UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

_____, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ORPHAZYME A/S, CHRISTOPHE BOURDON, KIM STRATTON, ANDERS VADSHOLT, THOMAS BLAETTLER, MOLLY PAINTER, GEORGES GEMAYEL, BO JESPER HANSEN, MARTIN BONDE, RÉMI DROLLER, STEN VERLAND, MARTIJN KLEIJWEGT, ANDERS HEDEGAARD, CATHERINE MOUKHEIBIR, and CARROLEE BARLOW, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

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 Orphazyme A/S ("Orphazyme" 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: (a) Orphazyme American depositary shares ("ADSs") pursuant and/or traceable to the Offering Documents (defined below) issued in connection with the Company's initial public offering conducted on or about September 29, 2020 (the "IPO" or "Offering"); and/or (b) Orphazyme securities between September 29, 2020 and June 18, 2021, both dates inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act").

2. Orphazyme is a biopharmaceutical company that develops therapies for the treatment of neurodegenerative orphan diseases. The Company conducts its U.S. operations through its wholly-owned subsidiary, Orphazyme US, Inc. ("Orphazyme US"), which is focused on U.S. regulatory review and preparing for the Company's first potential U.S. commercial launch, including legal, commercial, finance, advocacy relations, regulatory, and medical affairs functions.

3. Orphazyme's lead drug candidate is arimoclomol, which is in clinical development for four orphan diseases, including Niemann-Pick disease type C ("NPC"), Amyotrophic Lateral Sclerosis ("ALS"), and Inclusion Body Myositis ("IBM"). In August 2017, Orphazyme initiated a multicenter randomized 1:1, double blinded, placebo-controlled Phase 2/3 clinical trial for assessing efficacy and safety of arimoclomol citrate 400 mg three times per day in patients with IBM; in August 2018, Orphazyme initiated a 2:1 randomized, double blinded, placebo-controlled Phase 3 clinical trial assessing efficacy and safety of arimoclomol citrate 400 mg three times per

day in patients with ALS; and in September 2020, the U.S. Food and Drug Administration ("FDA") accepted Orphazyme's new drug application ("NDA") for arimoclomol for NPC.

4. On September 4, 2020, Orphazyme filed a registration statement on Form F-1 with the SEC in connection with the IPO, which, after several amendments, was declared effective by the SEC on September 28, 2020 (the "Registration Statement").

5. On September 29, 2020, pursuant to the Registration Statement, Orphazyme's ADSs began trading on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "ORPH." That same day, Orphazyme filed a prospectus on Form 424B4 with the SEC in connection with the IPO, which incorporated and formed part of the Registration Statement (collectively, the "Offering Documents").

6. Pursuant to the Offering Documents, Orphazyme conducted the IPO, issuing 3,966,146 of its ordinary shares to the U.S. public in the form of 3,966,146 ADSs at the Offering price of $11.00 per ADS, while concurrently offering 3,650,000 of its ordinary shares in Europe in a private placement to qualified investors, for total approximate proceeds of $77,913,174 to the Company before expenses and after applicable underwriting commissions.

7. The Offering Documents were negligently prepared and, as a result, contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading and were not prepared in accordance with the rules and regulations governing their preparation. Additionally, throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, the Offering Documents and Defendants made false and/or misleading statements and/or failed to disclose that: (i) arimoclomol was not as effective in treating IBM as Defendants had represented; (ii) arimoclomol was not as effective in treating ALS as Defendants

had represented; (iii) the arimoclomol NDA for NPC was incomplete and/or required additional evidence and data to support the benefit-risk assessment of that NDA; (iv) as a result of (iii), the FDA was unlikely to approve the arimoclomol NDA for NPC in its present form; (v) the Company's overall business prospects, as well as arimoclomol's commercial prospects, were significantly overstated; and (vi) as a result, the Offering Documents and Defendants' public statements throughout the Class Period were materially false and/or misleading and failed to state information required to be stated therein.

8. On March 29, 2021, Orphazyme issued a press release "announc[ing] its phase 2/3 trial evaluating arimoclomol for the treatment of [IBM] . . . did not meet its primary and secondary endpoints."

9. On this news, Orphazyme's ADS price fell $3.59 per ADS, or 28.97%, to close at $8.80 per ADS on March 29, 2021.

10. On May 7, 2021, Orphazyme issued a press release "announc[ing] topline data from pivotal trial of arimoclomol in [ALS.]" The press release disclosed that the Company's "pivotal trial . . . did not meet its primary and secondary endpoints to show benefit in people living with ALS."

11. On this news, Orphazyme's ADS price fell $2.81 per ADS, or 32.83%, to close at $5.75 per ADS on May 7, 2021.

12. Then, on June 18, 2021, Orphazyme issued a press release announcing receipt of a Complete Response Letter ("CRL") from the FDA following the agency's review of the NDA for arimoclomol for the treatment of NPC. The press release disclosed that the FDA had rejected the arimoclomol NDA for NPC "based on needing additional qualitative and quantitative evidence to further substantiate the validity and interpretation" of certain data and "that additional data are

needed to bolster confirmatory evidence beyond the single phase 2/3 clinical trial to support the benefit-risk assessment of the NDA."

13. On this news, Orphazyme's ADS price fell $7.23 per ADS, or 49.66%, to close at $7.33 per ADS on June 18, 2021.

14. Finally, on June 21, 2021, investor resource website *Seeking Alpha* reported that "Orphazyme [was] cut to sell at Guggenheim after [the Company's] regulatory snub" by the FDA, stating, among other things, that "[w]ith a $1.00 price target for the stock indicating a downside of ~86.4%, Guggenheim notes that there is 'little optionality left in the stock,' and adds 'it might make sense to wind down the company.'"

15. On this news, Orphazyme's ADS price fell $0.81 per ADS, or 11.05%, to close at $6.52 per ADS on June 21, 2021.

16. As of the time this Complaint was filed, the price of Orphazyme ADSs continues to trade below the $11.00 per ADS Offering price, damaging investors.

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

JURISDICTION AND VENUE

18. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o), and 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).

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

20. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Orphazyme's wholly-owned subsidiary, Orphazyme US, is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

21. 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

22. Plaintiff, as set forth in the attached Certification, purchased or otherwise acquired Orphazyme ADSs pursuant and/or traceable to the Offering Documents issued in connection with the IPO, and/or purchased or otherwise acquired Orphazyme securities at artificially inflated prices during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

23. Defendant Orphazyme is organized under the laws of the Kingdom of Denmark with principal executive offices located at Ole Maaløes Vej 3, DK-2200, Copenhagen N, Denmark. Additionally, the Company's wholly-owned subsidiary, Orphazyme US, is headquartered at 180 North LaSalle Street, Suite 3475, Chicago, Illinois 60601. The Company's ADSs trade in an efficient market on the NASDAQ under the ticker symbol "ORPH".

24. Defendant Christophe Bourdon ("Bourdon") has served as Orphazyme's Chief Executive Officer ("CEO") since April 1, 2021.

25. Defendant Kim Stratton ("Stratton") served as Orphazyme's CEO from before the start of the Class Period until December 10, 2020. Stratton signed or authorized the signing of the Offering Documents filed with the SEC.

26. Defendant Anders Vadsholt ("Vadsholt") has served as Orphazyme's Chief Financial Officer at all relevant times. Vadsholt also served as the Company's Interim CEO following Stratton's resignation, and until Bourdon's appointment, as CEO. Vadsholt signed or authorized the signing of the Offering Documents filed with the SEC.

27. Defendant Thomas Blaettler ("Blaettler"), M.D., has served as Orphazyme's Chief Medical Officer at all relevant times.

28. Defendant Molly Painter ("Painter") has served as Orphazyme's U.S. President since the Company established Orphazyme US in December 2020.

29. Defendants Bourdon, Stratton, Vadsholt, Blaettler, and Painter are sometimes referred to herein collectively as the "Exchange Act Individual Defendants."

30. The Exchange Act Individual Defendants possessed the power and authority to control the contents of Orphazyme's SEC filings, press releases, and other market communications. The Exchange Act Individual Defendants were provided with copies of Orphazyme'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 Orphazyme, and their access to material information available to them but not to the public, the Exchange Act 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 Exchange Act Individual Defendants are liable for the false statements and omissions pleaded herein.

31. Orphazyme and the Exchange Act Individual Defendants are sometimes referred to herein collectively as the "Exchange Act Defendants."

32. Defendant Georges Gemayel ("Gemayel"), Ph.D., has served as Orphazyme's Chairman of the Board of Directors at all relevant times. Gemayel signed or authorized the signing of the Offering Documents filed with the SEC.

33. Defendant Bo Jesper Hansen ("Hansen"), Ph.D., M.D., has served as Orphazyme's Deputy Chairman of the Board of Directors at all relevant times. Hansen signed or authorized the signing of the Offering Documents filed with the SEC.

34. Defendant Martin Bonde ("Bonde"), Ph.D., has served as a Director of Orphazyme at all relevant times. Bonde signed or authorized the signing of the Offering Documents filed with the SEC.

35. Defendant Rémi Droller ("Droller") served as a Director of Orphazyme at the time of the IPO. Droller signed or authorized the signing of the Offering Documents filed with the SEC.

36. Defendant Sten Verland ("Verland"), Ph.D., served as a Director of Orphazyme at the time of the IPO. Verland signed or authorized the signing of the Offering Documents filed with the SEC.

37. Defendant Martijn Kleijwegt ("Kleijwegt") served as a Director of Orphazyme at the time of the IPO. Kleijwegt signed or authorized the signing of the Offering Documents filed with the SEC.

38. Defendant Anders Hedegaard ("Hedegaard") served as a Director of Orphazyme at the time of the IPO. Hedegaard signed or authorized the signing of the Offering Documents filed with the SEC.

39. Defendant Catherine Moukheibir ("Moukheibir") has served as a Director of Orphazyme at all relevant times. Moukheibir signed or authorized the signing of the Offering Documents filed with the SEC.

40. Defendant Carrolee Barlow ("Barlow") has served as a Director of Orphazyme at all relevant times. Barlow signed or authorized the signing of the Offering Documents filed with the SEC.

41. Defendants Stratton, Vadsholt, Gemayel, Hansen, Bonde, Droller, Verland, Kleijwegt, Hedegaard, Moukheibir, and Barlow are sometimes referred to herein collectively as the "Securities Act Individual Defendants."

42. As directors, executive officers and/or major shareholders of the Company, the Securities Act Individual Defendants participated in the solicitation and sale of Orphazyme ADSs in the IPO for their own benefit and the benefit of Orphazyme. The Securities Act Individual Defendants were key members of the IPO working group and executives of Orphazyme who pitched investors to purchase the shares sold in the IPO, including in IPO road shows.

43. Orphazyme and the Securities Act Individual Defendants are sometimes referred to herein collectively as the "Securities Act Defendants."

44. The Exchange Act Defendants and the Securities Act Defendants are sometimes collectively, in whole or in part, referred to herein as the "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

45. Orphazyme is a biopharmaceutical company that develops therapies for the treatment of neurodegenerative orphan diseases. The Company focuses on the amplification of heat-shock proteins to develop and commercialize therapeutics for diseases caused by protein misfolding and aggregation, and lysosomal dysfunction, including lysosomal storage and neuromuscular degenerative diseases. Orphazyme conducts its U.S. operations through its wholly-owned subsidiary, Orphazyme US, which is focused on U.S. regulatory review and preparing for the Company's first potential U.S. commercial launch, including legal, commercial, finance, advocacy relations, regulatory, and medical affairs functions.

46. Orphazyme's lead drug candidate is arimoclomol, which is in clinical development for four orphan diseases, including NPC, ALS, and IBM. In August 2017, Orphazyme initiated a multicenter randomized 1:1, double blinded, placebo-controlled Phase 2/3 clinical trial for assessing efficacy and safety of arimoclomol citrate 400 mg three times per day in patients with IBM; in August 2018, Orphazyme initiated a 2:1 randomized, double blinded, placebo-controlled Phase 3 clinical trial assessing efficacy and safety of arimoclomol citrate 400 mg three times per day in patients with ALS; and in September 2020, the FDA accepted Orphazyme's NDA for arimoclomol for NPC.

47. On September 4, 2020, Orphazyme filed the Registration Statement on Form F-1 with the SEC in connection with the IPO, which, after several amendments, was declared effective by the SEC on September 28, 2020.

48. On September 29, 2020, pursuant to the Registration Statement, Orphazyme's ADSs began trading on the NASDAQ under the ticker symbol "ORPH." That same day,

Orphazyme filed the Prospectus on Form 424B4 with the SEC in connection with the IPO, which incorporated and formed part of the Registration Statement.

49. Pursuant to the Offering Documents, Orphazyme conducted the IPO, issuing 3,966,146 of its ordinary shares to the U.S. public in the form of 3,966,146 ADSs at the Offering price of $11.00 per ADS, while concurrently offering 3,650,000 of its ordinary shares in Europe in a private placement to qualified investors, for total approximate proceeds of $77,913,174 to the Company before expenses and after applicable underwriting commissions.

Materially False and Misleading Statements Issued in the Offering Documents

50. The Offering Documents touted arimoclomol's efficacy in treating IBM, stating, *inter alia*, that "[i]n a Phase 2 clinical trial of arimoclomol for the treatment of [sporadic IBM], arimoclomol . . . demonstrated a slowing in the rate of disease progression . . . with a 60% reduction in progression at four months when compared to placebo," which "was shown to persist for several months beyond the 4 month treatment period"; and that, "[b]ased on these results, we are conducting a Phase 2/3 registrational trial in [sporadic IBM], for which we expect top-line results in the first half of 2021."

51. Additionally, the Offering Documents made positive statements concerning arimoclomol's efficacy in treating ALS, stating, *inter alia*, that "[i]n a Phase 2 clinical trial of arimoclomol for the treatment of ALS and in a Phase 2/3 clinical trial for the treatment of superoxide dismutase 1 . . . ALS, arimoclomol . . . showed positive trends across clinical endpoints, including a 30% and 28% slowing of disease progression, respectively"; and that, "[b]ased on these results, we are conducting a Phase 3 registrational trial of arimoclomol for ALS, for which we expect to report top-line results in the first half of 2021."

52. Moreover, the Offering Documents, while noting that the FDA had recently flagged potential issues with the arimoclomol NDA for NPC, nonetheless touted that the Company was already in the process of addressing those issues, downplayed the potential impact of those issues, and asserted the continued viability of the arimoclomol NDA for NPC, stating, *inter alia*:

> On September 24, 2020, we received a filing communication from the FDA in connection with our NDA for arimoclomol for the treatment of NPC in which the FDA summarized six potential review issues, four of which we have previously discussed with the FDA . . . . The FDA has requested that we submit reports from the QTc clinical trial [to assess potential effects of arimoclomol on ventricular repolarization and arrhythmia risk] by October 1, 2020 and that, given the priority review timeline and both nonclinical and clinical evidence suggesting a potential QT safety signal, submission of these reports after that date may not allow the FDA sufficient time to review . . . . To date, we are not aware of any clinical evidence of a potential QT signal related to arimoclomol . . . .
>
> The filing communication constitutes preliminary notice from the FDA of potential review issues as part of its ordinary course review of our NDA and is not necessarily indicative of deficiencies that may be identified during the review. We intend to discuss the filing communication with the FDA. The receipt of the filing communication does not impact the FDA's acceptance of the NDA for arimoclomol, the target PDUFA date or the priority review determination. However, we cannot assure you that such issues will not result in a delay of any potential approval of arimoclomol for the treatment of NPC by the FDA or a determination by the FDA not to approve the product candidate for marketing in the United States.

53. The statements referenced in ¶¶ 50-52 were materially false and misleading because the Offering Documents were negligently prepared and, as a result, contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading and were not prepared in accordance with the rules and regulations governing their preparation. Specifically, the Offering Documents made false and/or misleading statements and/or failed to disclose that: (i) arimoclomol was not as effective in treating IBM as Defendants had represented; (ii) arimoclomol was not as effective in treating ALS as Defendants had represented; (iii) the arimoclomol NDA for NPC was incomplete and/or required additional evidence and data

to support the benefit-risk assessment of that NDA; (iv) as a result of (iii), the FDA was unlikely to approve the arimoclomol NDA for NPC in its present form; (v) the Company's overall business prospects, as well as arimoclomol's commercial prospects, were significantly overstated; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

Materially False and Misleading Statements Issued During the Class Period

54. The Class Period begins on September 29, 2020, when Orphazyme's securities began publicly trading on the NASDAQ pursuant to the materially false or misleading statements or omissions contained in the Offering Documents, as referenced in ¶¶ 50-52, *supra*.

55. On October 23, 2020, Orphazyme issued a press release announcing accelerated arimoclomol pre-launch activities and an updated financial outlook for 2020. That press release quoted Defendant Stratton, who touted that "[t]here is real momentum here at Orphazyme as we move closer to potential approval of arimoclomol in the U.S. in its first indication of NPC and accelerating our preparatory efforts now will help ensure a smooth launch"; and that "[t]here are currently no approved products for NPC in the US and arimoclomol has the potential to make a significant difference to patients with this devastating disease, so our team is working expeditiously to ensure we are optimally positioned for a successful launch if approved."

56. On December 27, 2020, Orphazyme issued a press release providing a regulatory update on arimoclomol for NPC (the "December 2020 Press Release"). That press release advised, in relevant part, that the FDA "has extended the review period of the [NDA] for arimoclomol for the treatment of [NPC] by a standard extension period of three months"; that "[t]his extension is necessary for the FDA to complete its review"; that "[t]he updated Prescription Drug User Fee Act (PDUFA) target action date is June 17, 2021"; and that "[t]he FDA has confirmed the NDA

remains under Priority Review, and the extension does not impede eligibility for a Pediatric Rare Disease Priority Review Voucher."

57. The December 2020 Press Release also quoted Defendant Painter, who assured investors that "Orphazyme is working closely with the FDA to support the final review of the [NDA] for arimoclomol," as well as quoted Defendant Blaettler, who represented that "[w]e have responded to all FDA information requests and submitted all outstanding information regarding the arimoclomol NDA for NPC[.]"

58. On March 2, 2021, Orphazyme issued a press release reporting the Company's business highlights and financial results for 2020 (the "4Q/FY20 Press Release"). That press release touted, *inter alia*, that Orphazyme "[a]ccelerated commercial and other pre-launch activities in preparation for potential approval of arimoclomol in NPC"; "[e]stablished [a] U.S. main office in Chicago in preparation for commercialization of arimoclomol"; and "[p]resented data supporting the profile of arimoclomol at the virtual WORLDSymposium in February 2021[.]"

59. The 4Q/FY20 Press Release also quoted Defendant Vadsholt, who represented, in relevant part, that Defendants "expect to execute on several important goals, including the [FDA] potential approval of arimoclomol in our first indication, [NPC], and reporting results from late-stage, pivotal, clinical trials of arimoclomol in [ALS] and [IBM]"; that Defendants "are operating with a strong financial and commercial position"; and that Defendants "believe we are well positioned to advance Orphazyme into a global, commercial-stage company and create value for our shareholders."

60. Also on March 2, 2021, Orphazyme filed an annual report on Form 20-F with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2020 (the "2020 20-F"). The 2020 20-F touted arimoclomol's efficacy in treating

IBM, stating, *inter alia*, that "[r]esults from an investigator-initiated, randomized, double blinded, placebo-controlled Phase 2 clinical trial in IBM were published in 2016[,]" which showed that "[a]fter four months of treatment the arimoclomol group demonstrated 60% reduction in progression on the IBMFRS sum score[[1]] from the baseline compared to placebo"; that "[t]he effect of arimoclomol on the change in IBMFRS sum score was maintained beyond the four-months treatment period"; that, "[c]ompared to the placebo group, the decline in IBMFRS sum score was reduced by 72.8% and 40% at eight months and at 12 months, respectively"; that, "[a]lthough not powered for efficacy, there was a trend in favor of arimoclomol on the IBMFRS (p=0.055) at eight months"; and that "[s]imilar effects were observed for the two other efficacy endpoints[.]"

61. With respect to arimoclomol's efficacy in treating ALS, the 2020 20-F represented, *inter alia*, that "[a]rimoclomol has so far been tested in two Phase 2 ALS trials, one dose-ranging trial with open-label extension in ALS, Trial AALS-001, and one trial in rapidly progressive ALS caused by SOD1 mutations, Trial 20100758"; that in Trial AALS-001, "[i]n the open label clinical trial, the rate of decline of ALSFRS-R[[2]] was slower in the arimoclomol-treated group than in a historical placebo control group"; that Trial 20100758 "also demonstrated that patients treated with arimoclomol showed positive trends across all clinical endpoints when compared to placebo treatment"; that, even though Trial 20100758 "was not powered to demonstrate efficacy[,]"

[1] The Inclusion Body Myositis Functional Rating Scale ("IBMFRS") is a scale that uses ten questions to score a person's ability to perform daily activities from scale of "0" (worst) to "40" (best). *See* Kevin Dooley, MD, *The Inclusion Body Myositis Functional Rating Scale (IBMFRS)*, CURE IBM (Nov. 5, 2018), https://cureibm.org/the-inclusion-body-myositis-functional-rating-scale-ibmfrs/.

[2] The ALS Functional Rating Scale-Revised ("ALSFRS-R") is a scale that uses twelve questions to score a person's physical functionality from a scale of "0" (worst) to "48" (best). *See ALS C.A.R.E. Program*, CTR. FOR OUTCOMES RES., U. MASS. MED. SCH., https://www.outcomes-umassmed.org/als/sf12.aspx (last visited July 7, 2021).

nonetheless, "pre-defined analyses revealed consistent trends in favor of the arimoclomol-treated group across all pre-defined clinical endpoints"; and that the "results observed in preclinical studies also support our hypothesis that arimoclomol may slow the rate of disease progression."

62. The 2020 20-F also touted the clinical data supporting the arimoclomol NDA for NPC, stating, *inter alia*, that Defendants "initiated a Phase 2/3, randomized placebo-controlled clinical trial in July 2016, after receiving regulatory advice from . . . the FDA"; that "a benefit of arimoclomol over placebo was established on . . . the primary endpoint, corresponding to a 63% relative reduction in disease progression"; that, "[i]n agreement with the FDA, a post-hoc analysis was conducted to exclude [certain] patients[,]" after which "the results showed a statistically significant benefit of arimoclomol over placebo[,]" which "correspond[ed] to a 77% relative reduction in disease progression"; that "[t]wo preplanned subgroup analyses were also conducted which also showed a statistically significant benefit of arimoclomol over placebo[,]" which "correspond[ed] to an 80% relative reduction in disease progression"; that "[a]rimoclomol was well-tolerated with a similar incidence of adverse events, or adverse events, for arimoclomol (88%) and placebo control (75%)"; that Defendants "also conducted an open-label Phase 2/3 extension clinical trial in NPC[,]" the data of which "showed sustained effect in reducing disease progression over two years and further demonstrated the potential of arimoclomol in NPC"; that "[a]rimoclomol was well-tolerated and no new safety signals were detected during the first 12 months of the open-label extension trial"; and that "[a] thorough QT trial with arimoclomol has been conducted to assess potential effects of arimoclomol on ventricular repolarization and arrhythmia risk by assessing the potential presence of a small change in the corrected QT, or QTc, interval[,]" the report from which "has been submitted to FDA as part of the NDA."

63. Appended as exhibits to the 2020 20-F were signed certifications pursuant to the Sarbanes-Oxley Act of 2002, wherein Defendant Vadsholt certified that "the [2020 20-F] fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act" and that "[t]he information contained in the [2020 20-F] fairly presents, in all material respects, the financial condition and results of operations of the Company."

64. The statements referenced in ¶¶ 54-63 were materially false and misleading because the Exchange Act 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, the Exchange Act Defendants made false and/or misleading statements and/or failed to disclose that: (i) arimoclomol was not as effective in treating IBM as Defendants had represented; (ii) arimoclomol was not as effective in treating ALS as Defendants had represented; (iii) the arimoclomol NDA for NPC was incomplete and/or required additional evidence and data to support the benefit-risk assessment of that NDA; (iv) as a result of (iii), the FDA was unlikely to approve the arimoclomol NDA for NPC in its present form; (v) the Company's overall business prospects, as well as arimoclomol's commercial prospects, were significantly overstated; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

65. On March 29, 2021, pre-market, Orphazyme issued a press release "announc[ing] its phase 2/3 trial evaluating arimoclomol for the treatment of [IBM] . . . did not meet its primary and secondary endpoints" (the "March 2021 Press Release"). Specifically, that press release stated, in relevant part:

> Orphazyme['s] . . . phase 2/3 trial evaluating arimoclomol for the treatment of [IBM] . . . did not meet its primary and secondary endpoints. The primary goal was

> to evaluate the treatment effect on disease progression as measured by the inclusion body myositis functional rating scale (IBMFRS).
>
> The randomized, placebo-controlled trial was conducted among 150 IBM patients at 12 sites in North America and Europe . . . . Participants were randomized (1:1 ratio) to receive either arimoclomol citrate (400 mg three times daily) or placebo for up to 20 months.

66. On this news, Orphazyme's ADS price fell $3.59 per ADS, or 28.97%, to close at $8.80 per ADS on March 29, 2021. Despite this decline in the Company's ADS price, Orphazyme securities continued to trade at artificially inflated prices throughout the remainder of the Class period because of Defendants' continued misrepresentations and omissions regarding the purported viability of arimoclomol to treat ALS, the arimoclomol NDA for NPC, and the Company's overall business prospects, as well as arimoclomol's commercial prospects.

67. For example, the March 2021 Press Release touted, in relevant part, that "Orphazyme expects data from a pivotal Phase 3 trial of arimoclomol in [ALS] . . . this spring" and that "[t]he [C]ompany's application[] for arimoclomol . . . for [NPC is] under priority review with the [FDA], with an expected action date in June 2021," while quoting Defendant Vadsholt, who assured investors that "[w]e continue to believe in the promise of arimoclomol and heat shock protein science[.]"

68. The statements referenced in ¶ 67 were materially false and misleading because the Exchange Act 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, the Exchange Act Defendants made false and/or misleading statements and/or failed to disclose that: (i) arimoclomol was not as effective in treating ALS as Defendants had represented; (ii) the arimoclomol NDA for NPC was incomplete and/or required additional evidence and data to support the benefit-risk assessment of that NDA; (iii) as a result of (ii), the

FDA was unlikely to approve the arimoclomol NDA for NPC in its present form; (iv) the Company's overall business prospects, as well as arimoclomol's commercial prospects, were significantly overstated; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

69. On May 7, 2021, pre-market, Orphazyme issued a press release "announc[ing] topline data from pivotal trial of arimoclomol in [ALS]" (the "May 2021 Press Release"). The press release disclosed that the Company' s "pivotal trial . . . did not meet its primary and secondary endpoints to show benefit in people living with ALS." Specifically, that press release stated, in relevant part:

> [T]he ORARIALS-01 pivotal trial of arimoclomol in [ALS] did not meet its primary and secondary endpoints to show benefit in people living with ALS. No important safety signals were reported in the trial.
>
> * * *
>
> The randomized, placebo-controlled Phase 3 trial was conducted among 245 patients at 29 sites in 12 countries in North America and Europe. Participants were randomized (2:1 ratio) to receive either arimoclomol (248 mg three times daily)i or placebo for up to 76 weeks. The primary endpoint was to determine the efficacy of chronic treatment with arimoclomol compared to placebo in participants with ALS as assessed by the combined assessment of function and survival (CAFS). This endpoint was selected to illustrate the overall treatment effect based on survival and the change in the [ALSFRS-R] score. Secondary endpoints included survival, change in ALSFRS-R, and slow vital capacity (SVC).

70. On this news, Orphazyme's ADS price fell $2.81 per ADS, or 32.83%, to close at $5.75 per ADS on May 7, 2021. Despite this decline in the Company's ADS price, Orphazyme securities continued to trade at artificially inflated prices throughout the remainder of the Class period because of Defendants' continued misrepresentations and omissions regarding the purported viability of the arimoclomol NDA for NPC and the Company's overall business prospects, as well as arimoclomol's commercial prospects.

71. For example, the May 2021 Press Release touted, in relevant part, that "Orphazyme's application[] for arimoclomol . . . for [NPC is] under priority review with the [FDA], with an expected PDUFA action date of June 17 2021," while quoting Defendant Blaettler, who represented, in relevant part, that although "unsuccessful, the data generated will contribute meaningfully to the scientific dialogue on this challenging disease" and Defendants "will apply the invaluable insights from this and other studies to further our pipeline as we continue to pursue the full potential of the heat shock protein response."

72. The statements referenced in ¶ 71 were materially false and misleading because the Exchange Act 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, the Exchange Act Defendants made false and/or misleading statements and/or failed to disclose that: (i) the arimoclomol NDA for NPC was incomplete and/or required additional evidence and data to support the benefit-risk assessment of that NDA; (ii) as a result of the foregoing, the FDA was unlikely to approve the arimoclomol NDA for NPC in its present form; (iii) the Company's overall business prospects, as well as arimoclomol's commercial prospects, were significantly overstated; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

73. On June 18, 2021, pre-market, Orphazyme issued a press release announcing receipt of a CRL from the FDA following the agency's review of the NDA for arimoclomol for the treatment of NPC (the "June 18, 2021 Press Release"). The press release disclosed that the FDA had rejected the arimoclomol NDA for NPC, stating, in relevant part:

> Orphazyme . . . has received a [CRL] from the [FDA] following its review of the [NDA] for arimoclomol . . . for the treatment of [NPC].

> The FDA issued the CRL based on needing additional qualitative and quantitative evidence to further substantiate the validity and interpretation of the 5-domain NPC Clinical Severity Scale (NPCCSS) and, in particular, the swallow domain. Further, the FDA noted in the CRL that additional data are needed to bolster confirmatory evidence beyond the single phase 2/3 clinical trial to support the benefit-risk assessment of the NDA.
>
> A primary endpoint of the phase 2/3 clinical trial was progression in disease severity as measured by the 5-domain NPCCSS. This is a disease-specific measure of disease progression consisting of the five clinically most relevant domains to patients with NPC, caregivers and physicians.

74. On this news, Orphazyme's ADS price fell $7.23 per ADS, or 49.66%, to close at $7.33 per ADS on June 18, 2021. Despite this decline in the Company's ADS price, Orphazyme securities continued to trade at artificially inflated prices throughout the remainder of the Class period because of Defendants' continued misrepresentations and omissions regarding the Company's overall business prospects, as well as arimoclomol's commercial prospects.

75. For example, the June 18, 2021 Press Release quoted Defendant Bourdon, who assured investors of the future commercial viability of arimoclomol, stating, in relevant part, that "we remain committed to working with the regulators, with the goal of delivering arimoclomol to families managing this challenging disease"; that "[w]e will focus our efforts on pursuing the European regulatory approval, with CHMP opinion expected in Q4 2021 and potential Marketing Authorization in Q1 2022"; that "[w]e are assessing the potential path forward in the U.S. in partnership with the FDA"; and that, "[i]n the short-term, we will need to reduce our costs substantially and freeze all company efforts not related to clinical and regulatory activities to support approval for NPC."

76. Additionally, the June 18, 2021 Press Release quoted Defendant Hansen, who represented, in relevant part, that "I strongly believe there is a path forward for Orphazyme based on our pursuit of regulatory approval from the European Medicines Agency and continued

dialogue with the FDA[,]" and that "[m]eeting these milestones in NPC will take great sacrifice from everyone in the organization, while we as a Board assist the management team in protecting as much value as possible."

77. The statements referenced in ¶¶ 75-76 were materially false and misleading because the Exchange Act 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, the Exchange Act Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company's overall business prospects, as well as arimoclomol's commercial prospects, were significantly overstated; and (ii) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Fully Emerges

78. On June 21, 2021, pre-market, investor resource website *Seeking Alpha* reported that "Orphazyme [was] cut to sell at Guggenheim after [the Company's] regulatory snub" by the FDA. Specifically, *Seeking Alpha* reported that "[w]ith a $1.00 price target for the stock indicating a downside of ~86.4%, Guggenheim notes that there is 'little optionality left in the stock,' and adds 'it might make sense to wind down the company.'" *Seeking Alpha* also quoted a Guggenheim analyst, who reportedly stated that "'[g]iven these recent failures, lack of future development opportunities, and the need for financing' to advance the operations, there will be a 'significant downside from current levels[.]'"

79. On this news, Orphazyme's ADS price fell $0.81 per ADS, or 11.05%, to close at $6.52 per ADS on June 21, 2021.

80. As of the time this Complaint was filed, the price of Orphazyme ADSs continues to trade below the $11.00 per ADS Offering price, damaging investors.

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

PLAINTIFF'S CLASS ACTION ALLEGATIONS

82. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired: (a) Orphazyme ADSs in the IPO or purchased Orphazyme ADSs thereafter in the stock market pursuant and/or traceable to the Company's Offering Documents issued in connection with the IPO; or (b) Orphazyme securities during the Class Period; and were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

83. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Orphazyme 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 Orphazyme 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.

84. 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.

85. 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.

86. 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 in the Offering Documents for the IPO, or during the Class Period, misrepresented material facts about the business, operations and management of Orphazyme;
- whether the Securities Act Individual Defendants negligently prepared the Offering Documents for the IPO and, as a result, the Offering Documents contained untrue statements of material fact or omitted to state other facts necessary to make the statements made not misleading, and were not prepared in accordance with the rules and regulations governing their preparation;
- whether the Exchange Act Individual Defendants caused Orphazyme to issue false and misleading financial statements during the Class Period;
- whether certain Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Orphazyme 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.

87. 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.

88. 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;
- Orphazyme 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 Orphazyme 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.

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

90. 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 11 of the Securities Act Against the Securities Act Defendants)

91. Plaintiff repeats and incorporates each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

92. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of the Class, against the Securities Act Defendants.

93. The Offering Documents for the IPO were inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

94. Orphazyme is the registrant for the IPO. The Securities Act Defendants named herein were responsible for the contents and dissemination of the Offering Documents.

95. As issuer of the shares, Orphazyme is strictly liable to Plaintiff and the Class for the misstatements and omissions in the Offering Documents.

96. None of the Securities Act Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Documents were true and without omissions of any material facts and were not misleading.

97. By reasons of the conduct herein alleged, each Securities Act Defendant violated, and/or controlled a person who violated Section 11 of the Securities Act.

98. Plaintiff acquired Orphazyme shares pursuant and/or traceable to the Offering Documents for the IPO.

99. Plaintiff and the Class have sustained damages. The value of Orphazyme ADSs has declined substantially subsequent to and because of the Securities Act Defendants' violations.

COUNT II

(Violations of Section 15 of the Securities Act Against the Securities Act Individual Defendants)

100. Plaintiff repeats and incorporates each and every allegation contained above as if fully set forth herein, except any allegation of fraud, recklessness or intentional misconduct.

101. This Count is asserted against the Securities Act Individual Defendants and is based upon Section 15 of the Securities Act, 15 U.S.C. § 77o.

102. The Securities Act Individual Defendants, by virtue of their offices, directorship, and specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Orphazyme within the meaning of Section 15 of the Securities Act. The Securities Act Individual Defendants had the power and influence and exercised the same to cause Orphazyme to engage in the acts described herein.

103. The Securities Act Individual Defendants' positions made them privy to and provided them with actual knowledge of the material facts concealed from Plaintiff and the Class.

104. By virtue of the conduct alleged herein, the Securities Act Individual Defendants are liable for the aforesaid wrongful conduct and are liable to Plaintiff and the Class for damages suffered.

COUNT III

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

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

106. This Count is asserted against the Exchange Act 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.

107. During the Class Period, the Exchange Act 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 Orphazyme securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Orphazyme securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, the Exchange Act Defendants, and each of them, took the actions set forth herein.

108. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Exchange Act 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 Orphazyme 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 Orphazyme's finances and business prospects.

109. By virtue of their positions at Orphazyme, the Exchange Act 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, the Exchange Act 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 the Exchange Act Defendants. Said acts and omissions of the Exchange Act Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Exchange Act

Defendants knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

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

111. The Exchange Act Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Exchange Act Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Orphazyme. As officers and/or directors of a publicly-held company, the Exchange Act Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Orphazyme'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 Orphazyme securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Orphazyme's business and financial condition which were concealed by the Exchange Act Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Orphazyme 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 the Exchange Act Defendants, and were damaged thereby.

112. During the Class Period, Orphazyme 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 Exchange Act Defendants made, issued or

caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Orphazyme securities at prices artificially inflated by the Exchange Act 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 Orphazyme securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Orphazyme securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

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

114. As a direct and proximate result of the Exchange Act 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 IV

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

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

116. During the Class Period, the Exchange Act Individual Defendants participated in the operation and management of Orphazyme, and conducted and participated, directly and

indirectly, in the conduct of Orphazyme's business affairs. Because of their senior positions, they knew the adverse non-public information about Orphazyme's misstatement of income and expenses and false financial statements.

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

118. Because of their positions of control and authority as senior officers, the Exchange Act Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Orphazyme disseminated in the marketplace during the Class Period concerning Orphazyme's results of operations. Throughout the Class Period, the Exchange Act Individual Defendants exercised their power and authority to cause Orphazyme to engage in the wrongful acts complained of herein. The Exchange Act Individual Defendants, therefore, were "controlling persons" of Orphazyme 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 Orphazyme securities.

119. Each of the Exchange Act Individual Defendants, therefore, acted as a controlling person of Orphazyme. By reason of their senior management positions and/or being directors of Orphazyme, each of the Exchange Act Individual Defendants had the power to direct the actions of, and exercised the same to cause, Orphazyme to engage in the unlawful acts and conduct complained of herein. Each of the Exchange Act Individual Defendants exercised control over the general operations of Orphazyme 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.

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

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.