

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

_____, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

v.

HELIUS MEDICAL TECHNOLOGIES,
INC., PHILIPPE DESCHAMPS, JOYCE
LAVISCOUNT, AND JONATHAN
SACKIER,

Defendants.

Case No.:

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

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 (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, 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 Helius Medical Technologies, Inc. (“Helius” or the “Company”), and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION AND OVERVIEW

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants who purchased or otherwise acquired the publicly traded securities of Helius between June 18, 2018 and January 24, 2019, both dates inclusive (the “Class Period”). Plaintiff seeks to recover compensable 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.

JURISDICTION AND VENUE

2. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

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

4. Venue is proper in this Judicial District pursuant to 28 U.S.C. §1391(b) and Section 27 of the Exchange Act (15 U.S.C. §78aa(c)) as the Company's headquarters are located in this judicial district.

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

PARTIES

6. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Helius securities at artificially inflated prices during the Class Period and was economically damaged thereby.

7. Defendant Helius is a medical technology company which focuses on the development of products for the treatment of neurological symptoms caused by disease or trauma. Helius' only product is the Portable Neuromodulation Stimulator ("PoNS") which purports to treat brain injuries by electrical stimulation of the tongue. Helius is incorporated in Delaware with headquarters located in Newtown, Pennsylvania. Helius' securities trade on NASDAQ under the ticker "HSDT."

8. Defendant Philippe Deschamps ("Deschamps") has been Helius' Chief Executive Officer ("CEO") during the Class Period.

9. Defendant Joyce LaViscount ("LaViscount") has been Helius' Chief Financial Officer ("CFO") during the Class Period.

10. Defendant Jonathan Sackier ("Sackier") has been Helius' Chief Medical Officer ("CMO") during the Class Period.

11. Defendants Deschamps, LaViscount, and Sackier are collectively referred to hereinafter as the “Individual Defendants.”

12. Each of the Individual Defendants:

- (a) directly participated in the management of the Company;
- (b) was directly involved in the day-to-day operations of the Company at the highest levels;
- (c) was privy to confidential proprietary information concerning the Company and its business and operations;
- (d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;
- (e) was directly or indirectly involved in the oversight or implementation of the Company’s internal controls;
- (f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or
- (g) approved or ratified these statements in violation of the federal securities laws.

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

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

14. Defendants Helius and Individual Defendants are collectively referred to herein as “Defendants.”

SUBSTANTIVE ALLEGATIONS

Background

15. The U.S. Food and Drug Administration (the “FDA”) is the federal government agency responsible for approval of medical devices, including Helius’ PoNS device. In order to get approved by the FDA, Helius must notify the FDA of its intention to market a medical device and this premarket notification is called a 510(k) clearance. According to the FDA, this process:

allows [the] FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Thus, ‘new’ devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.

16. The first clearance Helius is trying to obtain from the FDA is to treat balance disorders in patients with mild to moderate Traumatic Brain Injury (“TBI”).

17. On August 11, 2015, Helius announced that it was launching Phase 3 clinical trials to treat TBI for its PoNS device.

18. On November 9, 2017, Helius issued a press release entitled, “Helius Medical Technologies Announces Positive Results from its Registrational Clinical Trial for Traumatic Brain Injury (TBI).” The results of the PoNS device study were not as promising as hoped as the press release stated in relevant part:

Study results highlights:

- Primary effectiveness endpoint demonstrated a trend toward a higher responder rate in the high frequency PoNS™ Therapy group (75.4%) than in the low frequency PoNS™ Therapy group (60.7%), $p < 0.081$
 - ***Primary effectiveness endpoint was not reached because low frequency pulse treatment had a significant therapeutic effect***
- Secondary effectiveness endpoints demonstrated statistically and clinically significant increases (at least 8 points) in composite SOT scores:
 - The mean improvement at 2 weeks for combined-arms was 18.3 points, $p < 0.0005$
 - The mean improvement at 5 weeks for combined-arms was 24.6 points, $p < 0.0005$
- Successfully met primary and secondary safety endpoints as measured by a decrease in falls and headaches, in both groups
- There were no serious device related adverse events

(Emphasis added).

Materially False and Misleading Statements Issued During the Class Period

19. On June 18, 2018, Helius issued a press release entitled, “Helius Medical Technologies, Inc. Provides Update on its Anticipated Submission for FDA Clearance of the PoNS™ Device.” The press release discussed meetings with the FDA, stating in relevant part:

NEWTOWN, Pa., June 18, 2018 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) (“Helius” or the “Company”), a neurotech company focused on neurological wellness, updated today the expected timing for the Company’s submission of a request for U.S. Food and Drug Administration (“FDA”, “Agency”) clearance of the Portable Neuromodulation Stimulator (PoNS) investigational medical device.

“As part of the submission process for *de novo* classification and 510(k) clearance, FDA encourages companies to engage in pre-submission meetings to obtain the Agency’s perspective and feedback,” stated Jonathan Sackier, Helius’ Chief Medical Officer. ***“The breakthrough nature of our PoNS technology heightens the Company’s desire to work closely with FDA in advance of our submission. We have thus proactively engaged in FDA’s Pre-Submission Program to reduce the likelihood of questions from FDA during their review of the PoNS 510(k) submission.”***

Dr. Sackier continued: “We met with FDA in a pre-submission meeting held in April, which focused on the design verification testing used to support our

submission. We believe this meeting was very productive and we adjusted this element of our submission to incorporate feedback from FDA. We are scheduled to meet with FDA again in July and expect this meeting to be equally productive. Given the timing of this pre-submission meeting, we now expect to submit our request for *de novo* classification and 510(k) clearance in the third quarter of 2018.”

“The submission of our request for FDA clearance of the PoNS device for the treatment of chronic balance deficit due to mild- to moderate-traumatic brain injury is an important milestone for Helius, which the Company has been working towards since we began our registrational clinical trial in 2015,” added Philippe Deschamps, Helius’ President, CEO and Chairman. “We are excited about our data and continued collaboration with FDA to finalize our full submission package.”

(Emphasis added).

20. On September 4, 2018, Helius issued a press release entitled, “Helius Medical Technologies Submits Request for FDA 510(k) Clearance of the PoNS™ Device” which announced the 510(k) submission for the PoNS to the FDA, stating in relevant part:

NEWTOWN, PA., September 4, 2018 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (NASDAQ:HSDT) (TSX:HSM) (“Helius” or the “Company”), a neurotech company focused on neurological wellness, today announced that the Company has submitted a request to the U.S. Food and Drug Administration (“FDA”) for *de novo* classification and 510(k) clearance of the Portable Neuromodulation Stimulator (PoNS™) device.

“Helius is excited to announce the submission of our request for *de novo* classification and 510(k) clearance of the PoNS device for the treatment of chronic balance deficit due to mild- to moderate-traumatic brain injury,” said Philippe Deschamps, Helius’ President, CEO and Chairman. ***“This important milestone is the result of many years of hard work from the Helius team, and it brings us one step closer to making our novel PoNS Treatment available for U.S. patients who suffer from the potentially disabling effects of TBI-related chronic balance disorder.”***

The Company’s request for de novo classification and 510(k) clearance is supported by clinical data from two double-blind, randomized, controlled trials demonstrating the PoNS device’s safety and efficacy, with combined enrollment of 163 patients. It is also informed by feedback provided by FDA during pre-submission meetings that focused on the Company’s trial designs, clinical data and design verification testing.

Mr. Deschamps continued: “Looking ahead, the Company is focused on laying the groundwork for the commercial launch of our PoNS Treatment following FDA clearance and pursuing regulatory clearances in Canada, Australia, Europe.”

(Emphasis added).

21. On November 8, 2018, Helius held an earnings call for its third quarter of 2018 earnings. On this call, Defendant Deschamps discussed the PoNS device and the data from its clinical studies, stating in relevant part:

We believe that our PoNS Treatment has broad potential in treating the symptoms of multiple neurological conditions, including balance deficit in mild to moderate traumatic brain injury, or TBI, multiple sclerosis, stroke and cerebral palsy among others.

* * *

Our PoNS treatment is non-invasive, and its safety and efficacy for the treatment of balance deficit in mild to moderate TBI has been demonstrated in two double-blind, randomized, controlled clinical trials with a combined enrollment of 163 patients. The studies were of similar design and included patients who had a balance deficit due to an injury suffered at least one year prior to participation in the studies. Further, every patient in both trials had to have completed a physical therapy program to try and correct his or her balance deficit, and subsequently, was deemed by a health care professional to have plateaued on physical therapy alone. They also obviously had to continue to have significant balance deficit after completing the physical therapy program alone.

The primary endpoint of each of our trials was a responder analysis. A responder was established when a patient improved by a score of 15 points or higher on the SOT scale, which is 50% higher than the expectation in the medical literature for physical therapy alone. In the first study, patients were treated in a neurorehabilitation center for two weeks, and then were treated at home for three weeks to complete their five-week treatment.

In the second study, the long-term treatment study, subjects were treated for two weeks in the clinic and then were treated for 12 weeks at home. The patients then discontinued treatment and were evaluated for another three months to determine the durability of the treatment post discontinuation. In the trials, our PoNS treatment was observed to have a significant and lasting effect on the patients' balance. 71.6% of patients were responders in the trial, enabling 53.7% of patients with balance deficit in the trial to recover to normal balance function. ***These outcomes are significantly superior to outcomes for physical therapy alone, the current standard of care.***

In the long-term study, the active phase of the trial, patients improved by an average of 30 points from baseline on the SOT scale, which puts the population, on average, into the normal range of the SOT scale, representing a significant improvement in balance symptoms. Importantly, they maintained those gains they experienced in the active phase of the trial during the 12 weeks of washout, highlighting the durability of the PoNS Treatment and suggesting a permanent restoration of balance.

(Emphasis added).

22. The above statements contained in ¶¶19-21 were false and/or misleading, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, these statements were false and/or misleading statements and/or failed to disclose that: (1) the Company's 510(k) submission to the FDA for approval of its PoNS device was incomplete; (2) Defendants knew that the Phase 3 clinical trial data did not meet its primary endpoint but continued to use and manipulate this data; (3) accordingly, Defendants' positive statements about the Phase 3 clinical trial data and outlook for FDA approval of the PoNS device were unfounded; and (4) that, as a result of the foregoing, Defendants' statements about Helius' business, operations, and prospects, were false and misleading and/or lacked a reasonable basis.

THE TRUTH BEGINS TO EMERGE

23. On January 22, 2019, before the market opened, White Diamond Research published an article entitled, "Helius Medical: A Failed Clinical Trial, Redacted Data, And Questionable Leadership, Points To An Ineffective Device" which was available on *Seeking Alpha*. The article disclosed that Helius' clinical data was problematic and that Helius and its officers were hiding the true results of its data, stating in relevant part:

The PoNS Device Failed Its Phase III Traumatic Brain Injury Trial – And Helius Does Not Show Trial Details

The PoNS device missed its primary efficacy endpoint in the phase III trial to treat chronic balance deficit from TBI. This will make it harder for the PoNS to receive

FDA approval, and even harder to receive insurance coverage, even if it gets FDA approval due to its safety profile.

The PoNS phase III trial was a double-blinded, sham-controlled study (for those unfamiliar with medical trial terms, sham means placebo) of its safety and effectiveness in treating subjects with a chronic balance deficit due to mild-to-moderate traumatic brain injury (TBI). A total of 122 subjects (61 active and 61 control) received physical therapy plus either a high-frequency PoNS device (active) or a low-frequency PoNS device (control) which was the sham device.

The results of the trial were announced on 11/9/17. In the announcement, the company stated:

- Primary effectiveness endpoint demonstrated a trend toward a higher responder rate in the high frequency PoNS™ Therapy group (75.4%) than in the low frequency PoNS™ Therapy group (60.7%), $p < 0.081$
- Primary effectiveness endpoint was not reached because low frequency pulse treatment had a significant therapeutic effect

Helius statement above was the old “the placebo was unexpectedly strong” excuse for missing the primary endpoint. We believe that an undisclosed and likely very intense physical therapy protocol used for the Phase III TBI study was directly responsible for the unusually high placebo response. The publication for its earlier MS study described a very intense physical therapy treatment, so there probably was one for this trial as well. If so, it will be noticed by the FDA reviewers. ***But Helius doesn’t provide details on the physical therapy treatment anywhere for this TBI trial. It’s only mentioned that there was a physical therapy treatment.***

Helius Redacted Trial Details

Unlike with Helius’ MS trial, ***there was no detailed publication for the phase III TBI trial, or much information anywhere. That makes us suspicious. If the trial had a good result, then the company should be willing to show more information. We highlight the missing information in this section.***

If you go to the Clinical Trials page on Helius website, you’ll see a list of trials. The bottom TBI trial done at the University of Wisconsin has a link to the clinicaltrials.gov page for the trial info, screenshot below:

Study was completed at the University of Wisconsin-Madison.
For information, contact jlruhland@wisc.edu, or see <http://go.wisc.edu/i24mx8> (ClinicalTrials.gov ID: NCT02158494).
Recruitment is closed.

Source: Helius Medical Webpage

The above ClinicalTrials.gov link leads to a typical looking trial page with lots of various information about the trial.

Next, take a look at the pivotal trial to treat TBI at the top of the list on the Helius' clinical trials page on its website, and how it has many different study sites. This is the important, pivotal trial for the PoNS that Helius is presenting to the FDA in order to get marketing approval. It also shows the Clinicaltrials.gov ID like the other trial, but this one doesn't have a link, as shown in the screenshot below:

This multi-site study – “A double-blind, randomized, sham-controlled study of the safety and effectiveness of the PoNS™ device for cranial nerve noninvasive neuromodulation (“CN-NINM”) training in subjects with a chronic balance deficit due to mTBI” – launched on August 11th, 2015. [\(ClinicalTrials.gov ID: NCT02429167\)](#) ← NO LINK!!!

Source: Helius Medical Webpage

Why doesn't the above ClinicalTrials.gov ID have a link like the other one does? Either the website administrator forgot to put it on, or the company doesn't want you to go to that link. Because if you go to ClinicalTrials.gov and enter that ID, NCT02429167, what you'll find... is... basically nothing!

The Tabular View page has no trial information whatsoever. There's nothing about the primary or secondary endpoints, nothing about the participants, or about the trial design. The following is a screenshot of a part that represents what the entire page looks like:

Descriptive Information	
Brief Title <small>ICMJE</small>	[Trial of device that is not approved or cleared by the U.S. FDA]
Official Title <small>ICMJE</small>	[Trial of device that is not approved or cleared by the U.S. FDA]
Brief Summary	Not Provided
Detailed Description	Not Provided
Study Type <small>ICMJE</small>	Not Provided
Study Phase	Not Provided
Study Design <small>ICMJE</small>	Not Provided
Condition <small>ICMJE</small>	Not Provided
Intervention <small>ICMJE</small>	Not Provided
Study Arms	Not Provided
Publications *	Not Provided

Source

It says on the Study Details page:

Sponsor:

[Redacted]

Information provided by:

[Redacted]

Study Details

Tabul

The above shows that the information from the Sponsor, Helius Medical, is redacted. If you look further on that page and click the “History of Changes” link, you’ll find that the info there is redacted as well. That page has another link called the ClinicalTrials.gov Archive Site that shows the full history of changes of the trial. The links on that page, the historical changes, don’t show any trial info either. It also shows that Helius again redacted the information:

First Submitted: April 20, 2015
First Submitted that April 23, 2015
Met QC Criteria:
First Posted: April 29, 2015 [Estimate]
Last Update Submitted that November 20, 2018
Met QC Criteria:
Last Update Posted: November 22, 2018 [Estimate]
Sponsor/Collaborators
Sponsor: <u>[Redacted]</u>
Responsible Party:
Collaborators:

[Source](#)

Helius has redacted all information regarding this trial from ClinicalTrials.gov, even from the archive page.

It should be concerning to investors that Helius does not provide key details of the trial.

We wanted to find more information about this trial, but, of course, we weren’t getting it from ClinicalTrials.gov. We understood there was a webcast where the company explained that the trial really didn’t fail. This was stated in a medium.com article that we link to below. The PR of the trial results show a link to the webcast. It states:

- An archived copy of the webcast will be available at www.heliusmedical.com and <http://www.wsw.com/webcast/cc/hsdt>

However, when you click on that above link, there isn't an archived copy of the webcast. Instead, the page says:

This presentation has expired

[Source](#): *Webcast page*

It says the webcast is archived, and this is Helius's most important pivotal trial - but the webcast isn't even there. It appears that Helius has removed or redacted every piece of info about this trial except what's in the original PR. Why has Helius done this?

Helius has changed the endpoint of the trial. The announcement states:

Primary effectiveness endpoint was not reached because low frequency pulse treatment had a significant therapeutic effect

The high frequency, real PoNS device group didn't have a significantly greater improvement than the low frequency, sham device group. Therefore, what Helius did was combine the two groups and compare it to baseline. From the announcement:

We are very pleased with the findings from our registrational trial that demonstrate that PoNS™ Therapy, deployed independently across our seven study sites, produced statistically significant improvements in balance from baseline, on average over three times the clinically significant amount," said Helius' Chief Medical Officer, Dr. Jonathan Sackier.

They effectively changed the placebo, or the control, group to the baseline. However, the baseline was the group of participants before they had physical therapy treatments. Both the high frequency and low frequency groups had intense physical therapy treatments. Therefore, we conclude that it was the physical therapy treatments, and not the PoNS device, that made the improvements. We don't know how intense the physical therapy treatments were, because that's part of the information that Helius doesn't show us. But if it's anything like the previous trial they did for MS, then it was a rigorous treatment. We show information about the MS treatment trial, which the company abandoned, later in this report. We have a lot more details on it because there was a publication, which shows a lot more info than solely from the company's PRs.

An excuse for a failed trial being that the placebo was too strong usually doesn't hold water with the FDA. We've exposed biotechs who had this same excuse such as our reports on Ampio (AMPE) and Nymox (NYMX). Both of these stocks got destroyed not long after we published our reports on them. Another biotech, Histogenics (HSGX) had the same excuse for their failed trial and hasn't gotten any sympathy from the FDA.

(Emphasis added).

24. On this news Helius' shares fell \$0.97 or over 11.6% over the next two trading days to close at \$7.36 on January 23, 2019.

25. On January 25, 2019, before the market opened, Helius issued a press release entitled, "Helius Medical Technologies, Inc. Provides Update on FDA's Review of its Request for De Novo Classification and 510(k) Clearance of the PoNS™ Device." The press release disclosed a hurdle to FDA approval as the FDA required additional information regarding the PoNS device, stating in relevant part:

NEWTOWN, Pa., Jan. 25, 2019 (GLOBE NEWSWIRE) -- Helius Medical Technologies, Inc. (Nasdaq:HSDT) (TSX:HSM) ("Helius" or the "Company"), a neurotech company focused on neurological wellness, today announced that *it has received a request for an additional information ("AI") letter from the U.S. Food and Drug Administration (the "FDA") related to the Company's request for De Novo classification and 510(k) clearance of the Portable Neuromodulation Stimulator (PoNS™) device*

During the substantive review phase of a request for De Novo classification and 510(k) clearance, FDA may request additional information in order to obtain information necessary for the agency to continue or complete its review and, in such instances, places its review on hold until the requested information is submitted.

"We have enjoyed a good relationship with FDA in the development and review of our file. We believe we have the data and information to address FDA's questions and we look forward to submitting our response to enable FDA to resume its review process as expeditiously as possible," said Philippe Deschamps, Helius' Chief Executive Officer. "We will continue to work towards securing clearance of PoNS."

Mr. Deschamps continued: "The PoNS device is a novel technology and our pursuit of a clearance is focused on providing a solution for patients suffering from chronic balance deficit due to mild-to-moderate traumatic brain injury, a condition that impacts more than two million people in the United States. We understand and appreciate the thorough and detailed approach the FDA has taken to learn about our novel technology. We look forward to receiving clearance in the United States for our non-invasive treatment of chronic balance deficit due to mild-to-moderate traumatic brain injury."

(Emphasis added).

26. On news Helius' shares fell \$0.48 or approximately 6.3% to close at \$7.13 on January 25, 2019.

27. 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

26. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired Helius securities during the Class Period and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Helius, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Officer or Director Defendants have or had a controlling interest.

27. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Helius securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

28. 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.

29. 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.

30. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

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

31. 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.

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

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

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

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

FIRST CLAIM
Violation of Section 10(b) of
The Exchange Act and Rule 10b-5
Promulgated Thereunder Against All Defendants

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

36. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing

public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Helius' securities 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.

37. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Helius' securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

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

39. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Helius' value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Helius and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly

herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

40. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

41. The defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Helius' financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to

obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

42. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Helius' securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Helius' securities during the Class Period at artificially high prices and were damaged thereby.

43. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Helius was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Helius securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

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

45. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation of Section 20(a) of
The Exchange Act Against the Individual Defendants

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

47. The Individual Defendants acted as controlling persons of Helius within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

48. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

49. As set forth above, Helius and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct,

Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

- (a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- (b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- (d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated:

THE ROSEN LAW FIRM, P.A.

Jacob A. Goldberg, Esq. (PA ID: 66399)
101 Greenwood Avenue, Suite 440
Jenkintown, PA 19046
Tel: (215) 600-2817
Fax: (212) 202-3827
jgoldberg@rosenlegal.com

Attorneys for Plaintiff