UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. ACER THERAPEUTICS INC., CHRIS SCHELLING, and HARRY PALMIN, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff _____ ("Plaintiff"), individually and on behalf of all other persons 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 Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Acer Therapeutics Inc. ("Acer" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Acer securities between

September 25, 2017 and June 24, 2019, 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. Acer was founded in 2013 and is headquartered in Newton, Massachusetts. Acer is a pharmaceutical company that purportedly focuses on the acquisition, development, and commercialization of therapies for serious rare and life-threatening diseases. Acer's pipeline includes, *inter alia*, EDSIVO (celiprolol) for the treatment of vascular Ehlers-Danlos syndrome ("vEDS") in patients with a confirmed type III collagen mutation.

3. vEDS is a rare disease known to cause abnormal fragility in blood vessels, causing aneurysms, abnormal connections between blood vessels known as arteriovenous fistulas, arterial dissections, and spontaneous vascular ruptures, all of which are potentially life-threatening. According to Acer, "[t]he median survival age of vEDS patients in the United States is 51 years, with arterial rupture being the most common cause of sudden death."

4. In 2004, the French research hospital, Assistance Publique—Hôpitaux de Paris, Hôpital Européen Georges Pompidou ("AP-HP"), published data on vEDS patients. Based on AP-HP's research, investigators began assessing the preventive effect of celiprolol for major cardiovascular events in patients suffering from vEDS "through a multicenter, prospective, randomized, open trial with blinded evaluation of clinical events" (the "Ong Trial"). The Ong Trial was composed of fifty-three participants "randomized at eight centers in France and one center in Belgium." The Ong trial's results were published on October 30, 2010.

5. On December 13, 2016, Acer Therapeutics Inc. ("Private Acer")—a private Delaware corporation and Acer's predecessor—issued a press release announcing that it had obtained exclusive rights to NDA-enabling clinical data from AP-HP for the use of celiprolol in treating vEDS. Specifically, Private Acer had signed an agreement with AP-HP, which granted exclusive rights to access and use data from the Ong Trial. Private Acer announced it would use this data to support its New Drug Application ("NDA") for celiprolol in the treatment of vEDS.

6. On September 19, 2017, Private Acer announced that it had closed a merger with Opexa Therapeutics, Inc. ("Opexa"), a publicly-traded Texas pharmaceutical corporation, whereby Private Acer survived as a wholly-owned subsidiary of Opexa (the "Opexa Merger"). Following the Opexa Merger, Opexa changed its name to Acer Therapeutics Inc and Private Acer's management took control of the combined company. Immediately prior to the Opexa Merger, Opexa's Board of Directors and Neil K. Warma ("Warma"), Opexa's then-President, Chief Executive Officer ("CEO"), Acting Chief Financial Officer, and Secretary, resigned.

7. On September 21, 2017, Acer began trading on the NASDAQ under the ticker symbol "ACER."

8. On December 26, 2018, Acer announced that the U.S. Food and Drug Administration ("FDA") had accepted the Company's NDA for EDSIVO for the treatment of vEDS in patients with a confirmed type III collagen mutation, as well as the FDA's grant of priority review of the NDA and an assigned Prescription Drug User Fee Act ("PDUFA") target action date of June 25, 2019.

9. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Acer

lacked sufficient data to support filing EDSIVO's NDA with the FDA for the treatment of vEDS; (ii) the Ong Trial was an inadequate and ill-controlled clinical study by FDA standards, and was comprised of an insufficiently small group size to support EDSIVO's NDA; (iii) consequently, the FDA would likely reject EDSIVO's NDA; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

10. On June 25, 2019, Acer issued a press release titled "Acer Therapeutics Receives Complete Response Letter from U.S. FDA for use of EDSIVO™ (celiprolol) in vEDS Patients" (the "June 2019 Press Release"). In the June 2019 Press Release, Acer disclosed receipt of a Complete Response Letter ("CRL") from the FDA regarding its NDA for EDSIVO for the treatment of vEDS. Acer advised investors that "[t]he CRL states that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS" and that "Acer plans to request a meeting to discuss the FDA's response."

11. That same day, news sources reported that the small group size of the Ong Trial had raised questions among experts about the adequacy of EDSIVO's trial results.

12. Following this news, Acer's stock price fell $15.16 per share, or 78.63%, to close at $4.12 per share on June 25, 2019.

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

JURISDICTION AND VENUE

14. The claims asserted herein arise under 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).

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

16. 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). Acer securities trade on the Nasdaq Stock Market ("NASDAQ") located within this Judicial District.

17. 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

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

19. Defendant Acer is a Delaware corporation with its principal executive offices located at One Gateway Center, Suite 351, 300 Washington Street, Newton, Massachusetts. Acer's securities trade in an efficient market on the NASDAQ under the symbol "ACER."

20. Defendant Chris Schelling ("Schelling") has served as Acer's President and CEO at all relevant times.

21. Defendant Harry Palmin ("Palmin") has served as Acer's Chief Financial Officer ("CFO") at all relevant times. Defendant Palmin has also served as Acer's Chief Operating Officer since September 1, 2018.

22. Defendants Schelling and Palmin are sometimes referred to herein as the "Individual Defendants."

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

24. Acer was founded in 2013 and is headquartered in Newton, Massachusetts. Acer is a pharmaceutical company that purportedly focuses on the acquisition, development, and commercialization of therapies for serious rare and life-threatening diseases. Acer's pipeline includes, *inter alia*, EDSIVO (celiprolol) for the treatment of vEDS in patients with a confirmed type III collagen mutation.

25. vEDS is a rare disease known to cause abnormal fragility in blood vessels, causing aneurysms, abnormal connections between blood vessels known as arteriovenous fistulas, arterial dissections, and spontaneous vascular ruptures, all of which are potentially life-threatening. According to Acer, "[t]he median survival age of vEDS patients in the United States is 51 years, with arterial rupture being the most common cause of sudden death."

26. In 2004, the French research hospital, Assistance Publique—Hôpitaux de Paris, Hôpital Européen Georges Pompidou ("AP-HP"), published data on vEDS patients. Based on AP-HP's research, investigators began assessing the preventive effect of celiprolol for major cardiovascular events in patients suffering from vEDS "through a multicenter, prospective, randomized, open trial with blinded evaluation of clinical events" (the "Ong Trial"). The Ong Trial was composed of fifty-three participants "randomized at eight centers in France and one center in Belgium." The Ong trial's results were published on October 30, 2010.

27. On December 13, 2016, Private Acer issued a press release announcing that it had obtained exclusive rights to NDA-enabling clinical data from AP-HP for the use of celiprolol in treating vEDS. Specifically, Private Acer had signed an agreement with AP-HP, which granted exclusive rights to access and use data from the Ong Trial. Private Acer announced it would use this data to support its NDA for celiprolol in the treatment of vEDS.

28. On September 19, 2017, Private Acer announced that it had closed a merger with Opexa, a publicly-traded Texas pharmaceutical corporation, whereby Private Acer survived as a wholly-owned subsidiary of Opexa. Following the Opexa Merger, Opexa changed its name to Acer Therapeutics Inc. (the named Defendant in this action) and Private Acer's management took control at the helm of the combined company. Immediately prior to the Opexa Merger, as

effective, Opexa's Board of Directors and Warma, Opexa's then-President, CEO, Acting CFO, and Secretary, resigned.

29. On September 21, 2017, the combined company began trading on the NASDAQ under the ticker symbol "ACER."

30. On December 26, 2018, Acer announced that the FDA had accepted the Company's NDA for EDSIVO for the treatment of vEDS in patients with a confirmed type III collagen mutation, as well as the FDA's grant of priority review of the NDA and an assigned PDUFA target action date of June 25, 2019.

Materially False and Misleading Statements Issued During the Class Period

31. The Class Period begins on September 25, 2017, when Acer issued a press release announcing "Positive Results From Pivotal Clinical Trial of EDSIVO" for the treatment of vEDS (the "September 2017 Press Release"). Despite the Ong Trial's small group size of only fifty-three participants, the September 2017 Press Release touted the Ong Trial as a comprehensive study with positive results that would support Acer's NDA for EDSIVO, stating, in relevant part:

> Acer's retrospective source verified analysis of the trial data, including the primary and secondary endpoints, confirmed the data from a previously published randomized controlled clinical study of celiprolol(1). Acer will use this pivotal clinical data to support a New Drug Application (NDA) regulatory filing in the U.S. in the first half of 2018.
>
> * * *
>
> The previously completed European study, published on October 30, 2010, in *The Lancet*, was stopped early having achieved statistical significance in its primary endpoints, with arterial dissection or rupture affecting 5 (20%) celiprolol patients and 14 (50%) subjects in the non-treated control group (hazard ratio [HR] 0.36; p-value 0.04). The combined primary and secondary endpoints of intestinal or uterine rupture affected 6 (24%) celiprolol patients and 17 (61%) subjects in the non-treated control group (HR 0.31; p-value 0.01). The study was conducted in 53 patients, who were randomly assigned either a twice daily treatment of celiprolol or no treatment. Mean duration of follow-up was 47 months prior to trial halt.

32. The September 2017 Press Release also included a statement by Pierre Boutouyrie ("Boutouyrie") M.D., Ph.D., co-director of the clinical pharmacology service at AP-HP, and Principal Investigator for the published celiprolol study. Boutouyrie touted "nearly two decades" worth of data obtained on EDSIVO in vEDS patients and that the drug was the "standard of care" for vEDS patients in France. Specifically, Boutouyrie stated:

> We have studied celiprolol for nearly two decades in vEDS patients and this is the only drug to ever demonstrate a clinical benefit in this difficult to treat patient population in a randomized, controlled clinical study . . . . Having established celiprolol as the standard of care in France for vEDS patients, we are excited to collaborate with Acer to help bring celiprolol to U.S. patients who are suffering from this devastating, life-threatening disease.

33. Additionally, the September 2017 Press Release included a statement by Acer's Chief Medical Officer, Robert D. Steiner, M.D., who stressed that the Company had vetted the Ong Trial data, and that this data was a "critical element" of EDSIVO's NDA :

> Our confirmation of the published celiprolol clinical data with an Acer-sponsored retrospective source verified analysis of the trial data represents a critical element of the clinical module in our NDA, which we are diligently building, along with current manufacturing, non-clinical and other components of the regulatory package.

34. Finally, the September 2017 Press Release included a statement by Defendant Schelling, who touted the Ong Trial as a "robust" clinical study with endpoints verified by Acer, which would "rapidly advance" EDSIVO's product development:

> We continue to successfully rapidly advance our lead product candidate, EDSIVO™, a potential life-saving therapy for patients with vEDS, towards an NDA filing, which we expect to accomplish in the first half of 2018 . . . . In addition to source verifying a definitive Event-Free Survival endpoint from a previously completed robust clinical study, modernizing manufacturing and assembling other components of the regulatory package, we are executing on a number of key medical affairs focused initiatives for vEDS patients. Specifically, we are setting up Centers of Excellence to optimize patient care, and intend to develop a prospective vEDS Patient Registry and provide integrated care support programs.

35. On March 7, 2018, Acer filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the fiscal year ended December 31, 2017 (the "2017 10-K"). Under the 2017 10-K's "Rationale for EDSIVO™ Treatment in vEDS" section heading, Defendants heavily relied upon the methodology and results of the Ong Trial. Additionally, under the 2017 10-K's "Registration Plan" section heading for EDSIVO, Defendants touted their meeting with the FDA and indicated that the agency had sanctioned the Ong Trial as a sufficient source of data to support the EDSIVO NDA, stating, in relevant part:

> In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS. The FDA indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ is likely to qualify for priority review. Priority review provides an expedited six-month review cycle after acceptance of the NDA for filing, instead of the traditional ten-month review cycle, for drugs that treat a serious condition and demonstrate the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is accepted for filing.

36. Additionally, according to the 2017 10-K, Acer had consulted with the FDA regarding potential data gaps that could hinder the Company's EDSIVO NDA filing. According to the 2017 10-K, Defendants had received additional guidance concerning these gaps. Specifically, the 2017 10-K stated, in relevant part:

> In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.
>
> We plan to have a pre-NDA meeting, which may consist of one or more consults, with the FDA in the second quarter of 2018. Subsequently, we expect to submit

> the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS at the end of the first half of 2018.

37. The 2017 10-K also contained generic, boilerplate representations concerning the risk that regulatory approval for EDSIVO might prove more expensive and time-consuming than Defendants initially anticipated. For example, the 2017 10-K stated, in relevant part:

> ***Our product candidate EDSIVO™ has not been approved for any indication in the United States, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects.***
>
> EDSIVO™ is a repurposing of celiprolol for the treatment of vEDS. An NDA for this drug in the treatment of hypertension was submitted to the FDA in 1987, however, the NDA was withdrawn prior to review. However, the drug has been approved in Europe for the treatment of hypertension since 1984. Regulatory approval of EDSIVO™ may be more expensive and take longer than for other, more well-known or extensively studied pharmaceutical product candidates due to our and regulatory agencies' lack of experience with celiprolol. The novelty of this product candidate may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. There is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our clinical trials and beyond. Any such events could adversely impact our business prospects, financial condition and results of operations.

(Emphasis in original.)

38. Additionally, the 2017 10-K contained generic, boilerplate representations concerning the risk that Acer's stock price could suffer dramatic changes due to, *inter alia*, "the development status of any of [Acer's] drug candidates, such as EDSIVO™[.]"

39. Appended as exhibits to the 2017 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein the Individual Defendants certified that "[t]he [2017 10-K] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934[,]" and that "[t]he information contained in the [2017 10-K] fairly

presents, in all material respects, the financial condition and results of operations of the Company."

40. On October 29, 2018, Acer issued a press release announcing the Company's submission of its NDA for EDSIVO to the FDA for the treatment of vEDS (the "October 2018 Press Release"). The October 2018 Press Release contained a statement by William Andrews ("Andrews"), M.D., FACP, Chief Medical Officer of Acer. Andrews's statement acclaimed EDSIVO's NDA as the culmination of the "extensive efforts" of, *inter alia*, Acer's employees and clinical sites, and Acer's continued work with the FDA as the FDA reviewed EDSIVO's NDA. Specifically, the Andrews' statement in the October 2018 Press Release read:

> Our NDA submission represents the culmination of extensive efforts of our employees, investigators, clinical trial sites, contract research organizations, caregivers and patients . . . . We now look forward to continuing to work with the FDA as they review our NDA, with hopes to make EDSIVO™ available as quickly as possible in the U.S. We are grateful to the vEDS patient and advocacy community for their continued involvement, support and feedback as we work together to advance EDSIVO™, which has the potential to be a significant step forward in the care of patients with this devastating disease.

41. On December 26, 2018, Acer issued a press release announcing the FDA's acceptance of, and grant of priority review for, the EDSIVO NDA (the "December 2018 Press Release"). The December 2018 Press Release boasted that the FDA's grant of priority review for EDSIVO's NDA indicated that EDSIVO "offer[ed] a significant improvement in treatment or provide[d] treatment where no satisfactory alternative therapy exists."

42. The December 2018 Press Release also included a statement by Andrews, again acclaiming EDSIVO's NDA, this time as the product of the Company's "hard work, passion and complete dedication[,]" which the Company would continue to exert alongside the FDA as EDSIVO's NDA was reviewed by the FDA. Specifically, Andrews' statement in the December 2018 Press Release read:

> The acceptance of our NDA for EDSIVO™ is an important step in our efforts to help patients with vEDS, who suffer with a devastating disease that currently has no approved treatment . . . . We have had the honor of learning about the significant challenges of living with vEDS directly from patients and their families. This has in large part driven the hard work, passion and complete dedication that our small team has given to this effort, and we will continue to do so as the FDA reviews our NDA for EDSIVO™. We are excited about the possibility of making EDSIVO™ available in the U.S. for patients in the near future.

43. The December 2018 Press Release also contained a statement by Defendant Schelling, which touted Acer's "accelerat[ion]" of "pre-commercial activites" to launch EDSIVO in the United States. Specifically, Schelling's statement in the December 2018 Press Release read:

> We continue to accelerate our pre-commercial activities supporting the potential U.S. launch of EDSIVO™ for the treatment of vEDS if it is approved by the FDA . . . . Additionally, we are working diligently on advancing and expanding our pipeline with the goal of bringing multiple products to patients with serious rare diseases over the next several years.

44. On March 7, 2019, Acer filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the fiscal year ended December 31, 2018 (the "2018 10-K"). Under the 2018 10-K's "Rationale for EDSIVO™ Treatment in vEDS" section heading, Defendants again heavily relied upon the methodology and results of the Ong Trial. Under the 2018 10-K's "Registration Plan" section heading for EDSIVO, Defendants touted the FDA's acceptance of EDSIVO's NDA for priority review, which purportedly meant that EDSIVO "offer[ed] a significant improvement in treatment or provide[d] treatment where no satisfactory alternative therapy exists." Under the same section heading, Defendants touted "a manuscript for the Paris (AP-HP) vEDS patient registry data" that was "submitted for publication in a top-tier cardiology journal" and currently under peer review. According to the

2018 10-K, "[i]f published, [Defendants would] submit the manuscript to the FDA for review as part of our NDA and as supplemental data to the Ong trial."

45. The 2018 10-K also contained nearly identical and substantively the same merely generic, boilerplate representations as the 2017 10-K, quoted in ¶¶ 37 and 38 above.

46. Finally, the 2018 10-K touted the risk profile of its drug candidates, stating, in relevant part:

> Our product candidates are believed to present a comparatively de-risked profile, having one or more of a favorable safety profile, clinical proof-of-concept data, mechanistic differentiation, and an accelerated path for development, which may include utilizing expedited programs (such as Priority Review) established by the FDA and/or using the regulatory pathway established under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FFDCA") that allows an applicant to rely at least in part on third-party data for approval, which may expedite the preparation, submission, and approval of a marketing application.

47. Appended as exhibits to the 2018 10-K were signed SOX certifications wherein the Individual Defendants certified that "[t]he [2018 10-K] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934[,]" and that "[t]he information contained in the [2018 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

48. The statements referenced in ¶¶ 31-47 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, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Acer lacked sufficient data to support filing EDSIVO's NDA with the FDA for the treatment of vEDS; (ii) the Ong Trial was an inadequate and ill-controlled clinical study by FDA standards, and was comprised of an insufficiently small group size to support EDSIVO's NDA; (iii)

consequently, the FDA would likely reject EDSIVO's NDA; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

49. On June 25, 2019, Acer issued the June 2019 Press Release, disclosing that the FDA had rejected the Company's NDA for EDSIVO. The June 2019 Press Release cited the need for an "adequate and well-controlled trial" evaluating EDSIVO's effectiveness in reducing the risk of clinical events in patients with vEDS. Specifically, the June 2019 Press Release stated, in relevant part:

> Acer Therapeutics Inc. (Nasdaq: ACER), a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs, today announced it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for EDSIVO™ for the treatment of vascular Ehlers-Danlos syndrome (vEDS). ***The CRL states that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS.*** Acer plans to request a meeting to discuss the FDA's response.
>
> "We remain committed to working closely with the FDA to fully understand its response," said Chris Schelling, CEO and Founder of Acer. "We expect to respond to the FDA in the third quarter of this year."

(Emphasis added.)

50. That same day, *Reuters* published an article titled "FDA declines to approve Acer Therapeutics' rare genetic disorder treatment" (the "*Reuters* Article"). In discussing the FDA's rejection of the Company's FDA, the *Reuters* Article noted, among other things, how "[t]he small group size" of the Ong Trial had "raised questions among experts about the adequacy of the trial results."

51. Following this news, Acer's stock price fell $15.16 per share, or 78.63%, to close at $4.12 per share on June 25, 2019.

52. 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

53. 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 Acer 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.

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

55. 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.

56. 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.

57. 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 Acer;
- whether the Individual Defendants caused Acer 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 Acer 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.

58. 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.

59. 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;
- Acer 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 Acer 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.

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

61. 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)

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

63. 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.

64. 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 Acer securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Acer 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.

65. 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 Acer 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 Acer's finances and business prospects.

66. By virtue of their positions at Acer, 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.

67. 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 Acer, the Individual Defendants had knowledge of the details of Acer's internal affairs.

68. 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 Acer. 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 Acer'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 Acer securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Acer's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Acer 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.

69. During the Class Period, Acer 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 Acer 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 Acer securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Acer securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

70. 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.

71. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, 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)

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

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

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

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

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

77. 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 Acer.

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.