emphasis added).

24. The statement in ¶ 23 was materially false and misleading because it omitted that a single adverse event in the Heart-1 Trial, even an asymptomatic one where abnormalities were resolved within a few days, could cause the Company to halt enrollment in the Heart-1 trial.

25. On March 2, 2023, the Company filed with the SEC its annual report on Form 10-K for the period ending December 31, 2022 (the "2022 Annual Report"). Attached to the 2022 Annual Report were certifications pursuant to SOX signed by Defendants Kathiresan and Dorval attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting, and the disclosure of all fraud.

26. The 2022 Annual Report contained the following risk disclosure:

> ***If any of the product candidates we may develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidates, limit the commercial potential or result in significant negative consequences following any potential marketing approval.***
>
> ***We only recently initiated our heart-1 clinical trial for VERVE-101***. Moreover, there have been only a limited number of clinical trials involving the use of gene editing technologies and there are no completed clinical trials involving base editing technology similar to the gene editing technology we are using in VERVE-101. Furthermore, there has not been any gene editing product candidate that has received regulatory approval for use in humans. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that gene editing technologies will not cause

undesirable side effects, as improper editing of a patient's DNA could lead to lymphoma, leukemia or other cancers or other aberrantly functioning cells.

A significant risk in any gene editing product candidate is that "off-target" edits may occur, which could cause serious adverse events, undesirable side effects or unexpected characteristics. We cannot be certain that off-target editing will not occur in any of our ongoing or future clinical studies, and the lack of observed side effects in preclinical studies does not guarantee that such side effects will not occur in human clinical studies. There is also the potential risk of delayed or late presentation of adverse events following exposure to gene editors due to the potential permanence of edits to DNA or due to other components of product candidates used to carry the genetic material. Further, because gene editing makes a permanent change, the therapy cannot be withdrawn, even after a side effect is observed.

We are using LNPs to deliver our gene editors to the liver. LNPs have recently been used to deliver mRNA in humans, including the COVID-19 vaccines developed by Pfizer Inc., or Pfizer, and BioNTech SE and by Moderna, Inc., and LNPs are being used to deliver mRNA for therapeutic use in clinical trials. LNPs have the potential to induce liver injury and/or initiate a systemic inflammatory response, either of which could potentially be fatal. While we aim to continue to optimize our LNPs, there can be no assurance that our LNPs will not have undesired effects. Our LNPs could contribute, in whole or in part, to one or more of the following: liver injury, immune reactions, infusion reactions, complement reactions, opsonization reactions, antibody reactions including IgA, IgM, IgE or IgG or some combination thereof, or reactions to the polyethylene glycol, or PEG, from some lipids or PEG otherwise associated with the LNP. ***Certain aspects of our investigational medicines may induce immune reactions from either the mRNA or the lipid as well as adverse reactions within liver pathways or degradation of the mRNA or the LNP, any of which could lead to significant adverse events in one or more of our ongoing or future clinical trials***. Some of these types of adverse effects have been observed for other LNPs. There may be uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in ongoing or future clinical trials and would result in significant delays in our programs.

Our GalNAc-LNPs, which we plan to use in VERVE-201, are a novel delivery mechanism for delivery of gene editors to the liver and have not yet been studied in humans.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of

which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If in the future we are unable to demonstrate that any of the above adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we are able to develop for any or all targeted indications. They could also revoke a marketing authorization if a serious safety concern is identified in any post-marketing follow up studies. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate we may develop, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations, and prospects significantly.

(Emphasis added).

27. The statement in ¶ 26 was materially false and misleading because it omitted that a single adverse event in the Heart-1 Trial, even an asymptomatic one where abnormalities were resolved within a few days, could cause the Company to halt enrollment in the Heart-1 trial.

28. On November 12, 2023, Verve Therapeutics issued a press release entitled "Verve Therapeutics Announces Interim Data for VERVE-101 Demonstrating First Human Proof-of-Concept for In Vivo Base Editing with Dose-Dependent Reductions in LDL-C and Blood PCSK9 Protein in Patients with Heterozygous Familial Hypercholesterolemia." It stated the following, in pertinent part:

heart-1 Safety and Tolerability

The safety profile observed in the heart-1 trial supports continued development of VERVE-101, and the adverse events have been consistent with the severe, advanced ASCVD patient population enrolled.

VERVE-101 was well-tolerated in the two lower dose cohorts, with no treatment-related adverse events observed. In the two higher dose cohorts, treatment-related adverse events were observed, including transient, mild or moderate infusion

reactions and transient, asymptomatic increases in liver transaminases with mean bilirubin levels below the upper limit of normal. All infusion reactions and liver transaminase elevations resolved without clinical sequelae.

Two patients experienced serious adverse events, which were each cardiovascular events in the context of severe underlying ASCVD. One patient dosed in the 0.3 mg/kg cohort had a fatal cardiac arrest approximately five weeks after treatment due to underlying ischemic heart disease, which was determined by the investigator and independent data and safety monitoring board (DSMB) to be not related to treatment.

One patient dosed in the 0.45 mg/kg cohort experienced a myocardial infarction (Grade 3)[commonly known as a "heart attack"] the day after treatment. The event was considered potentially related to treatment due to the proximity to dosing. The event occurred in the setting of unstable chest pain symptoms prior to dosing that were unreported to investigators. Coronary angiography taken after the event showed critical left main equivalent coronary artery disease. The same patient also experienced non-sustained ventricular tachycardia (Grade 2) more than four weeks after dosing, which was determined to be unrelated to the treatment.

All safety events were reviewed with the independent DSMB ***who recommended continuation of trial enrollment with no protocol changes required***.

(Emphasis added).

29. The statement in ¶ 28 was materially false and misleading because it omitted that if even a single patient who had received a dose in the 0.45 mg/kg cohort experienced an "adverse event" that was found to be caused by VERVE-101, that that could lead to enrollment in the trial being halted.

30. On February 27, 2024, Verve Therapeutics issued a press release entitled "Verve Therapeutics Provides Pipeline Progress and Reports Fourth Quarter and Full Year 2023 Financial Results." It stated the following:

In November 2023, Verve presented interim data from the ongoing Heart-1 trial of VERVE-101 in a late-breaking science presentation at the American Heart Association (AHA) Scientific Sessions highlighting first human proof-of-concept data for *in vivo* base editing. Treatment with VERVE-101 led to dose-dependent reductions of disease-causing LDL-C in patients living with HeFH. Time-averaged LDL-C reductions of up to 55% and blood PCSK9 protein reductions of

> up to 84% were observed after a single infusion of VERVE-101 at potentially therapeutic doses. These results suggest successful editing at the intended genomic target. Dose-dependent LDL-C reductions, a validated measure of clinical efficacy for this patient population, were observed one month after treatment at the 0.45 and 0.6 mg/kg dose cohorts, and the reduction was sustained out to six months for the single patient in the highest dose cohort. ***A review of the safety data of VERVE-101 by an independent data and safety monitoring board supported the continued development of VERVE-101 in the Heart-101 trial, and the adverse events were consistent with expectations in the severe, advanced ASCVD patient population enrolled in the trial***.
>
> ***The Heart-1 trial is enrolling patients in the 0.45 and 0.6 mg/kg cohorts of the single ascending dose portion***, and Verve expects to complete enrollment of the Heart-1 clinical trial in 2024. Verve plans to provide a data update from the Heart-1 clinical trial in the second half of 2024.
>
> (Emphasis added).

31. The statement in ¶ 30 was materially false and misleading because it emphasized successful interim data, including as it related to safety and adverse events, without warning that the trial could be stopped if there was even a single adverse event in the 0.45 cohort.

32. On February 27, 2024, the Company filed with the SEC its annual report on Form 10-K for the period ending December 31, 2023 (the "2023 Annual Report"). Attached to the 2023 Annual Report were certifications pursuant to SOX signed by Defendants Kathiresan and Dorval attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting, and the disclosure of all fraud.

33. The 2023 Annual Report contained the following statement about the Company's lipid nanoparticals "LNP" delivery system:

> To achieve our goal of transforming the treatment of ASCVD [atherosclerotic cardiovascular disease], we are developing a pipeline of single-course gene editing treatments that leverage multiple breakthroughs of 21st century biomedicine—human genetic analysis, gene editing, mRNA-based therapies and LNP-mediated delivery. We believe our approach benefits from the following potential advantages:

* * *

- *Designed and optimized approach to reduce or avoid safety risks*: To optimize the safety profile of our gene editing programs, we utilize non-viral LNP delivery of a gene editor to the liver, including our proprietary GalNAc-LNP delivery technology, due to the potentially superior safety profile of LNPs compared with available viral delivery approaches, specifically the minimization of genome integration risk and immunogenicity. In addition, we use base editing for our lead programs, which enables highly precise editing at the single base pair level of the specified gene target. Gene editing has the potential to avoid random gene insertions that occur with viral vector gene therapy DNA construct. Base editing may also minimize the risk of unwanted DNA modifications associated with double-stranded breaks from nuclease-based editing approaches. Finally, we extensively screen pairs of gene editors with gRNA in human cells, mice and non-human primates, or NHPs, to maximize the likelihood that our gene editing programs will have limited or no off-target editing effects.

34. The statement in ¶ 33 was materially false and misleading because it overstated the potential of LNP delivery technology and omitted that it might in fact be inferior to available viral delivery approaches.

35. The 2023 Annual Report contained the following statement about the Heart-1 clinical trial:

> The Heart-1 clinical trial is designed to enroll patients with HeFH who have established ASCVD and uncontrolled hypercholesterolemia and evaluate the safety and tolerability of VERVE-101 administration, with additional analyses for pharmacokinetics and changes in blood PCSK9 protein and LDL-C. The trial includes three parts—(A) a single ascending dose portion, followed by (B) an expansion single-dose cohort, in which additional participants will receive the selected potentially therapeutic dose and (C) an optional second-dose cohort, in which eligible participants in lower dose cohorts in Part A have the option to receive a second treatment at the selected potentially therapeutic dose. During our interactions with regulators in New Zealand and the United Kingdom as well as the FDA, country-specific protocols have been developed to account for various modifications to eligibility, design, and conduct in each country.
>
> In November 2023, we presented interim data from our Heart-1 clinical trial. Initial safety data reported were from all ten patients enrolled as of a data cut-off date of October 16, 2023. One patient who received a 0.45 mg/kg dose had not reached day 28 as of the data cut-off date and was not included in the efficacy analysis.

Following a single infusion of VERVE-101, dose-dependent reductions in pharmacodynamic measures of blood PCSK9 protein levels and LDL-C, a validated measure of clinical efficacy for this patient population, were observed one month after treatment. In the interim dataset, six patients were treated at sub-therapeutic doses (0.1 mg/kg and 0.3 mg/kg) and three patients were treated at potentially therapeutic doses (0.45 mg/kg and 0.6 mg/kg). The two patients treated with 0.45 mg/kg of VERVE-101 had a time-averaged blood PCSK9 protein reduction of 59% and 84% and a time-averaged LDL-C reduction of 39% and 48%. The patient treated with 0.6 mg/kg of VERVE-101 had a time-averaged blood PCSK9 protein reduction of 47% and a time-averaged LDL-C reduction of 55%. In this single participant in the highest dose cohort, the 55% reduction in LDL-C was durable out to 180 days, with follow-up ongoing. Blood PCSK9 protein and LDL-C reductions were quantified as percent change from baseline using the time-weighted average from day 28 through last available follow-up.

The initial safety profile observed in the Heart-1 clinical trial supported continued development of VERVE-101, and the adverse events were consistent with the severe, advanced ASCVD patient population enrolled. VERVE-101 was well-tolerated in the two lower dose cohorts, with no treatment-related adverse events observed. ***In the two higher dose cohorts, treatment-related adverse events were observed, including transient, mild or moderate infusion reactions and transient, asymptomatic increases in liver transaminases with mean bilirubin levels below the upper limit of normal***. The increase in liver transaminases in the patient dosed in the 0.6 mg/kg cohort was classified as a Grade 3 laboratory abnormality. All infusion reactions and liver transaminase elevations resolved without clinical sequelae. Two patients experienced serious adverse events, which were each cardiovascular events in the context of severe underlying ASCVD. One patient dosed in the 0.3 mg/kg cohort had a fatal cardiac arrest approximately five weeks after treatment due to underlying ischemic heart disease, which was determined by the investigator and independent data and safety monitoring board, or the DSMB, to be unrelated to treatment. One patient dosed in the 0.45 mg/kg cohort experienced a myocardial infarction (Grade 3) the day after treatment. The event was considered potentially related to treatment due to the proximity to dosing. The event occurred in the setting of unstable chest pain symptoms prior to dosing that were unreported to investigators. Coronary angiography taken after the event showed critical left main equivalent coronary artery disease. The same patient also experienced non-sustained ventricular tachycardia (Grade 2) more than four weeks after dosing, which was determined to be unrelated to treatment. All safety events were reviewed with the independent DSMB who recommended continuation of trial enrollment with no protocol changes required.

Enrollment is ongoing in the 0.45 mg/kg and 0.6 mg/kg cohorts of the single ascending dose portion, and we expect to complete enrollment of the Heart-1 clinical trial in 2024. With the FDA's clearance of our IND for VERVE-101, we

are working to activate U.S. trial sites and to dose the first patient in the United States for the Heart-1 clinical trial. We expect to provide a data update from the Heart-1 clinical trial in the second half of 2024.

(Emphasis added).

36. The statement in ¶ 35 was materially false and misleading because omitted that an adverse event, even if asymptomatic and quickly resolved, could cause the Company to stop enrollment in the Heart-1 clinical trial.

37. The 2023 Annual Report contained the following risk disclosure:

If any of the product candidates we develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects or unexpected characteristics, such adverse events, side effects or characteristics could delay or prevent regulatory approval of the product candidates, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

We initiated our Heart-1 clinical trial for VERVE-101 in July 2022 and have not yet completed a clinical trial. Moreover, there have been only a limited number of clinical trials involving the use of gene editing technologies and there are no completed clinical trials involving base editing technology similar to the gene editing technology we are using in VERVE-101. Furthermore, there has not been any gene editing product candidate that has received regulatory approval for use in humans. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. There can be no assurance that gene editing technologies will not cause undesirable side effects, as improper editing of a patient's DNA could lead to lymphoma, leukemia or other cancers or other aberrantly functioning cells.

A significant risk in any gene editing product candidate is that "off-target" edits may occur, which could cause serious adverse events, undesirable side effects or unexpected characteristics. We cannot be certain that off-target editing will not occur in any of our ongoing or future clinical trials, and the lack of observed side effects in preclinical studies does not guarantee that such side effects will not occur in human clinical trials. There is also the potential risk of delayed or late presentation of adverse events following exposure to gene editors due to the potential permanence of edits to DNA or due to other components of product candidates used to carry the genetic material. Further, because gene editing makes a permanent change, the therapy cannot be withdrawn, even after a side effect is observed.

We are using LNPs to deliver our gene editors to the liver. LNPs have recently been used to deliver mRNA in humans, including the COVID-19 vaccines developed by Pfizer Inc., or Pfizer, and BioNTech SE and by Moderna, Inc., and LNPs are being used to deliver mRNA for therapeutic use in clinical trials. LNPs have the potential to induce liver injury and/or initiate a systemic inflammatory response, either of which could potentially be fatal. While we aim to continue to optimize our LNPs, there can be no assurance that our LNPs will not have undesired effects. Our LNPs could contribute, in whole or in part, to one or more of the following: liver injury, immune reactions, infusion reactions, complement reactions, opsonization reactions, antibody reactions including IgA, IgM, IgE or IgG or some combination thereof, or reactions to the polyethylene glycol, or PEG, from some lipids or PEG otherwise associated with the LNP. Certain aspects of our investigational medicines may induce immune reactions from either the mRNA or the lipid as well as adverse reactions within liver pathways or degradation of the mRNA or the LNP, any of which could lead to significant adverse events in one or more of our ongoing or future clinical trials. Some of these types of adverse effects have been observed for other LNPs. There may be uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in ongoing or future clinical trials and would result in significant delays in our programs.

Our proprietary GalNAc-LNPs, which we are utilizing in VERVE-102 and VERVE-201, are a novel delivery mechanism for delivery of gene editors to the liver and have not yet been studied in humans.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

If in the future we are unable to demonstrate that any of the above adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we are able to develop for any or all targeted indications. They could also revoke a marketing authorization if a serious safety concern is identified in any post-marketing follow up studies. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate we may develop, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify

> and develop product candidates, and may harm our business, financial condition, result of operations, and prospects significantly.
>
> (Emphasis added).

38. The statement in ¶ 37 was materially false and misleading because it omitted that a single adverse event in the Heart-1 Trial, even an asymptomatic one where abnormalities were resolved within a few days, could cause the Company to halt enrollment in the Heart-1 trial.

39. The statements contained in ¶¶ 20, 23, 26, 28, 30, 33, 35, and 37 were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) Defendants did not fully disclose the circumstances under which the Heart-1 trial would be halted; (2) Defendants overstated the potential benefits of its proprietary LNP delivery system (3) as a result, Defendants' statements about its business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

THE TRUTH BEGINS TO EMERGE

40. On April 2, 2024, before the market opened, Verve Therapeutics issued a press release entitled "Verve Therapeutics Announces Updates on its PCSK9 Program." It disclosed that the Heart-1 clinical trial would be halted due to an adverse event in an individual who had been dosed at 0.45 mg/kg of VERVE-101, and that the LNP delivery system was to blame. It stated the following:

> Verve Therapeutics, a clinical-stage biotechnology company pioneering a new approach to the care of cardiovascular disease with single-course gene editing medicines, today announced updates from the Heart-1 phase 1b clinical trial of VERVE-101 and clearance of its Clinical Trial Applications (CTAs) by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) and Health

Canada for VERVE-102, with the Heart-2 Phase 1b clinical trial expected to initiate in the second quarter of this year.

VERVE-101 is being evaluated in the Heart-1 Phase 1b clinical trial with trial endpoints of safety and tolerability as well as changes in blood PCSK9 protein and low-density lipoprotein cholesterol (LDL-C) levels in patients living with heterozygous familial hypercholesterolemia (HeFH), established atherosclerotic cardiovascular disease (ASCVD), and uncontrolled hypercholesterolemia. ***Six participants have been dosed at 0.45 mg/kg of VERVE-101, with a total of 13 participants dosed in the study. For the first five participants in the 0.45 mg/kg cohort with follow-up to at least 28 days, VERVE-101 demonstrated time-averaged LDL-C reductions ranging from 21% to 73%,*** and averaging 46% (as of a data cut-off date of March 18, 2024). In the two patients with the longest follow-up in the 0.45 mg/kg or 0.6 mg/kg cohorts, LDL-C lowering has been durable out to 270 days, with follow-up ongoing.

However, the sixth participant treated in the 0.45 mg/kg cohort experienced a Grade 3 drug induced transient increase in serum alanine aminotransferase (ALT) as well as a serious adverse event of Grade 3 drug-induced thrombocytopenia within the first four days after dosing. The participant did not experience any bleeding or other symptoms related to the laboratory abnormalities, and the abnormalities resolved fully within a few days.

In light of such observed laboratory abnormalities associated with VERVE-101, Verve, in consultation with the study's independent data and safety monitoring board (DSMB), has decided to pause enrollment in the Heart-1 clinical trial. Verve is conducting an investigation into the laboratory abnormalities and based on those results, expects to work with regulatory authorities to define a path forward for VERVE-101. These safety events were reported to the U.S. Food and Drug Administration (FDA), MHRA, and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). The VERVE-101 Investigational New Drug Application (IND) and other CTAs remain active.

Verve is now prioritizing the development of VERVE-102 and the initiation of the Heart-2 clinical trial. …

"The Heart-1 clinical trial continues to support proof-of-concept for *in vivo* base editing of the *PCSK9* gene in the liver, with a meaningful and durable lowering of LDL-C," said Sekar Kathiresan, M.D., co-founder and chief executive officer of Verve. "***However, at potentially therapeutic dose levels of VERVE-101, we have observed certain asymptomatic laboratory abnormalities, which we believe are attributable to the LNP delivery system***. The safety of patients in our clinical trials is of the utmost importance. We plan to further investigate the laboratory abnormalities observed in the Heart-1 clinical trial in order to inform the next steps for VERVE-101. At this time, we are prioritizing the initiation of the Heart-2 clinical trial of VERVE-102 due to its proximity to the clinic ***and its use of a***

> ***different LNP that incorporates an ionizable lipid which has been well-tolerated in third-party clinical trials***. We are grateful to our study participants and to our investigators, who share our belief in the promise of single-course gene editing medicines for the treatment of cardiovascular disease. We look forward to initiating the Heart-2 clinical trial in the second quarter of this year."

(Emphasis added).

41. On this news, the price of Verve Therapeutics stock fell by $4.47, or 34.9%, to close at $8.32 on April 2, 2024.

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

PLAINTIFF'S 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 other than defendants who acquired Verve Therapeutics securities publicly traded on the NASDAQ during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Verve Therapeutics, members of the Individual Defendants' 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, Verve Therapeutics securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

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. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

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:

- whether the Exchange Act was violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and financial condition of Verve Therapeutics;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Defendants caused Verve Therapeutics to issue false and misleading filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false filings;
- whether the prices of Verve Therapeutics securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is 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 make 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.

49. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Verve Therapeutics shares met the requirements for listing, and were listed and actively traded on NASDAQ, an efficient market;
- As a public issuer, Verve Therapeutics filed periodic public reports;
- Verve Therapeutics regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- Verve Therapeutics' securities were liquid and traded with moderate to heavy volume during the Class Period; and
- Verve Therapeutics was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

50. Based on the foregoing, the market for Verve Therapeutics securities promptly digested current information regarding Verve Therapeutics from all publicly available sources and reflected such information in the prices of the shares, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

51. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

COUNT I
For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder
Against All Defendants

52. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

53. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

54. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

55. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;

- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Verve Therapeutics securities during the Class Period.

56. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of Verve Therapeutics were materially false and 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 securities laws. These defendants by virtue of their receipt of information reflecting the true facts of Verve Therapeutics, their control over, and/or receipt and/or modification of Verve Therapeutics' allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning Verve Therapeutics, participated in the fraudulent scheme alleged herein.

57. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Verve Therapeutics personnel to members of the investing public, including Plaintiff and the Class.

58. As a result of the foregoing, the market price of Verve Therapeutics securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of Verve Therapeutics securities during the Class Period in purchasing Verve Therapeutics securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

59. Had Plaintiff and the other members of the Class been aware that the market price of Verve Therapeutics securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased Verve Therapeutics securities at the artificially inflated prices that they did, or at all.

60. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

61. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of Verve Therapeutics securities during the Class Period.

COUNT II
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

62. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

63. During the Class Period, the Individual Defendants participated in the operation and management of Verve Therapeutics, and conducted and participated, directly and indirectly,

in the conduct of Verve Therapeutics' business affairs. Because of their senior positions, they knew the adverse non-public information about the Company's business practices.

64. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Verve Therapeutics' financial condition and results of operations, and to correct promptly any public statements issued by Verve Therapeutics which had become materially false or misleading.

65. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Verve Therapeutics disseminated in the marketplace during the Class Period concerning Verve Therapeutics' results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Verve Therapeutics to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Verve Therapeutics within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Verve Therapeutics securities.

66. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Verve Therapeutics.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of himself and the Class, prays for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and designating plaintiff's counsel as Lead Counsel;

(b) awarding damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, together with interest thereon;

awarding plaintiff and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding plaintiff and other members of the Class such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: