

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

SHLOMO SPAR, Individually and On  
Behalf of All Others Similarly  
Situated,

Plaintiff,

v.

CELSION CORPORATION,  
MICHAEL H. TARDUGNO,  
JEFFREY W. CHURCH, and  
NICHOLAS BORYS,

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Shlomo Spar (“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 ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Celsion Corporation ("Celsion" 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 Celsion securities between November 2, 2015 and July 10, 2020, 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. Celsion was founded in 1982 and is headquartered in Lawrenceville, New Jersey. Celsion is an integrated development clinical stage oncology drug company that focuses on the development and commercialization of directed

chemotherapies, DNA-mediated immunotherapy, and RNA-based therapies for the treatment of cancer.

3. Celsion's lead product candidate is ThermoDox, a heat-activated liposomal encapsulation of doxorubicin that is in Phase III clinical development for treating primary liver cancer.

4. In February 2014, Celsion announced that the U.S. Food and Drug Administration ("FDA") had reviewed and provided clearance for the Company's planned pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox in combination with radio frequency ablation ("RFA") in primary liver cancer, also known as hepatocellular carcinoma ("HCC"), called the "OPTIMA Study." The trial design was purportedly based on a comprehensive analysis of data from the Company's Phase III HEAT Study, which purportedly demonstrated that treatment with ThermoDox resulted in a 55% improvement in overall survival ("OS") in a substantial number of HCC patients that received an optimized RFA treatment.

5. The OPTIMA Study was expected to enroll 550 patients globally, with up to 100 sites in the U.S., Europe, China and Asia Pacific, to evaluate ThermoDox in combination with RFA. The primary endpoint for the trial was OS, and the statistical plan called for two interim efficacy analyses by an independent Data Monitoring Committee ("DMC").

6. 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) Defendants had significantly overstated the efficacy of ThermoDox; (ii) the foregoing significantly diminished the approval and commercialization prospects for ThermoDox; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

7. On July 13, 2020, Celsion announced that "it ha[d] received a recommendation from the independent [DMC] to consider stopping the global Phase III OPTIMA Study of ThermoDox® in combination with [RFA] for the treatment of [HCC], or primary liver cancer." According to the Company, "[t]he recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020," which "found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903."

8. On this news, Celsion's stock price fell \$2.29 per share, or 63.97%, to close at \$1.29 per share on July 13, 2020.

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

### **JURISDICTION AND VENUE**

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

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

12. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Celsion is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

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

## **PARTIES**

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

15. Defendant Celsion is a Delaware corporation with principal executive offices located at 997 Lenox Drive, Suite 100, Lawrenceville, New Jersey 08648. Celsion securities trade in an efficient market on the Nasdaq Capital Market (“NASDAQ”) under the symbol “CLSN.”

16. Defendant Michael H. Tardugno (“Tardugno”) has served as Celsion’s President and Chief Executive Officer at all relevant times.

17. Defendant Jeffrey W. Church (“Church”) has served as Celsion’s Executive Vice President and Chief Financial Officer at all relevant times.

18. Defendant Nicholas Borys (“Borys”) has served as Celsion’s Chief Medical Officer at all relevant times, has served as Celsion’s Executive Vice President since February, 2019, and served as Senior Vice President from prior to the start of the Class Period until February, 2019.

19. Defendants Tardugno and Church are sometimes referred to herein as the “Individual Defendants.”

20. The Individual Defendants possessed the power and authority to control the contents of Celsion’s SEC filings, press releases, and other market

communications. The Individual Defendants were provided with copies of Celsion'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 Celsion, 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.

21. Celsion and the Individual Defendants are collectively referred to herein as "Defendants."

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

22. Celsion was founded in 1982 and is headquartered in Lawrenceville, New Jersey. Celsion is an integrated development clinical stage oncology drug company that focuses on the development and commercialization of directed chemotherapies, DNA-mediated immunotherapy, and RNA-based therapies for the treatment of cancer.

23. Celsion's lead product candidate is ThermoDox, a heat-activated liposomal encapsulation of doxorubicin that is in Phase III clinical development for treating primary liver cancer.

24. In February 2014, Celsion announced that the FDA had reviewed and provided clearance for the Company's planned pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox in combination with RFA in primary liver cancer, also known as HCC, called the "OPTIMA Study." The trial design was purportedly based on a comprehensive analysis of data from the Company's Phase III HEAT Study, which purportedly demonstrated that treatment with ThermoDox resulted in a 55% improvement in OS in a substantial number of HCC patients that received an optimized RFA treatment.

25. The OPTIMA Study was expected to enroll 550 patients globally, with up to 100 sites in the U.S., Europe, China and Asia Pacific, to evaluate ThermoDox in combination with RFA. The primary endpoint for the trial was OS, and the statistical plan called for two interim efficacy analyses by an independent DMC.

#### **Materially False and Misleading Statements Issued During the Class Period**

26. The Class Period begins on November 2, 2015, when, during pre-market hours, Celsion issued a press release announcing "the presentation of data from the Company's HEAT Study, highlighting the curative potential for ThermoDox® plus optimized [RFA] in intermediate primary liver cancer, also

known as [HCC], as well as preclinical data on the correlation of heating duration during RFA in combination with ThermoDox.” Specifically, that press release touted, in relevant part:

“There is clear evidence that the duration of the RFA regimen is critical when treating patients with ThermoDox,” said Professor Tak, lead investigator in South Korea for the Company’s HEAT and OPTIMA studies. “Findings from the data presented at ACTA, including the multivariate analysis, HEAT Study data demonstrating compelling survival outcomes and supportive preclinical data, underscore the importance of Celsion’s ongoing OPTIMA Study, which is designed to demonstrate the potential of ThermoDox with an optimized RFA regimen in this setting.”

27. Moreover, the press release quoted Dr. Shi-Ming Lin, lead investigator in Taiwan for the Company’s HEAT and OPTIMA studies, who stated, in relevant part, “[t]he totality of the data presented demonstrate that ThermoDox plus optimized RFA has a strong potential to serve as a curative therapy for patients with liver cancer, where there exists a strong unmet need for effective treatment options.”

28. On November 7, 2015, Celsion hosted an earnings call with investors and analysts to discuss the Company’s financial and operating results for the third quarter of 2015 (the “Q3 2015 Earnings Call”). On the Q3 2015 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

***The message from the medical community could not be clearer, the OPTIMA Study based on convincing findings from the OS subgroup that we’ve been following, has the potential to be the best and perhaps the only new opportunity for HCC patients in the foreseeable future.***

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We view the OPTIMA study as a highly U.S. pivotal trial with strong supportive data from the HEAT Study further supported by multi-variate analyses and with the prospect of revealing preclinical data, while our competing trials can [add a deviant] to our primary liver cancer at this time.

29. On May 16, 2016, Celsion issued a press release entitled, “Celsion Corporation Reports First Quarter 2016 Financial Results and Provides Business Update,” touting, in relevant part:

Mr. Tardugno continued, “We have made great strides to advance our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer with clinical sites currently enrolling patients in 13 countries world-wide. With enrollment now open in China and approximately 50% of the 850,000 new cases of primary liver cancer diagnosed each year originating there, China represents a significant market opportunity and key element of our global development and commercialization strategy for ThermoDox®.

30. That same day, Celsion hosted an earnings call with investors and analysts to discuss the Company’s financial and operating results for the first quarter of 2016 (the “Q1 2016 Earnings Call”). On the call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

In summary, primary liver cancer represents the largest unmet medical need remaining in oncology. We are committed to fully exploring the potential that ThermoDox has demonstrated so far. We are pleased with the progress we have seen in the OPTIMA trial and we remain on track to complete enrollment on or around, tough, now with China coming on, on or around the end of 2017. That would be followed by a

preplanned interim efficacy analysis, the first of two which should read out in the first half of 2018.

31. On July 11, 2016, Celsion issued a press release entitled, “Celsion Announces Presentation Highlighting Phase III OPTIMA Study at the Asia-Pacific Primary Liver Cancer Expert Meeting,” which touted, in relevant part:

“The strength of the preclinical and clinical data to date reinforces our confidence in the potential of ThermoDox in HCC and for a successful trial outcome,” stated Michael H. Tardugno, Celsion’s chairman, president and chief executive officer. “We are extremely encouraged with the investigators’ interest and enthusiasm for our approach. With the trial enrolling patients in 13 countries, and in 9 of up to 20 sites in the Peoples Republic of China, we remain focused on the efficient execution of the only active Phase III study in newly diagnosed HCC patients.”

32. On August 15, 2016, Celsion issued a press release entitled, “Celsion Corporation Reports Second Quarter 2016 Financial Results and Provides Business Update,” which touted, in relevant part:

Mr. Tardugno continued, “We have also made great strides to advance our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer, with clinical sites currently enrolling patients in 13 countries worldwide. In addition, data presentations and publications in multiple peer-reviewed forums continue to highlight the potential for a curative approach of ThermoDox® plus optimized RFA.[“]

33. That same day, Celsion hosted an earnings call with investors and analysts to discuss the Company’s financial and operating results for the second quarter of 2016 (the “Q2 2016 Earnings Call”). On the Q2 2016 Earnings Call,

Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

So in summary, primary liver cancer represents the largest unmet medical need in oncology, we are committed to fully exploring the potential of ThermoDox which has demonstrated thus far and we are pleased with further progress we've seen in our OPTIMA trial and remain on-track to complete enrollment and/or in or around the end of 2017 followed by a preplanned interim efficacy analysis, hopefully the first and only but we have two preplanned in the study followed by the preplanned interim efficacy analysis read on in 2018.

34. On November 10, 2016, Celsion issued a press release entitled, "Celsion Corporation Reports Third Quarter 2016 Financial Results and Provides Business Update," which stated, in relevant part:

Mr. Tardugno continued, "Our ongoing global, pivotal Phase III OPTIMA Study of ThermoDox® in primary liver cancer remains on track with clinical sites currently enrolling patients in 13 countries worldwide. Investigators continue to recognize the value of findings from the HEAT Study and their continued interest reinforces substantial and mounting support for the OPTIMA Study. The recent independent analysis conducted by the National Institutes of Health provides further confirmatory support indicating that the use of radiofrequency ablation (RFA) for more than 45 minutes in patients treated with ThermoDox® can have a correlative impact on reductions in tumor size and overall survival in patients with primary liver cancer."

35. On November 11, 2016, Celsion hosted an earnings call with investors and analysts to discuss the Company's financial and operating results for the third quarter of 2016 (the "Q3 2016 Earnings Call"). On the Q3 2016 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part, "at the same time, data supporting

the OPTIMA study become stronger, if not encounter vertical with each analysis, now for over four years, no matter whether conducted by Celsion or independently scrutinized.”

36. On November 30, 2016, Celsion issued a press release announcing “that following a review of data from [the OPTIMA Study], the study’s [DMC] ha[d] unanimously recommended that the trial continue enrollment.” Specifically, that press release touted, in relevant part:

“Following the recent presentation by the NIH confirming our hypothesis that ThermoDox® in combination with optimized RFA can be a treatment with curative intent for HCC, we could not be more pleased that the DMC has recommended continuation of the OPTIMA Study without modification. Based on their review of all the available study data, the DMC has concluded that ThermoDox is safe for newly diagnosed, intermediate stage patients and that the study is being conducted according to the highest of clinical research standards,” said Michael H. Tardugno, Celsion’s chairman, president and chief executive officer. “We remain optimistic and encouraged by this decision, and by the potential that ThermoDox® has consistently demonstrated in patients with primary liver cancer, a patient population in dire need of new therapeutic options.”

37. On December 16, 2016, Celsion issued a press release announcing progress with ThermoDox development efforts in China and Asia Pacific, which touted, in relevant part:

“We are building momentum with our efforts for ThermoDox in the Asia Pacific region, particularly China, which represents a significant market opportunity with over 50% of new diagnosed cases of this devastating cancer,” stated Michael H. Tardugno, Celsion’s chairman, president and chief executive officer. “[. . .] We believe that the remarkable data from the Chinese cohort of the HEAT study

underscores the potentially curative nature of ThermoDox in patients with primary liver cancer, and we are pleased that the CFDA has both recognized its potential and offered a straightforward path to a regulatory filing in China.”

38. On March 16, 2017, Celsion issued a press release entitled, “Celsion Corporation Reports Year End 2016 Financial Results and Provides Business Update,” which stated, in relevant part:

[“]With sound fundamentals, the superb execution of our ongoing global, pivotal Phase III OPTIMA Study in primary liver cancer, continues to attract interest and support from the medical community, international regulatory agencies, and research organizations like the National Institutes of Health for this ground-breaking study,” said Michael H. Tardugno, Celsion’s chairman, president and CEO.

39. That same day, Celsion hosted an earnings call with investors and analysts to discuss the Company’s financial and operating results for the fourth quarter and full-year 2016 (the “Q4 2016 Earnings Call”). On the Q4 2016 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

During 2016, we made significant progress with our lead trial, the Phase 3 OPTIMA study, which is evaluating ThermoDox in combination with optimized RFA, optimized meaning standardized to a minimum of 45 minutes across all investigators at all sites for treating larger single lesions greater than three centimeters versus optimized RFA alone in the same population.

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NIH concluded its discussion in a very well attended to a large audience, concluded this discussion with clear and convincing support for the OPTIMA study. We believe that this analyses not only advances

our understanding of ThermoDox and its potential curative implication, that's not our words we hear that from researchers and presenters quite regularly now, the curative implication of a single dose of ThermoDox in combination with controlled RFA in patients with larger lesions, larger HCC lesions, the curative potential. It also strengthens our confidence in our ongoing global Phase 3 OPTIMA study.

40. On May 12, 2017, Celsion issued a press release entitled, "Celsion Corporation Reports First Quarter 2017 Financial Results and Provides Business Update," which stated, in relevant part:

"Celsion continues to make major progress with respect to our ongoing global, pivotal Phase III OPTIMA Study in primary liver cancer. This ground-breaking study continues to attract interest and support from the medical community, international regulatory agencies, and research organizations like the National Institutes of Health," said Michael H. Tardugno, Celsion's chairman, president and CEO.

41. That same day, Celsion hosted an earnings call with investors and analysts to discuss the Company's financial and operating results for the first quarter of 2017 (the "Q1 2017 Earnings Call"). On the Q1 2017 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

So in summary, with minimal operation risk, we are now looking forward to study completion and data. *If you believe our many analyses that support the OPTIMA study or if you have any confidence in the independent opinion of the National Institute of Health, then you should have to agree that there are chances of success with our OPTIMA study is as good as it gets in our industry.*

(Emphasis added).

42. On August 7, 2017, Celsion issued a press release announcing “that the independent [DMC] for the [the OPTIMA study], has completed a planned interim analysis of the first 50% of patients randomized in the trial as of April 2017 for safety and efficacy and unanimously recommended that the study continue according to protocol to its final data readout based on the risk to benefit analysis by the Committee.” Specifically, that press release represented, in relevant part:

[“]Based on their review of all the available study data from 275 patients enrolled as of April 2017, the DMC has concluded that ThermoDox® is safe for newly diagnosed, intermediate stage patients and that the study is being conducted according to the highest of clinical research standards,” said Nicholas Borys, MD, Celsion’s senior vice president and chief medical officer. “A key component of the OPTIMA Study protocol is the investigators’ adherence to the recommended RFA heating time for tumors greater than 3 cm. We are pleased to report that there has been a greater than 99% compliance rate with the study protocol.”

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“We are very pleased that the DMC has unanimously recommended continuation of the OPTIMA study based on their review of all available clinical data, both safety and efficacy, in over 275 patients,” stated Mr. Michael H. Tardugno, Celsion’s chairman, president and chief executive officer. “The DMC’s affirmative review is further evidence of ThermoDox’s potential to provide a new and important first line therapeutic option for patients with primary liver cancer.”

43. On August 15, 2017, Celsion issued a press release entitled, “Celsion Corporation Reports Second Quarter 2017 Financial Results and Provides Business Update,” which stated, in relevant part:

Mr. Tardugno continued, “We have also made great strides to advance our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer, with clinical sites currently enrolling patients in 14 countries worldwide. In addition, we are pleased to report that the independent Data Monitoring Committee recently recommended continuation of the OPTIMA Study after their review of the safety and efficacy data for 275 patients enrolled in the study.[“]

44. That same day, Celsion hosted an earnings call with investors and analysts to discuss the Company’s financial and operating results for the second quarter of 2017 (the “Q2 2017 Earnings Call”). On the Q2 2017 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

*So, with virtually no operational risk and all the major costs behind us, we now look forward to study completion and data readout, and **if you believe the many analyses supporting OPTIMA conducted by the company and by others, including an independent analysis of the OS data conducted by the National Institutes of Health, that’s the NIH, and you have to agree that our chances for success in this very important study are quite good.***

(Emphasis added).

45. On September 27, 2017, Celsion issued a press release providing an update on ThermoDox in the OPTIMA study of primary liver cancer, which represented, in relevant part:

“With independent confirmation by the NIH of the relationship between RFA heating time and the significant impact that it has on overall survival when combined with ThermoDox®, OPTIMA Study investigators fully recognize the value of the findings from the HEAT Study, reinforcing their interest and support for our highly de-risked, ongoing global Phase III OPTIMA Study,” said Michael H. Tardugno,

Celsion's chairman, president and chief executive officer. "The previously announced unanimous recommendation for study continuation by the independent Data Monitoring Committee was based on their review of all available clinical data from 275 patients, and is further evidence of ThermoDox's recognized potential to provide a new and important first line therapeutic option for patients with primary liver cancer."

46. That same day, Celsion hosted an earnings call with investors and analysts to discuss the Company's financial and operating results for the third quarter of 2017 (the "Q3 2017 Earnings Call"). On the Q3 2017 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part, "the hypothesis is supported with *some of most persuasive and productive perspective and retrospective data that has ever been taken in my experience for clinical trial*. Much of this data analysis were included and accepted by peer review and recently published manuscript of the HEAT study in clinical cancer research. It's a high impact medical journal." (Emphasis added).

47. On May 11, 2018, Celsion hosted an earnings call with investors and analysts to discuss the Company's financial and operating results for the first quarter of 2018 (the "Q1 2018 Earnings Call"). On the Q1 2018 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part, "[o]ur investigators are excited about the results that concluded that the single dose of ThermoDox with properly administered

RFA has the potential to be cured. We have been presenting this narrative at multiple medical conferences over the last number of years.”

48. On August 14, 2018, Celsion hosted an earnings call with investors and analysts to discuss the Company’s financial and operating results for the second quarter of 2018 (the “Q2 2018 Earnings Call”). On the Q2 2018 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

That the final readout of 550 patient studies Optima study powered to detect a 33% reduction in the risk for death. ***The evidence supporting the thesis for the Optima study is overwhelming*** and is based on our understanding of the application of RFA for 3 centimeter and larger lesions and the survival impact when RFA used correctly that is for 45 minutes heating and combined with ThermoDox. In 285 patient subgroup that was 42% of the entire population from a prior heat study a group that was followed every quarter for 2.5 years many time death in the treatment arm was never reached after 80 months. That’s more than 7.5 years median survival more than two years better than the control group, again single dose of ThermoDox with properly used RFA in intermediate sized tumors has the potential to be curative now that’s not my word that’s the word our investigators are using when they present this data to their colleagues.

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This is a problem and ladies and gentlemen if we’re right ThermoDox is successful in the OPTIMA study it will be one of the most important new drugs in oncology and the generation if not our lifetime I believe that sincerely.

(Emphasis added).

49. On March 29, 2019, Celsion hosted an earnings call with investors and analysts to discuss the Company's financial and operating performance for the fourth quarter and full-year 2018 (the "Q4 2018 Earnings Call"). On the Q4 2018 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

Among our many accomplishments, I'd like to emphasize that enrollment of our pivotal 556 patient global phase 3 OPTIMA study in primary liver cancer, also known as HCC, hepatocellular carcinoma, was completed ahead of projections in August of 2018. And then we're now looking forward to the first of two pre-planned interim efficacy analysis for the OPTIMA study expected later this year. And if needed, the second interim will be sometime in mid-2020.

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Our global HCC incidence is about 750,000. It's growing at about 3% annually. This is the largest unmet medical need in oncology today irrefutably, the largest unmet medical need remaining on oncology. These statistics come from the latest Global Cancer Statistical Database. We are well positioned for the market, OPTIMA is being conducted in 14 countries in North America, Europe, China and Eastern Asia, all the major markets for this indication.

50. On August 15, 2019, Celsion hosted an earnings call with investors and analysts to discuss the Company's financial and operating performance for the second quarter of 2019 (the "Q2 2019 Earnings Call"). On the Q2 2019 Earnings Call, Defendant Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

And I say perspective, I want to repeat this, I say at every conference call. Different than other subgroups, we identified a metric 45 minutes

of heating to be critical for ThermoDox in combination with RFA to improve survival. We identified those patients in the study who had been treated with 45 minutes or more of RFA plus-minus ThermoDox. And then we followed them for 3 years to determine an overall survival benefit. ***And what we saw is I'll repeat again is nothing short of remarkable.*** In this prospective evaluation of patients who are treated with standardized RFA more than 45 minutes, they demonstrate a median survival of more than 7.5 years when they combine this standardized RFA with ThermoDox. And that's a survival benefit of more than two years of the control group who received 45 minutes or more of RFA alone. I hope that's clear.

(Emphasis added).

51. On November 4, 2019, Celsion issued a press release entitled, "Celsion Reports Unanimous Independent Data Monitoring Committee Recommendation to Continue the Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer," which stated, in relevant part:

Michael H. Tardugno, Celsion's chairman, president and chief executive officer, said, "We are encouraged by the recommendation of the iDMC to continue the OPTIMA Study according to plan. While we have not unblinded the study to report a hazard ratio, PFS is tracking similarly to the subgroup of patients who received more than 45 minutes of RFA in our HEAT Study and were followed prospectively for more than three years. This subgroup in the HEAT Study demonstrated a 2-year overall survival advantage and a median time to death of more than 7 ½ years. ***We believe this tracking bodes well for success at our next pre-planned interim efficacy analysis,*** which is intended after a minimum of 158 patient deaths. We also note that the median follow-up for survival was only 25 months at time of data cut-off, which is too early for OS estimates, particularly when compared to the median follow-up for the HEAT Study subgroup which was 67 months.["]

(Emphasis added).

52. On November 14, 2019, Celsion issued a press release entitled, “Celsion Corporation Reports Third Quarter 2019 Financial Results and Provides Business Update,” which stated, in relevant part:

“Our focus on shareholder value remains uncompromised as Celsion continues to deliver results from our ongoing clinical development programs for ThermoDox® and GEN-1. Our smart use of venture debt to leverage the holdings of our equity investors, along with our strategy to avoid punitive financing deals has worked well for us and our shareholders. We enter the fourth quarter with sound fundamentals and a strong balance sheet that is expected to fund our clinical programs through transformative milestones over the next 16 months,” added Mr. Tardugno. “With the first of two preplanned interim efficacy analyses for the OPTIMA Study successfully behind us, we look forward to the promise and potential for success at the 2nd preplanned analysis, now expected to occur in the second quarter of 2020.[“]

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**iDMC Unanimously Recommends Continuation of Celsion’s Phase III OPTIMA Study for ThermoDox® in Primary Liver Cancer.** On November 4, 2019 the Company announced that the iDMC unanimously recommended the OPTIMA Study continue according to protocol. The recommendation was based on a review of blinded safety and data integrity from 556 patients enrolled in the Company’s multinational, double-blind, placebo-controlled pivotal Phase III study with ThermoDox® plus RFA in patients with HCC.

The iDMC’s pre-planned interim efficacy review followed 128 patient events, or deaths, which occurred in August 2019. Data presented demonstrated that progression-free survival (PFS) and overall survival (OS) data appear to be tracking with patient data observed at a similar point in the Company’s 285 patient, well-balanced subgroup of patients followed prospectively in the earlier Phase III study (the “Prospective Subgroup”) upon which the OPTIMA Study is based. This Prospective Subgroup demonstrated a 2-year overall survival advantage and a median time to death of more than 7 ½ years.

From the data review, *the Company believes that the OPTIMA Study is well positioned for success at the next pre-planned interim efficacy analysis*, which is intended after a minimum of 158 patient deaths and is projected to occur during the second quarter of 2020. The hazard ratio for success at 158 events is 0.70. This is below the hazard ratio of 0.65 observed for the 285 patients in the HEAT Study Prospective Subgroup treated with RFA > 45 minutes.

53. On November 15, 2019, Celsion hosted an earnings call with investors and analysts to discuss the Company's financial and operating results for the third quarter of 2019 (the "Q3 2019 Earnings Call"). On the Q3 2019 Earnings Call, Defendant Tardugno made multiple positive statements ThermoDox and the OPTIMA study, including, in relevant part:

I'll now turn to the positive news regarding the recommendation from the DMC from the OPTIMA Study following a review of the unblinded data at the first pre-specified interim efficacy analysis. The committee unanimously recommended that we continue the study as planned. For this analysis, the DMC reviewed data following 128 patient deaths which occurred early in August 2019. The committee found no evidence of futility or any safety issues of concern in this 556 patient study.

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Even more encouraging was the suggestion that they made, that the company should consider a compassionate use program in China. We see this as a positive, we certainly do; and are making plans under Dr. Borys' direction to launch a program in high volume, high quality clinical sites to participate in the OPTIMA Study.

54. On March 3, 2020, Celsion published a letter from Defendant Tardugno to Celsion shareholders, which stated, in relevant part:

**First**, we now count among our stockholders four institutional investors that have been following our progress with ThermoDox® over a sufficiently long period of time to fully understand our technology and the potential for success of our global Phase III OPTIMA Study in primary liver cancer, or HCC. As we have said, positive trial results will be transformational – for patients with HCC, for physicians, for our employees and for you, our stockholders. I believe these new investors recognize they are financing a drug development program that holds the promise to make a measurable difference for the global medical community.

55. On April 15, 2020, Celsion issued a press release entitled “Celsion Reports that Sufficient Events Have Been Reached for the Second Interim Analysis of the Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer,” which stated, in relevant part:

Michael Tardugno, Celsion’s chairman, president and chief executive officer, said, “We look forward to receiving the iDMC’s recommendation from this data analysis, and are *quite optimistic for a positive outcome. Regardless, we believe that the OPTIMA Study is ultimately well-positioned for success.* [ . . . ] We base our confidence on published pre-clinical data supporting the OPTIMA Study, the National Institutes of Health’s independent analysis of and support for the Study’s hypothesis, and the OPTIMA Study’s current timeline for disease progression and patient death, both tracking in line with the prospective HEAT Study subgroup. The prospective subgroup demonstrated a remarkable 7 ½ years plus survival when treated with ThermoDox® plus RFA. A successful study has “blockbuster” revenue potential and more importantly, will be transformational for patients with HCC, with over 750,000 incidence annually, the largest unmet need in oncology.”

56. On May 15, 2020, Celsion hosted an earnings call with investors and analysts to discuss the Company’s financial and operating results for the first quarter of 2020 (the “Q1 2020 Earnings Call”). On the Q1 2020 Earnings Call, Defendant

Tardugno made multiple positive statements regarding ThermoDox and the OPTIMA study, including, in relevant part:

*We've had a great deal of exciting news during the first quarter in recent weeks from both of our lead programs, first and critically important, our ThermoDox Phase III OPTIMA Study for the treatment of newly diagnosed hepatocellular carcinoma or primary liver cancer reached the prescribed number of events in April for our second pre-planned in term efficacy analysis and I will discuss this more in a minute.*

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Now, as I said before, *we believe that, there's a very good potential for success at this analysis*, but of course it's not a short, the Company remains blinded. I'd like to give you some insight into the support for our belief that the study is on track for success. Supporting our belief is our comparison of the threshold for success to the data from the data that OPTIMA Study was based on. The P-value and the hazard ratio for OPTIMA success and 158 events are 0.022 and 0.7 respectively. P-value for success is 0.022. The hazard ratio for success is 0.70 respectively.

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*I will again remind you also that our confidence of any underlying hypothesis supporting the OPTIMA Study is not hours long. Thought leaders from the medical community and distinguished scientists have weighed in. Conclusions from peer reviewed manuscripts including published preclinical data supporting the OPTIMA Study, the public HEAT Study manuscript validating the subgroup results, and again, the NIH is published analysis in support of the HEAT studies hypothesis all pointing in the same direction.*

(Emphases added).

57. On June 25, 2020, Celsion issued a press release entitled, “Celsion Affirms July Timing for Second Interim Analysis of the Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer,” which stated, in relevant part:

Michael H. Tardugno, Celsion’s chairman, president and chief executive officer, said, “The iDMC meeting is expected to take place as planned and we look forward to receiving their recommendation. While we are hopeful for a positive outcome, it is not a binary event for the OPTIMA Study. Should the data not reach the threshold for success, we believe the OPTIMA Study is ultimately well-positioned for success at the final analysis, if necessary. The final analysis would be based on 197 patient deaths where the hazard ratio for success is 0.75 or a 25% reduction in the risk of death, with a p-Value = 0.042. We believe that a successful study has blockbuster revenue potential and, more importantly, will be globally transformational for patients with HCC, the largest unmet need in oncology with more than 750,000 cases annually.”

58. The statements referenced in ¶¶ 26-57 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) Defendants had significantly overstated the efficacy of ThermoDox; (ii) the foregoing significantly diminished the approval and commercialization prospects for ThermoDox; and (iii) as a result, the Company’s public statements were materially false and misleading at all relevant times.

## **The Truth Emerges**

59. On July 13, 2020, during pre-market hours, Celsion announced that “it ha[d] received a recommendation from the independent [DMC] to consider stopping the global Phase III OPTIMA Study of ThermoDox® in combination with [RFA] for the treatment of [HCC], or primary liver cancer.” According to the Company, “[t]he recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020,” which “found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903.”

60. On this news, Celsion’s stock price fell \$2.29 per share, or 63.97%, to close at \$1.29 per share on July 13, 2020.

61. 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**

62. 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 Celsion 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.

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

64. 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.

65. 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.

66. 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 Celsion;
- whether the Individual Defendants caused Celsion 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 Celsion 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.

67. 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.

68. 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;
- Celsion 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 Celsion 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.

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

70. 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)**

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

72. 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.

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

74. 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 Celsion 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 Celsion's finances and business prospects.

75. By virtue of their positions at Celsion, 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.

76. 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 Celsion, the Individual Defendants had knowledge of the details of Celsion's internal affairs.

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

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

79. 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.

80. 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)**

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

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

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

84. 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 Celsion disseminated in the marketplace during the Class Period concerning Celsion's results of operations.

Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Celsion to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were “controlling persons” of Celsion 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 Celsion securities.

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

86. 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 Celsion.

### **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.

Dated: