UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

_____, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. HOMOLOGY MEDICINES, INC., ARTHUR O. TZIANABOS, W. BRADFORD SMITH, and ALBERT SEYMOUR, Defendants.	Case No. CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, 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, *inter*

alia, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Homology Medicines, Inc. ("Homology" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Homology securities between June 10, 2019 and February 18, 2022, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Homology, a genetic medicines company, focuses on transforming the lives of patients suffering from rare genetic diseases. The Company's lead product candidate is HMI-102, which is in Phase I/II pheNIX clinical trial, a gene therapy for the treatment of phenylketonuria (PKU) in adults (the "HMI-102 Trial").

3. On June 10, 2019, Homology issued a press release announcing that it had commenced enrollment of the HMI-102 Trial.

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company had overstated HMI-102's efficacy and risk mitigation; (ii) accordingly, it was unlikely that the Company would be able to commercialize HMI-102 in its present form; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On July 21, 2020, Mariner Research ("Mariner") published a report questioning statements by Homology and its officers about the efficacy of HMI-102, the Company's lead product candidate for treatment of phenylketonuria. Mariner focused on Homology's HMI-102 dose escalation pheNIX trial, concluding that the Company concealed data showing HMI-102's lack of efficacy and indicating that the program was unlikely to proceed to commercialization. Among other evidence, Mariner cited an email from Homology's Chief Communications Officer appearing to indicate the Company's awareness that a HMI-102 high dose patient had adverted to the adverse efficacy issue in a social media post during April 2020.

6. On this news, Homology's stock price fell $1.71 per share, or 10.38%, over the following three trading days, closing at $14.77 per share on July 24, 2020.

7. Then, on February 18, 2022, Homology issued a press release disclosing that "the U.S. Food and Drug Administration (FDA) has notified the company that its pheNIX gene therapy trial of HMI-102 in adults with phenylketonuria (PKU) has been placed on clinical hold due to the need to modify risk mitigation measures in the study in response to observations of elevated liver function tests" and that "[t]he Company expects to receive an official clinical hold letter within 30 days."

8. On this news, Homology's stock price fell $1.26 per share, or 32.64%, to close at $2.60 per share on February 22, 2022.

9. 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

10. 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).

11. 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.

12. Venue is proper in this judicial district pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as the alleged misstatements entered and the

subsequent damages took place in this judicial district. Further, Plaintiff is a resident of Los Angeles County.

13. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

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

15. Defendant Homology is a Delaware corporation with principal executive offices located at One Patriots Park, Bedford MA 01730. The Company's securities trade in an efficient market in the U.S. on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "FIXX."

16. Defendant Arthur O. Tzianabos ("Tzianabos") has served as Homology's President, Chief Executive Officer, and Director at all relevant times.

17. Defendant W. Bradford Smith ("Smith") has served as Homology's Chief Financial Officer and Treasurer at all relevant times.

18. Defendant Albert Seymour ("Seymour") has served as Homology's Chief Scientific Officer at all relevant times.

19. Defendants Tzianabos, Smith, and Seymour are sometimes referred to herein as the "Individual Defendants."

20. The Individual Defendants possessed the power and authority to control the contents of Homology's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Homology'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 Homology, 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

21. Homology, a genetic medicines company, focuses on transforming the lives of patients suffering from rare genetic diseases. The Company's lead product candidate is HMI-102, which is in Phase I/II pheNIX clinical trial, a gene therapy for the treatment of phenylketonuria (PKU) in adults.

Materially False and Misleading Statements Issued During the Class Period

22. The Class Period begins on June 10, 2019, when Homology issued a press release entitled, "Homology Medicines Initiates Phase 1/2 Study for HMI-102 Gene Therapy Candidate for Adults with PKU and Expects Initial Clinical Results by Year End 2019." The press release stated, in relevant part:

> Homology [. . .] announced today that it has commenced enrollment of the Phase 1/2 pheNIX trial for HMI-102, a one-time gene therapy development candidate for the treatment of adults with phenylketonuria (PKU). The pheNIX study is designed to evaluate the safety and efficacy of the investigational gene therapy in a randomized, concurrently-controlled, dose-escalation study. PKU is an inborn error of metabolism caused by a mutation in the PAH gene that results in a potentially toxic buildup of phenylalanine (Phe), an essential amino acid derived primarily from dietary protein.
>
> "Our early work with the clinical sites has enabled us to move expeditiously from receiving IND clearance to enrolling patients," said Arthur Tzianabos, Ph.D., President and Chief Executive Officer of Homology Medicines. "We now have both external and internal operational GMP capabilities utilizing our proprietary process development and commercial manufacturing platform that can supply HMI-102 for the pheNIX trial all the way through to commercial scale. Our early investment in manufacturing is a key strategic advantage for Homology that has allowed us to progress this program rapidly to the clinic."

23. On June 17, 2019, Homology issued a press release entitled, "Homology Medicines Presents Data Showing Single Dose HMI-102 Resulted in Long-Term Correction of PKU, Including Reduction of Phe and Increased Brain Neurotransmitters in Murine Model." The press release stated, in relevant part:

> "These findings are part of a larger body of preclinical data demonstrating the therapeutic potential and efficacy of HMI-102, which provided a strong

> foundation for the recent initiation of our Phase 1/2 pheNIX study, the first gene therapy candidate for PKU to enter clinical trials," said Albert Seymour, Ph.D., Chief Scientific Officer of Homology Medicines. "With initial results from the pheNIX trial expected later this year, we believe that a one-time, potentially curative treatment that addresses the underlying cause of PKU may offer patients a sustained reduction of Phe and freedom from a life-long, protein-restricted diet."

24. On August 8, 2019, Homology issued a press release announcing the Company's Q2 2019 financial results and recent highlights. The press release stated, in relevant part:

> "We have been pleased by the positive reception we are getting from additional clinical sites eager to participate in our trial, as well as from patients with PKU looking for a new solution," said Albert Seymour, Ph.D., Chief Scientific Officer of Homology. "As a company founded and focused on developing our science into potential cures for the benefit of patients, we continue to present our data at peer-reviewed meetings, as evidenced by the 11 presentations by Homology at scientific conferences during the second quarter alone."

25. On October 21, 2019, Homology issued a press release entitled, "Homology Medicines Presents Data from Investigational PKU and MLD Gene Therapy Programs that Demonstrate Preclinical Proof-of-Concept for Potential One-Time Therapies." The press release stated, in relevant part:

> Homology [. . .] announced today the presentation of preclinical data that support its investigational gene therapy programs for the treatment of metachromatic leukodystrophy (MLD) and phenylketonuria (PKU) at the American Society of Human Genetics (ASHG) 2019 Meeting. [. . .] In addition, preclinical data on gene therapy candidate HMI-102 showed that a single administration resulted in sustained Phe reduction and increased tyrosine and other important downstream biochemical metabolites in the PKU murine model.

> "The MLD presentation is part of a growing foundation of HMI-202 data to support a future IND filing, and the PKU preclinical data supported the initiation of our Phase 1/2 trial, which is ongoing and expected to report initial data by the end of this year," said Albert Seymour, Ph.D., Chief Scientific Officer of Homology Medicines. "Taken together, these presentations demonstrate the potential of our genetic medicines platform, investigational PKU and MLD gene therapies and our continued focus on advancing these treatments to help patients and their families."

26. On October 25, 2019, Homology issued a press release entitled, "Homology Medicines Presents Preclinical Data From Its Investigational PKU Gene Editing Program, Demonstrating Phenotypic Correction and Molecular Confirmation of Editing Precision." The press release stated, in relevant part:

> "The ability of AAVs to induce nuclease-free gene editing through homologous recombination has been established for decades, and here we presented data showing that our AAVHSCs induced in vivo targeted gene insertion into genomes using this natural DNA repair pathway in humanized and PKU murine models," stated Albert Seymour, Ph.D., Chief Scientific Officer of Homology Medicines. "Importantly, the in vivo gene insertion was characterized and confirmed at the DNA level, demonstrating the efficiency and precision of editing supporting our PKU gene editing program."

27. On November 12, 2019, Homology issued a press release announcing the Company's Q3 2019 financial results and recent highlights. The press release stated, in relevant part:

> "Our Phase 1/2 pheNIX gene therapy trial for adults with PKU is enrolling patients at multiple clinical sites, and we are on track to share initial clinical data from the first few patients by the end of the year." Dr. Tzianabos added, "Our human gene editing development candidate for pediatric patients with PKU is also progressing, with preclinical data presented that showed molecular confirmation of precise, selective and efficient in vivo editing that meets a therapeutic threshold in a disease model. For our MLD program, we

presented human ARSA protein levels confirming crossing of the blood-brain-barrier and blood-nerve-barrier in non-human primates after a single intravenous administration. Importantly, our internal manufacturing platform is established with a commercial process and scale featuring 500liter capacity and expanding, and it is now supplying the pheNIX clinical trial."

Third Quarter 2019 and Recent Accomplishments

- Continued to advance the Phase 1/2 pheNIX clinical trial with investigational HMI-102 gene therapy for adults with phenylketonuria (PKU) at multiple sites in the U.S.

28. On December 17, 2019, Homology issued a press release entitled, "Homology Medicines Announces Encouraging Initial Clinical Data from its pheNIX Gene Therapy Trial for PKU." The press release stated, in relevant part:

"We believe that the initial efficacy from Cohort 2 suggest HMI-102 is delivering the PAH gene that produces the functional PAH enzyme and restores the biochemical pathway that converts Phe to Tyr," stated Albert Seymour, Ph.D., Chief Scientific Officer of Homology Medicines. "We are pleased with the data with HMI-102, as this trial represents the first time one of our novel, human-derived AAVHSCs has been administered to patients, and provides initial evidence supporting our vector platform. The safety results observed and trial design allowed us to quickly execute on our plan to dose-escalate, and our wide safety margin provides potential for further dose-escalation."

***

"Over a year-and-a-half ago as a preclinical company, we made a commitment to report initial clinical data from the pheNIX trial by the end of 2019. Today, we provide more data than we promised, which I believe is a testament to our team's ability to execute as well as the strong interest from patients and physicians," stated Arthur Tzianabos, Ph.D., President and Chief Executive Officer of Homology Medicines.

29. On March 12, 2020, Homology issued a press release announcing the Company's Q4 and full year 2019 financial results and recent accomplishments. The press release stated, in relevant part:

> "In 2019, we delivered on our goals to launch the first ever PKU gene therapy trial and announce initial clinical data," said Arthur Tzianabos, Ph.D., President and Chief Executive Officer of Homology Medicines. "We reported encouraging safety and efficacy data from the dose-escalation portion of the trial, an important milestone for Homology and for the PKU community. We plan to provide an update on pheNIX when we choose the dose for the randomized, concurrently controlled part of the trial, which we anticipate will occur in mid-2020."
>
> ***
>
> **Fourth Quarter 2019 and Recent Accomplishments**
>
> - Shared initial encouraging clinical data from a single I.V. administration of investigational gene therapy HMI-102 in the pheNIX trial, the first gene therapy clinical trial in phenylketonuria (PKU). Keeping with guidance initially set in 2018, Homology released initial data from Cohort 1 (low-dose, n=2) and the first patient in Cohort 2 (mid-dose) at the end of 2019. As of the data cut-off date of December 2, 2019:
>   - Preliminary safety data from Cohorts 1 and 2 showed HMI-102 was well-tolerated.
>   - Efficacy data from the first patient in Cohort 2 indicated a dose-response effect with an observed reduction in phenylalanine (Phe) levels from baseline at Weeks 1 and 4, increase in tyrosine (Tyr), and reduction in the Phe to Tyr ratio, suggestive of increased enzymatic activity.

30. That same day, Homology filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2019 (the "2019 10-K"). The 2019 10-K stated, in relevant part:

We are currently in the dose-escalation portion of our Phase 1/2 pheNIX clinical trial with our first and lead product candidate, HMI-102, a gene therapy for the treatment of PKU. Once a dose is chosen, we will initiate the randomized, concurrently controlled Part B of the trial, which has the potential to be converted to a registrational trial. In December 2019, in accordance with a corporate goal that we had established in early 2018, we reported encouraging initial clinical data from the pheNIX trial from Cohort 1 (low dose, n=2) and Cohort 2 (mid-dose, n=1) based on the data cutoff date of December 2, 2019. Preliminary safety data from three subjects in Cohorts 1 and 2 showed HMI-102 was well-tolerated with no treatment-emergent adverse events, or TEAEs, or serious TEAEs. Efficacy data from the first patient in Cohort 2 suggested a dose-response effect with an observed reduction in Phe levels from baseline and a corresponding increase in Tyr which translated to an overall reduction in the Phe/Tyr ratio, suggestive of increased enzymatic activity. Phe levels have been evaluated as a primary registrable endpoint in previous PKU clinical trials, Tyr is a product of Phe metabolism and a precursor to neurotransmitters, and the Phe/Tyr ratio is a clinically relevant diagnostic measurement for PKU.

31. Further, in providing an overview of the Company's strategy, the 2019 10-K stated, in relevant part:

Our goal is to transform the lives of patients suffering from severe genetic diseases by using gene editing and gene therapy to cure the underlying cause of the disease. The critical components of our strategy to achieve this goal include:

***

- ***Advance our pipeline programs through clinical proof-of-concept and commercialization***. We are continuing to advance the Phase 1/2 pheNIX clinical trial with investigational HMI-102 gene therapy for adults with PKU at multiple sites in the U.S., and have reported encouraging initial clinical data in 2019. We believe that our approach of initially utilizing one of our AAVHSCs for gene therapy in adult PKU patients while, in parallel, advancing gene editing for pediatric PKU patients will maximize the efficiency of our pipeline development while providing potential solutions for the unique needs of each

> particular PKU patient population. Given the well-defined nature of PKU and the concentration of treatment centers, we intend to bring HMI-102, if approved, to patients through a small, targeted internal commercial organization.

32. Appended to the 2019 10-K as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Tzianabos and Smith attesting that "the information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

33. On March 16, 2020, Homology issued a press release entitled, "Homology Medicines Announces Peer-Reviewed Publication of HMI-102 Investigational Gene Therapy Demonstrating Restoration of Normal Metabolic Pathway in PKU Disease Model." The press release stated, in relevant part:

> "We developed a robust preclinical data package for our investigational HMI-102 gene therapy, which supported the initiation of our ongoing Phase 1/2 pheNIX clinical trial for adults with PKU," stated Albert Seymour, Ph.D., Chief Scientific Officer of Homology Medicines. "These published data demonstrated that a single dose of HMI-102 was able to restore the normal biochemical pathway in the established PKU model on normal protein diet. Initial data from the pheNIX trial suggests that the increased PAH enzymatic activity after administration of HMI-102 seen in the preclinical model was also observed in the clinical study."

34. On May 7, 2020, Homology issued a press release announcing the Company's Q1 2020 financial results and recent highlights. The press release stated, in relevant part:

First Quarter 2020 Financial Results and Recent Accomplishments

- Progressed the dose-escalation phase of the pheNIX clinical trial evaluating HMI-102 gene therapy for the treatment of adults with phenylketonuria (PKU).
    - Following encouraging initial clinical data from the trial announced in December 2019, additional PKU centers across the U.S. were initiated, bringing the total to eight trial sites.
    - Produced all the HMI-102 supply for the dose-escalation and expansion phases of the trial using Homology's commercial manufacturing process and began producing supply for a pivotal trial.
    - As previously announced, Homology plans to provide an update on the trial mid-year when a dose is selected for the expansion phase, which has the potential to be converted to a registrational trial.
- Highlighted preclinical data supporting the HMI-102 program in a peer-reviewed publication in Molecular Therapy: Methods & Clinical Development. The data demonstrated HMI-102 restored the normal biochemical pathway in the established PKU murine model on normal protein diet; initial data from the pheNIX trial announced in December 2019 suggest that the increased PAH enzymatic activity seen in the preclinical model was also observed in the clinical study following a single I.V. administration of HMI-102.

35. On August 10, 2020, Homology issued a press release announcing the Company's Q2 2020 financial results and providing a business update. The press release stated, in relevant part:

> "The pheNIX trial for adult patients with PKU is ongoing, and we continue to be encouraged by both the clinical data suggesting enzymatic activity and the safety profile of HMI-102. We have dosed patients in three cohorts in the dose-escalation phase of our trial, and this has taken more time than we anticipated due to the pandemic. We continue to assess the data, which includes a recently dosed patient, before we select the dose for our expansion phase. As a result, we are extending our timeline and still expect to provide an update once we have selected a dose for the expansion phase, which has the potential to be a registrational trial." "In the second quarter, we achieved a milestone in our nuclease-free gene editing program with the peer-reviewed

publication of the quantitative molecular methods that we used to show the precision and efficiency of our technology in preclinical studies of PKU.["]

***

Second Quarter 2020 and Recent Accomplishments

- Announced today an update to the Phase 1/2 pheNIX gene therapy clinical trial with HMI-102 for adults with phenylketonuria (PKU):
  - Since the Company's initial trial data reported in December 2019:
    - Homology continued to observe encouraging clinical data that suggest PAH enzymatic activity.
    - High-dose Cohort 3 patients were enrolled and dosed.
    - No treatment-related serious adverse events were reported.

36. On November 6, 2020, Homology issued a press release entitled, "Homology Medicines Announces Presentation of Positive Data from the Dose-Escalation Phase of the pheNIX Gene Therapy Trial for Adults with PKU." The press release stated, in relevant part:

> Homology [. . .] announced today the presentation of positive data from the dose-escalation portion of the Phase 1/2 gene therapy pheNIX clinical trial for adults with phenylketonuria (PKU). The results showed that product candidate HMI-102 was generally well-tolerated, and resulted in marked reductions in phenylalanine (Phe) and the Phe-to-tyrosine (Tyr) ratio (Phe/Tyr ratio) at two doses. Phe is a registrable endpoint in PKU, and the Phe/Tyr ratio is a clinically relevant diagnostic measurement for PKU. With these positive results, Homology is progressing to the randomized, concurrently controlled expansion phase of the trial, which has the potential to be converted to a registrational trial.

37. On November 9, 2020, Homology issued a press release announcing the Company's Q3 2020 financial results and recent highlights. The press release stated, in relevant part:

> "At the end of last week, we announced an important milestone for the PKU community and Homology with the positive data from the dose-escalation phase of our pheNIX PKU gene therapy clinical trial and plans to initiate the dose expansion phase by early 2021," stated Arthur Tzianabos, Ph.D., President and Chief Executive Officer of Homology Medicines.
>
> ***
>
> **Third Quarter 2020 Financial Results and Recent Accomplishments**
>
> - Announced today a $60 million equity investment from Pfizer Inc. with the purchase of 5,000,000 shares of common stock at a price of $12.00 per share, which is expected to close on or about November 10, 2020. The investment includes a right of first refusal on future transactions for the Company's phenylketonuria (PKU) product candidates: HMI-102 gene therapy candidate for adults with PKU and HMI-103 gene editing candidate for pediatric patients with PKU.
> - As announced on November 6, 2020, plans to progress the pheNIX gene therapy clinical trial for adults with PKU to the randomized, concurrently controlled dose expansion phase with two doses. The expansion phase has the potential to be converted to a registrational trial. In the dose-escalation phase:
>   - Development candidate HMI-102 was generally well-tolerated, and there were no treatment-related serious adverse events (SAEs).
>   - There were marked reductions in phenylalanine (Phe) and the Phe-to-tyrosine (Phe/Tyr) ratio in some patients in Cohorts 2 and 3 (mid- and high-dose cohorts).
>   - The mean percent change from baseline in Phe observed in patients in Cohorts 2 and 3 were significant, compared to low-dose Cohort 1*. These Phe reductions occurred while patients self-liberalized their diets.

38. On January 6, 2021, Homology issued a press release entitled, "Homology Medicines Announces Plans for Three Clinical Programs in 2021 Spanning Phenylketonuria (PKU) and Hunter Syndrome (MPS II)." The press release stated, in relevant part:

> "We ended 2020 with positive data from the dose-escalation phase of the world's first PKU gene therapy clinical trial, pheNIX, and validation of both our PKU gene therapy and gene editing programs with an equity investment from Pfizer, a leader in genetic medicines," stated Arthur Tzianabos, Ph.D., President and Chief Executive Officer of Homology Medicines. "The pheNIX clinical trial sites are recruiting for the Phase 2 dose expansion phase of the trial, and we anticipate clinical data by the end of the year. Continuing this momentum, we outlined today our plans to initiate two additional Phase 1/2 dose-escalation trials in 2021 with our gene therapy candidate for Hunter syndrome and our first gene editing candidate, which is for PKU."

39. On March 11, 2021, Homology issued a press release announcing the Company's Q4 and full year 2020 financial results and recent highlights. The press release stated, in relevant part:

> "In 2020, we remained focused on our mission, proactive in our preparations and successfully advanced our genetic medicines platform to meet our goals," stated Arthur Tzianabos, Ph.D., President and Chief Executive Officer of Homology Medicines. "We ended the year with positive data from the dose-escalation phase of our pheNIX PKU gene therapy clinical trial and a subsequent $60 million equity investment from Pfizer.["]

40. That same day, Homology filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K contained substantively similar

descriptions of the HMI-102 Trial and the Company's strategy as discussed, *supra*, in ¶¶ 30-31.

41. Appended to the 2020 10-K as exhibits were signed certifications pursuant to SOX by Defendants Tzianabos and Smith attesting that "the information contained in the [2020 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

42. On May 6, 2021, Homology issued a press release announcing the Company's Q1 2021 financial results and recent highlights. The press release stated, in relevant part:

> We are in the midst of a transformational time at Homology as we continue to mature and expand our genetic medicines platform and we are on track to report initial Phase 2 data from our pheNIX clinical trial and move two additional programs into the clinic this year," stated Arthur Tzianabos, Ph.D., President and Chief Executive Officer of Homology Medicines.
>
> ***
>
> **First Quarter 2021 and Recent Accomplishments**
>
> - Progressed the dose expansion phase of the Phase 1/2 pheNIX trial evaluating HMI-102 gene therapy for the treatment of adults with phenylketonuria (PKU), which has the potential to be converted to a registrational trial.
>   - Following encouraging clinical data from the dose-escalation phase of pheNIX, Homology continued to engage additional sites to enroll patients.

43. On August 12, 2021, Homology issued a press release announcing the Company's Q2 2021 financial results and recent highlights. The press release stated, in relevant part:

> "We continue to demonstrate the breadth and depth of our genetic medicines platform with three clinical programs expected this year, which span in vivo gene therapy and gene editing trials for rare liver and CNS-based diseases," stated Arthur Tzianabos, Ph.D., President and CEO of Homology Medicines. "With additional data from our gene therapy trial and the start of our first gene editing trial, both of which are focused on developing one-time treatments for PKU and are expected this year, we will be closer to our goal of helping adults and children living with this challenging inherited metabolic disorder. In addition, we remain on track to initiate our clinical trial for Hunter syndrome and we believe our single I.V. delivery may address both peripheral and CNS aspects of this disease."

44. On November 15, 2021, Homology issued a press release announcing the Company's Q3 2021 financial results and recent highlights. The press release stated, in relevant part:

> "We realized our goal to have three clinical programs underway this year by moving our gene editing candidate for PKU and gene therapy for Hunter syndrome into the clinic, both evaluating first-of-a-kind approaches for these diseases," stated Arthur Tzianabos, Ph.D., President and CEO of Homology Medicines. "We have always planned to develop two solutions for people living with PKU, first with our ongoing pheNIX gene therapy trial in adults and now with our gene editing trial, which is focused initially on adults and then pediatric patients over time. In addition, our gene therapy program for patients with Hunter syndrome plans to evaluate a much needed one-time therapy designed to address both peripheral organ and cognitive manifestations of this disease with an I.V. infusion."

***

- Provided an update on the ongoing pheNIX clinical trial, a Phase 2 dose expansion study evaluating HMI-102 gene therapy in adults with PKU. Specifically:
  - Both doses were generally well-tolerated and showed evidence of biological activity, including clinically meaningful reductions in phenylalanine (Phe) levels, increases in tyrosine (Tyr) and reductions in the Phe-to-Tyr ratio;
  - Added new clinical trial sites for a total of 13 with more expected shortly, and expanded Medical Affairs, Clinical Development and Operations teams to support ongoing trials; and
  - Plans to provide a detailed data update in mid-2022 when more patients are expected to be enrolled in the trial.

45. The statements referenced in ¶¶ 22-44 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company had overstated HMI-102's efficacy and risk mitigation; (ii) accordingly, it was unlikely that the Company would be able to commercialize HMI-102 in its present form; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

46. On July 21, 2020, Mariner Research published a report questioning statements by Homology and its officers about the efficacy of HMI-102, the Company's lead product candidate for treatment of phenylketonuria. Mariner focused on Homology's HMI-102 dose escalation pheNIX trial, concluding that the Company

concealed data showing HMI-102's lack of efficacy and indicating that the program was unlikely to proceed to commercialization. Among other evidence, Mariner cited an email from Homology's Chief Communications Officer appearing to indicate the Company's awareness that a HMI-102 high dose patient had adverted to the adverse efficacy issue in a social media post during April 2020.

47. On this news, Homology's stock price fell $1.71 per share, or 10.38%, over the following three trading days, closing at $14.77 per share on July 24, 2020.

The Truth Fully Emerges

48. Then, on February 18, 2022, Homology issued a press release providing an update on the HMI-102 Trial. Specifically, the press release stated, in relevant part:

> Homology Medicines, Inc. (Nasdaq: FIXX), a genetic medicines company, announced today that the U.S. Food and Drug Administration (FDA) has notified the company that its pheNIX gene therapy trial of HMI-102 in adults with phenylketonuria (PKU) has been placed on clinical hold due to the need to modify risk mitigation measures in the study in response to observations of elevated liver function tests. The Company expects to receive an official clinical hold letter within 30 days. Homology plans to provide an update pending further clarity from the FDA.
>
> "We look forward to working with the FDA to address the Agency's questions and feedback once we receive the letter," stated Arthur Tzianabos, Ph.D., President and Chief Executive Officer of Homology Medicines. "This hold on our PKU gene therapy trial is based on clinical observations in the pheNIX study and does not relate to CMC/manufacturing capabilities or Homology's other clinical programs. We plan to provide next steps once we have more information following our FDA interactions."

> Homology has two ongoing clinical programs, the pheEDIT gene editing trial of HMI-103 for PKU and the juMPStart gene therapy trial of HMI-203 for Hunter syndrome, with program updates expected by the end of this year.

49. On this news, Homology's stock price fell $1.26 per share, or 32.64%, to close at $2.60 per share on February 22, 2022.

50. 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.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

51. 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 those who purchased or otherwise acquired Homology securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, 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.

52. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Homology securities were actively traded on the 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 or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Homology or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

53. 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.

54. 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.

55. 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 federal securities laws were 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, operations and management of Homology;
- whether the Individual Defendants caused Homology to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Homology 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.

56. 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.

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

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Homology securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Homology securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

58. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

59. 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, 92 S. Ct. 2430 (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

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

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

61. This Count is asserted against Defendants and 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.

62. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon

Plaintiff and the other members of the Class; made various untrue statements of material facts and 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; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Homology securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Homology securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

63. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Homology securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Homology's finances and business prospects.

64. By virtue of their positions at Homology, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

65. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Homology, the Individual Defendants had knowledge of the details of Homology's internal affairs.

66. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Homology. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Homology's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and

misleading reports, releases and public statements, the market price of Homology securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Homology's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Homology securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

67. During the Class Period, Homology securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Homology securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Homology securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Homology securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

68. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

69. 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, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

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

70. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

71. During the Class Period, the Individual Defendants participated in the operation and management of Homology, and conducted and participated, directly and indirectly, in the conduct of Homology's business affairs. Because of their senior positions, they knew the adverse non-public information about Homology's misstatement of income and expenses and false financial statements.

72. 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

Homology's financial condition and results of operations, and to correct promptly any public statements issued by Homology which had become materially false or misleading.

73. 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 Homology disseminated in the marketplace during the Class Period concerning Homology's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Homology to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Homology 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 Homology securities.

74. Each of the Individual Defendants, therefore, acted as a controlling person of Homology. By reason of their senior management positions and/or being directors of Homology, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Homology to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Homology and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

75. 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 Homology.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.