UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. EXTHERA MEDICAL CORPORATION, Defendant	CRIMINAL No. 26cr10056

DEFERRED PROSECUTION AGREEMENT

Defendant EXTHERA MEDICAL CORPORATION (the "Company"), pursuant to authority granted by the Company's Board of Directors reflected in Attachment B, and the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section"), and the United States Attorney's Office for the District of Massachusetts (the "Office") (collectively, the "Offices") enter into this deferred prosecution agreement (the "Agreement"). The terms and conditions of this Agreement are as follows:

Criminal Information and Acceptance of Responsibility

1. The Company acknowledges and agrees that the Offices will file the attached one-count criminal Information in the United States District Court for the District of Massachusetts charging the Company with one count of failure to file adverse event reports with the intent to defraud or mislead, in violation of Title 21, United States Code, Sections 331(q)(1)(B), 333(a)(2), and 360i, as well as a criminal forfeiture allegation. In so doing, the Company: (a) knowingly waives any right it may have to indictment on this charge, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) knowingly waives any legal or

procedural defects in the Information; (c) knowingly waives any objection with respect to venue to any charges by the United States arising out of the conduct described in the Statement of Facts attached hereto as Attachment A ("Statement of Facts") and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the District of Massachusetts; and (d) agrees that the charges in the Information and any charges arising from the conduct described in the Statement of Facts are not time-barred by the applicable statute of limitations on the date of the signing of this Agreement. The Offices agree to defer prosecution of the Company pursuant to the terms and conditions described below.

2. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Information, and as set forth in the Statement of Facts, and that the allegations described in the Information and the facts described in the Statement of Facts are true and accurate. The Company agrees that, effective as of the date the Company signs this Agreement, in any prosecution that is deferred by this Agreement, it will not dispute the Statement of Facts set forth in this Agreement, and, in any such prosecution, the Statement of Facts shall be admissible as: (a) substantive evidence offered by the government in its case-in-chief and rebuttal case; (b) impeachment evidence offered by the government on cross-examination; and (c) evidence at any sentencing hearing or other hearing. In addition, in connection therewith, the Company agrees not to assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, Section 1B1.1(a) of the United States Sentencing Guidelines, or any other federal rule that the Statement of Facts should be suppressed or is otherwise inadmissible as evidence in any form.

Term of the Agreement

3. This Agreement is effective for a period beginning on the date on which the Information is filed and ending 36 months from that date (the "Term"). The Company agrees, however, that, in the event the Offices determine, in their sole discretion, that the Company has knowingly violated any provision of this Agreement or has failed to completely perform or fulfill each of the Company's obligations under this Agreement, an extension or extensions of the Term may be imposed by the Offices, in their sole discretion, for up to a total additional time period of 12 months, without prejudice to the Offices' right to proceed as provided in Paragraphs 20-23 below. Any extension of the Agreement extends all terms of this Agreement, including the terms of the reporting requirement in Attachment D, for an equivalent period. Conversely, in the event the Offices find, in their sole discretion, that there exists a change in circumstances sufficient to eliminate the need for the reporting requirement in Attachment D, and that the other provisions of this Agreement have been satisfied, the Agreement may be terminated early.

Relevant Considerations

4. The Offices enter into this Agreement based on the individual facts and circumstances presented by this case and the Company, including:

a. the nature and seriousness of the offense conduct, as described in the Statement of Facts, including the Company's intentional concealment of multiple patients' adverse medical events from the Food and Drug Administration, including life-threatening complications and deaths of patients, while the Company continued sales and facilitated the use of its product, resulting in profits of approximately $5,694,750 to the Company;

b. the Company did not receive voluntary disclosure credit pursuant to the Criminal Division's Corporate Enforcement and Voluntary Self-Disclosure Policy ("Criminal

Division CEP"), or pursuant to U.S. Sentencing Guidelines ("U.S.S.G." or "Sentencing Guidelines") § 8C2.5(g)(1), because it did not voluntarily and timely disclose to the Offices the conduct described in the Statement of Facts;

c. the Company received credit for its cooperation with the Offices' investigation pursuant to U.S.S.G. § 8C2.5(g)(2) because it cooperated with their investigation and demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct; the Company also received credit for its cooperation pursuant to the Criminal Division CEP. The Company's cooperation included, among other things, (i) providing expedited, thorough, and detailed disclosure of all non-privileged facts known to the Company and relevant to the wrongdoing at issue; (ii) conducting on-site investigations at ExThera's offices in January 2025, within 10 days of publication of a news article relating to issues described in the Statement of Facts; (iii) conducting interviews of current and former ExThera employees, and reporting relevant facts obtained during interviews to the Offices; (iv) providing multiple thorough and well-organized factual presentations reporting the results of the Company's investigation; and (v) discovering and disclosing additional misconduct by Company personnel outside the scope of the subpoena;

d. the Company provided to the Offices all relevant facts known to it, including information about the individuals involved in the conduct described in the attached Statement of Facts and conduct disclosed to the Offices prior to the Agreement;

e. the Company also received credit pursuant to the Criminal Division CEP because it engaged in timely remedial measures, including: (i) engaging new senior personnel, including onboarding an outside general counsel and a chief of staff with significant regulatory experience; (ii) implementing structural and reporting changes to better ensure appropriate

reporting and independent review and approval of key processes; (iii) revising, enhancing, and standardizing employee training on company policies and applicable law, including adverse event reporting processes and requirements; (iv) significantly enhancing management risk reporting practices, including compliance and quality system risk reporting; (v) initiating an enhanced reporting and tracking system for centralized documentation, review, and response to employee concerns and complaints; and (vi) establishing regular audits conducted by a third-party and creating new internal monitoring and review processes for company systems and controls. Therefore, the Offices determined that a reduction of 20 percent off the bottom of the applicable Sentencing Guidelines fine range was appropriate pursuant to the CEP based on the Company's cooperation and remediation;

f. the Company has enhanced and has committed to continuing to enhance its compliance program and internal controls, including ensuring that its compliance program satisfies the minimum elements set forth in Attachment C to this Agreement ("Corporate Compliance Program");

g. based on the Company's remediation, the state of its compliance program, its agreement to report to the Offices as set forth in Attachment D to this Agreement ("Compliance Reporting Requirements"), and because the Company has only minimal remaining operations, the Offices determined that an independent compliance monitor was unnecessary;

h. the Company has no prior criminal or civil enforcement history;

i. the Company has agreed to continue to cooperate with the Offices in any ongoing investigation or prosecution as described in Paragraph 5 below; and

j. the Company met its burden of establishing an inability to pay the criminal penalty sought by the Offices. The Offices, with the assistance of a forensic accounting expert,

conducted an independent ability to pay analysis, considering a range of factors outlined in the Justice Department's Inability to Pay Guidance (*see* October 8, 2019 Memorandum from Assistant Attorney General Brian Benczkowski to All Criminal Division Personnel re: Evaluating a Business Organization's Inability to Pay a Criminal Fine or Criminal Monetary Penalty), including but not limited to: (i) the factors outlined in 18 U.S.C. § 3572 and the U.S.S.G. § 8C3.3(b); (ii) the Company's current financial condition; (iii) the Company's alternative sources of capital; and (iv) the collateral consequences of the imposition of the full criminal penalty amount. Based on that independent analysis, the Offices determined that paying a criminal penalty greater than $750,000 would substantially threaten the continued viability of the Company;

k. accordingly, after considering (a) through (j) above, the Offices have determined that the appropriate resolution in this case is a deferred prosecution agreement; a criminal monetary penalty of $750,000, based on the inability-to-pay analysis, to be paid in accordance with Paragraph 10; and the Company's consent to entry of a forfeiture order of $5,694,750, in accordance with Paragraph 11.

Ongoing Cooperation and Disclosure Requirements

5. The Company shall cooperate fully with the Offices in any and all matters relating to the conduct described in this Agreement and the Statement of Facts and other conduct under investigation by the Fraud Section, the Office, or any other component of the Department of Justice at any time during the Term until the later of the date upon which all investigations and prosecutions arising out of such conduct are concluded, or the end of the Term. At the request of the Offices, the Company shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies in any investigation of the Company, its parent company or its affiliates, or any of its present or former officers, directors, employees,

agents, and consultants, or any other party, in any and all matters relating to the conduct described in this Agreement and the Statement of Facts and other conduct under investigation by the Offices or any other component of the Department of Justice at any time during the Term. The Company's cooperation pursuant to this Paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Offices a log of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such an assertion. The Company agrees that its cooperation pursuant to this paragraph shall include, but not be limited to, the following:

a. The Company represents that it has timely and truthfully disclosed all factual information with respect to its activities, those of its subsidiaries and affiliates, and those of its present and former directors, officers, employees, agents, and consultants relating to the conduct described in this Agreement and the Statement of Facts, as well as any other conduct under investigation by the Offices at any time about which the Company has any knowledge. The Company further agrees that it shall promptly and truthfully disclose all factual information with respect to its activities, those of its parent company and affiliates, and those of its present and former directors, officers, employees, agents, and consultants about which the Company shall gain any knowledge or about which the Offices may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company to provide to the Offices, upon request, any document, record or other tangible evidence about which the Offices may inquire of the Company including evidence that is responsive to any requests made prior to the execution of this Agreement.

b. Upon request of the Offices, the Company shall designate knowledgeable employees, agents or attorneys to provide to the Offices the information and materials described in Paragraph 5(a) above on behalf of the Company. It is further understood that the Company must at all times provide complete, truthful, and accurate information.

c. The Company shall use its best efforts to make available for interviews or testimony, as requested by the Offices, present or former officers, directors, employees, agents and consultants of the Company. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with domestic or foreign law enforcement and regulatory authorities. Cooperation under this Paragraph shall include identification of witnesses who, to the knowledge of the Company, may have material information regarding the matters under investigation.

d. With respect to any information, testimony, documents, records or other tangible evidence provided to the Offices pursuant to this Agreement, the Company consents to any and all disclosures, subject to applicable laws and regulations, to other governmental authorities, including United States authorities and those of a foreign government of such materials as the Offices, in their sole discretion, shall deem appropriate.

6. In addition to the obligations in Paragraph 5, during the Term, should the Company learn of any evidence or allegation of violations of the U.S. fraud laws or violations of the federal Food, Drug, and Cosmetic Act's adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i, the Company shall promptly report such evidence or allegation to the Offices.

Payment of Monetary Penalty

7. The Offices and the Company agree that application of the United States Sentencing Guidelines ("USSG" or "Sentencing Guidelines") to determine the applicable fine range yields the following analysis:

a. The November 1, 2025 USSG are applicable to this matter.

b. Offense Level. Based upon USSG § 2B1.1, the total offense level is 26, calculated as follows:

Offense Level		
Guideline Subsection	**Description**	**Score**
§ 2N2.1(c)(1); 2B1.1	Base Offense Level	6
§ 2B1.1(b)(1)(J)	Profit exceeding $3,500,000 but Not More than $9,500,000	+18
§ 2B1.1(b)(16)	Offense involved conscious/reckless risk of death or serious bodily injury	+2
TOTAL OFFENSE LEVEL		=26

c. Pursuant to USSG § 8C2.4(a)(1), the base fine is $6,500,000 (the fine indicated in the Offense Level Fine Table)

d. Based upon USSG § 8C2.5, the culpability score is 4, calculated as follows:

Culpability Score		
Guideline Subsection	**Description**	**Score**
§ 8C2.5(a)	Start with 5 points	5
§ 8C2.5(b)(5)	Organization had 10 or more employees and an individual within substantial authority personnel participated in, condoned, or was willfully ignorant of the offense	+1
§ 8C2.5(g)(2)	Organization fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct	–2
TOTAL		4

e. Under U.S.S.G. § 8C2.6, a culpability score of four results in a fine multiplier range of .8 to 1.6. Therefore the fine range is $5,200,000 to $10,400,000.

8. The Offices and the Company agree, based on the application of the Sentencing Guidelines, that the appropriate criminal penalty is $4,160,000. This reflects a 20 percent discount off the bottom of the Sentencing Guidelines fine range.

9. Consistent with the Criminal Division's policy on Evaluating a Business Organization's Inability to Pay a Criminal Fine or Criminal Monetary Penalty, despite agreeing that a larger amount otherwise would be appropriate based on the law and the facts, the Company also made representations to the Offices, and provided supporting evidence, that the Company has an inability to pay the criminal penalty. Based on those representations, the Offices, with the assistance of a forensic accounting expert, conducted an independent inability-to-pay analysis, considering a range of factors outlined in the Justice Department's Inability to Pay Guidance (*see* October 8, 2019 Memorandum from Assistant Attorney General Brian Benczkowski to All Criminal Division Personnel re: Evaluating a Business Organization's Inability to Pay a Criminal Fine or Criminal Monetary Penalty), including but not limited to: (i) the factors outlined in 18 U.S.C. § 3572 and the United States Sentencing Guidelines § 8C3.3(b); (ii) the Company's current financial condition; and (iii) the Company's alternative sources of capital. Based on that independent analysis, the Offices determined that paying a criminal penalty greater than $750,000 would substantially threaten the continued viability of the Company.

10. The Company agrees to pay a monetary penalty in the amount of $750,000. The Company and the Offices agree that $750,000 is appropriate given the facts and circumstances of this case, including the factors described in Paragraph 4 and those in Title 18, United States Code, Section 3553(a). No later than ten days after the filing of the Information, the Company shall establish an escrow account into which, within 60 days, it shall deposit $750,000 (the "Escrow

Amount"). In the event the Company is not able to pay amounts owed, if any, in civil litigation relating to the conduct described in the Statement of Facts, the Escrow Amount shall be used to pay amounts owed in civil litigation on a pro rata basis. Thirty days prior to the end of the Term, any remainder of the Escrow Amount shall revert to the United States Treasury as a criminal monetary penalty. The $750,000 penalty is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the Offices that $750,000 is the maximum penalty that may be imposed in any future prosecution, and the Offices are not precluded from arguing in any future prosecution that the Court should impose a higher fine, although the Offices agree that under those circumstances, it will recommend to the Court that any amount paid under this Agreement should be offset against any fine the Court imposes as part of a future judgment. The Company acknowledges that no tax deduction may be sought in connection with the payment of any part of this $750,000 penalty. The Company shall not seek or accept directly or indirectly reimbursement or indemnification from any source with regard to the penalty or disgorgement amounts that the Company pays pursuant to this Agreement or any other agreement entered into with an enforcement authority or regulator concerning the facts set forth in the Statement of Facts.

Forfeiture

11. As a result of the Company's conduct, including the conduct set forth in the Statement of Facts, the parties agree the Offices could institute a civil and/or criminal forfeiture action against certain funds held by the Company and that such funds would be forfeitable pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7). The Company hereby admits that the facts set forth in the Statement of Facts establish that $5,694,750, representing the proceeds traceable to the commission of the offense, is forfeitable to the United States (the "Forfeiture

Amount"). In the event that the Offices later determine the Company's financial condition changes and the Offices institute civil or criminal forfeiture proceedings, the Company agrees that this Agreement and the Statement of Facts may be attached to and incorporated into any forfeiture filing. The Company further agrees to consent to entry of all orders of forfeiture for the Forfeiture Amount and to refrain from filing any claim with the Court, any petitions for remission, restoration, or any other assertion of ownership or request for return relating to the Forfeiture Amount. The Company agrees to assist fully in the forfeiture of the Forfeiture Amount; to promptly take all steps necessary to pass clear title to the Forfeiture Amount to the United States; to sign any additional documents necessary to complete forfeiture of the Forfeiture Amount; and not to assist any third party in asserting a claim to the Forfeiture Amount. The Company further agrees to waive all constitutional, legal, and equitable challenges to the seizure, restraint, and forfeiture of the Forfeiture Amount, including but not limited to notice, statute of limitations, and venue.

12. Any portion of the Forfeiture Amount that is paid is final and shall not be refunded should the Offices later determine that the Company has breached this Agreement and commence a prosecution against the Company. In the event of a breach of this Agreement and subsequent prosecution, the Offices are not limited to the Forfeiture Amount. The Offices agree that in the event of a subsequent breach and prosecution, they will recommend to the Court that the amounts paid pursuant to this Agreement be offset against whatever forfeiture the Court shall impose as part of its judgment. The Company understands that such a recommendation will not be binding on the Court.

Conditional Release from Liability

13. Subject to Paragraph 20, the Offices agree, except as provided in this Agreement, that they will not bring any criminal or civil case against the Company relating to any of the conduct described in the Statement of Facts or the criminal Information filed pursuant to this Agreement. The Offices, however, may use any information related to the conduct described in the Statement of Facts against the Company: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

a. This Agreement does not provide any protection against prosecution for any future conduct by the Company, or any of its subsidiaries or affiliates.

b. In addition, this Agreement does not provide any protection against prosecution of any individuals, regardless of their affiliation with the Company, or any of its subsidiaries or affiliates.

Corporate Compliance Program

14. The Company represents that it has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of U.S. fraud laws and the federal Food, Drug, and Cosmetic Act's adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i, throughout its operations, including those of its affiliates, agents, and joint ventures, and those of its contractors and subcontractors whose responsibilities pertain in any way to the Company's medical device(s), including, but not limited to, the minimum elements set forth in Attachment C.

15. In order to address any deficiencies in its internal controls, policies, and procedures, the Company represents that it has undertaken, and will continue to undertake in the future, in a manner consistent with all of its obligations under this Agreement, a review of its existing internal controls, policies, and procedures regarding compliance with U.S. fraud laws and the federal Food, Drug, and Cosmetic Act's adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i. Where necessary and appropriate, the Company agrees to adopt a new compliance program, or to modify its existing one, including internal controls, compliance policies, and procedures in order to ensure that it maintains: (a) an effective system of internal controls designed to ensure the making and keeping of fair and accurate records; and (b) a rigorous anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance program that incorporates relevant internal controls, as well as policies and procedures designed to effectively detect and deter violations U.S. fraud laws and federal Food, Drug, and Cosmetic Act adverse event reporting law. The compliance program, including the internal controls system will include, but not be limited to, the minimum elements set forth in Attachment C.

Corporate Compliance Reporting

16. The Company agrees that it will report to the Offices annually during the Term regarding remediation and implementation of the compliance measures described in Attachment C. These reports will be prepared in accordance with Attachment D.

17. On the date the Term expires, the Company, by the Chief Executive Officer and Chief Compliance Officer, will certify to the Offices, in the form of executing the document attached as Attachment F to this Agreement, that the Company has met its compliance obligations pursuant to this Agreement. Each certification will be deemed a material statement and

representation by the Defendant to the executive branch of the United States for purposes of Title 18, United States Code, Sections 1001 and 1519, and it will be deemed to have been made in the judicial district in which this Agreement is filed.

Deferred Prosecution

18. In consideration of the undertakings agreed to by the Company herein, the Offices agree that any prosecution of the Company for the conduct set forth in the Statement of Facts be and hereby is deferred for the Term. To the extent there is conduct disclosed by the Company that is not set forth in the Statement of Facts, such conduct will not be exempt from further prosecution and is not within the scope of or relevant to this Agreement.

19. The Offices further agree that if the Company fully complies with all of its obligations under this Agreement, the Offices will not continue the criminal prosecution against the Company described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire. Within six months after the Agreement's expiration, the Offices shall seek dismissal with prejudice of the criminal Information filed against the Company described in Paragraph 1, and agrees not to file charges in the future against the Company based on the conduct described in this Agreement and the Statement of Facts. If, however, the Offices determine during this six-month period that the Company breached the Agreement during the Term, as described in Paragraph 20, the Offices' ability to extend the Term, as described in Paragraph 3, or to pursue other remedies, including those described in Paragraphs 20-23, remains in full effect.

Breach of the Agreement

20. If, during the Term, the Company (a) commits any felony under U.S. federal law; (b) provides in connection with this Agreement deliberately false, incomplete, or misleading

information, including in connection with its disclosure of information about individual culpability; (c) fails to cooperate as set forth in Paragraphs 5 and 6 of this Agreement; (d) fails to implement a compliance program as set forth in Paragraphs 14-15 of this Agreement and Attachment C; (e) commits any acts that, had they occurred within the jurisdictional reach of U.S. fraud laws or the federal Food, Drug, and Cosmetic Act adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i, would be a violation of U.S. fraud laws or the federal Food, Drug, and Cosmetic Act adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i; or (f) otherwise fails to completely perform or fulfill each of the Company's obligations under the Agreement, regardless of whether the Offices become aware of such a breach after the Term is complete, the Company shall thereafter be subject to prosecution for any federal criminal violation of which the Offices have knowledge, including, but not limited to, the charges in the Information described in Paragraph 1, which may be pursued by the Offices in the U.S. District Court for the District of Massachusetts or any other appropriate venue. Determination of whether the Company has breached the Agreement and whether to pursue prosecution of the Company shall be in the Offices' sole discretion. Any such prosecution may be premised on information provided by the Company or its personnel. Any such prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the Offices prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against the Company, notwithstanding the expiration of the statute of limitations, between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution that is not time-barred on

the date of the signing of this Agreement shall be tolled for the Term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Offices are made aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

21. In the event the Offices determine that the Company has breached this Agreement, the Offices agree to provide the Company with written notice of such breach prior to instituting any prosecution resulting from such breach. Within thirty days of receipt of such notice, the Company shall have the opportunity to respond to the Offices in writing to explain the nature and circumstances of such breach, as well as the actions the Company has taken to address and remediate the situation, which explanation the Offices shall consider in determining whether to pursue prosecution of the Company. The parties expressly understand and agree that if the Company fails to make the above-noted presentation within such period, it shall be presumed that the Company is in willful and material breach of this Agreement. The parties further understand and agree that the Offices' exercise of discretion under this paragraph is not subject to review in any court or tribunal outside the Department of Justice and the Offices.

22. In the event that the Offices determine that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company to the Offices or to the Court, including the Statement of Facts, and any testimony given by the Company before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any

and all criminal proceedings brought by the Offices against the Company; and (b) the Company shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer or employee, or any person acting on behalf of, or at the direction of, the Company, will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the Offices.

23. The Company acknowledges that the Offices have made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company breaches this Agreement and this matter proceeds to judgment. The Company further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

24. On the date that the period of deferred prosecution specified in this Agreement expires, the Company, by the Chief Executive Officer of the Company and the Chief Financial Officer of the Company, will certify to the Offices in the form of executing the document attached as Attachment E to this Agreement that the Company has met its disclosure obligations pursuant to Paragraph 6 of this Agreement. Each certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of 18 U.S.C. §§ 1001 and 1519, and it will be deemed to have been made in the judicial district in which this Agreement is filed.

Sale, Merger, or Other Change in Corporate Form of Company

25. Except as may otherwise be agreed by the parties in connection with a particular transaction, the Company agrees that in the event that, during the Term, it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's consolidated operations, or to the operations of any subsidiaries or affiliates involved in the conduct described in the Statement of Facts, as they exist as of the date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the Offices' ability to determine a breach under this Agreement is applicable in full force to that entity. The Company agrees that the failure to include these provisions in the transaction will make any such transaction null and void. The Company shall provide notice to the Offices at least thirty (30) days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The Offices shall notify the Company prior to such transaction (or series of transactions) if they have determined that the transaction or transactions will have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined in the sole discretion of the Offices. If at any time during the Term the Company engages in a transaction(s) that has the effect of circumventing or frustrating the enforcement purposes of this Agreement, the Offices may deem it a breach of this Agreement pursuant to Paragraphs 20-23 of this Agreement. Nothing herein shall restrict the Company from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from

any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the Offices. Notwithstanding the foregoing, based on the individual facts and circumstances of this case, including the considerations set forth in Paragraph 4, including that the Company has only minimal remaining operations, in the event that the Company is acquired by an independent third party that is not under the control of any current or former executive, officer, member of the board of directors, or an investor holding more than 1% of the Company's outstanding shares on a diluted basis (a "Third Party"), the Offices and the Company agree that the Corporate Compliance Program and Corporate Compliance Reporting obligations set forth in Paragraphs 14-17 shall not be binding on, and shall not be deemed to apply in any manner whatsoever to, a Third Party or any of its affiliates, including but not limited to, a Third Party who acquires the Company through a reorganization transaction under a chapter 11 plan under the Bankruptcy Code (11 U.S.C. §§ 101, *et seq.*), or through a purchase of any of the Company's assets whether under the Bankruptcy Code or otherwise.

Public Statements

26. The Company expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents or any other person authorized to speak for the Company make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company set forth above or the facts described in the Statement of Facts. Any such contradictory statement shall, subject to cure rights of the Company described below, constitute a breach of this Agreement, and the Company thereafter shall be subject to prosecution as set forth in Paragraphs 20-23 of this Agreement. The decision whether any public statement by any such

person contradicting a fact contained in the Statement of Facts will be imputed to the Company for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Offices. If the Offices determine that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the Offices shall so notify the Company, and the Company may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. The Company shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. This Paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of the Company in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of the Company.

27. The Company agrees that if it or any of its direct or indirect subsidiaries or affiliates issues a press release or holds any press conference in connection with this Agreement, the Company shall first consult with the Offices to determine (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Offices and the Company; and (b) whether the Offices have any objection to the release.

28. The Offices agree, if requested to do so, to bring to the attention of law enforcement and regulatory authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of the Company's cooperation and remediation. By agreeing to provide this information to such authorities, the Offices are not

agreeing to advocate on behalf of the Company, but rather are agreeing to provide facts to be evaluated independently by such authorities.

Limitations on Binding Effect of Agreement

29. This Agreement is binding on the Company and the Offices but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, or any other authorities, although the Offices will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company. If the court refuses to grant exclusion of time under the Speedy Trial Act, 18 U.S.C. § 3161(h)(2), all the provisions of this Agreement shall be deemed null and void, and the Term shall be deemed to have not begun, except that the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts shall be tolled from the date on which this Agreement is signed until the date the Court refuses to grant the exclusion of time plus six months, and except for the provisions contained within Paragraph 2 of this Agreement.

Notice

30. Any notice to the Offices under this Agreement shall be given by electronic mail and/or personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to Jacob Foster, Deputy Chief, Health Care Fraud Unit, Fraud Section, Criminal Division, United States Department of Justice, 1400 New York Avenue Northwest, Washington, D.C. 20005; and to Chief, Health Care Fraud Unit, U.S. Attorney's Office for the District of Massachusetts, John Joseph Moakley Federal Courthouse, One Courthouse Way, Boston, MA 02210. Any notice to the Company under this Agreement shall be given by personal

delivery, overnight delivery by a recognized delivery service, or registered or certified mail, with copies by electronic mail, addressed to Robert Ward, ExThera Medical Corporation, 757 Arnold Dr. B, Martinez, CA 94553 and Seth Ducharme, Bracewell LLP, 31 W. 52nd Street, Suite 1900, New York, NY, 10019-6118. Notice shall be effective upon actual receipt by the Fraud Section and the Office or the Company.

Complete Agreement

31. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company and the Offices. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the Offices, the attorneys for the Company and a duly authorized representative of the Company.

AGREED:

FOR EXTHERA MEDICAL CORPORATION:

Date: March 5, 2026

By: _____
Robert Ward
Chairman and President
ExThera Medical Corporation

Date: March 5, 2026

By: _____
Seth D. Ducharme
Bracewell LLP

FOR THE DEPARTMENT OF JUSTICE:

Lorinda I. Laryea
Chief, Fraud Section
Criminal Division
United States Department of Justice

Date: 3/5/26

BY: _____
Kevin P. Lowell
William E. Schurmann
Assistant Chiefs
John W. Howard
Sarah W. Rocha
Trial Attorneys

Leah B. Foley
United States Attorney

Date: 3/5/26

BY: _____
William F. Abely
Chief, Criminal Division
Mackenzie A. Queenin
Chief, Health Care Fraud Unit
Sarah B. Hoefle
Assistant United States Attorney

COMPANY OFFICER'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for EXTHERA MEDICAL CORPORATION (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

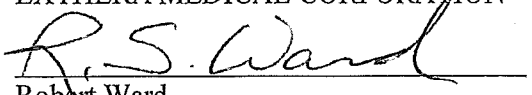
I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have advised and caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Chairman and President of the Company and that I have been duly authorized by the Company to execute this Agreement on behalf of the Company.

Date:

March 5, 2026

EXTHERA MEDICAL CORPORATION

By: 

Robert Ward
Chairman and President

CERTIFICATE OF COUNSEL

I am counsel for EXTHERA MEDICAL CORPORATION (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement with the Company Board of Directors. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of the Company has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of this Agreement with the Board of Directors and the general counsel of the Company. I have fully advised them of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: March 5, 2026

By: Seth D. Ducharme

Seth D. Ducharme
Bracewell LLP
Counsel for ExThera Medical Corporation

STATEMENT OF FACTS

The following Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (the "Agreement") between the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section"), the United States Attorney's Office for the District of Massachusetts (the "Office") (collectively, the "Offices"), and the defendant ExThera Medical Corporation ("ExThera" or the "Company"). ExThera hereby agrees and stipulates that the following information is true and accurate. ExThera admits, accepts, and acknowledges that it is responsible for the acts of its former officers, directors, employees, and agents as set forth below. Should the Fraud Section and the Office pursue the prosecution that is deferred by the Agreement, ExThera agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The following facts establish beyond a reasonable doubt the charges set forth in the criminal Information attached to this Agreement.

I. Overview

1. ExThera, a Northern California-based medical technology company and device manufacturer, secured an exclusive agreement with a private medical device distribution company (the "Distributor"). Distributor and/or its affiliates used ExThera's blood filtration device (the "Device") on end stage cancer patients at a medical clinic in Antigua (the "Antigua Clinic"). Throughout in or around 2024, cancer patients and their families traveled from the United States to the Antigua Clinic believing that the Device may help treat their own or their loved ones' cancer. Some patients or their families reported that the patients suspended chemotherapy or delayed starting chemotherapy to undergo treatment with the Device. The Device had not—and to this day

has never—obtained full U.S. Food & Drug Administration ("FDA") approval or clearance for any condition.[1]

2. At the time it undertook a business relationship with the Distributor, ExThera had never been profitable despite receiving financing of more than $70 million. The exclusive distribution agreement that ExThera secured with the Distributor delivered an immediate $10 million cash payment to ExThera, generating excitement among management and investors. According to its own financial projections, ExThera could generate up to an additional $150 million in revenue from its partnership with the Distributor and distribution of the Device to Antigua and other offshore locations.

3. At the time of ExThera's distribution agreement with the Distributor, Sanja Ilic ("Ilic"), then ExThera's Chief Regulatory Officer, was responsible for ensuring that ExThera complied with United States laws and regulations enforced by the FDA. Among other things, Ilic was responsible for reporting adverse events to the FDA. Adverse events included instances in which a medical device, for example, may have caused or contributed to serious injury or death of a person. Critically, the FDA relied on adverse event reports filed by companies to protect the public from potentially harmful and dangerous products or medical devices. In the event that a medical technology company, such as ExThera, concealed adverse events from the FDA, it would undermine the FDA's ability to protect Americans from potentially dangerous medical devices.

4. Just prior to the start of the treatments at the Antigua Clinic, in December 2023, Ilic circulated an email to some of ExThera's leadership and regulatory staff titled, "Potential Device-

[1] However, as described in more detail below, ExThera had received an Emergency Use Authorization ("EUA") from the FDA to treat certain patients with confirmed COVID-19 infections and had also obtained Investigational Device Exemptions allowing for certain limited clinical study uses, including treating sepsis and a certain form of pancreatic cancer. The Device had also been approved in Europe for the removal of blood-borne pathogens.

Related Adverse Events." In that email, Ilic provided a list of potential adverse events, including potentially "life-threatening" complications, that patients could experience from use of the Device. As described below, at least some of the patients at the Antigua Clinic and their treating physicians reported that they believed those patients had subsequently experienced some of these medical events after being filtered with the Device.

5. While treatments were being administered at the Antigua Clinic, Ilic learned contemporaneously of patients developing serious health conditions and/or dying soon after they were treated with the Device. Ilic specifically learned of the declining health and deaths of at least two patients who died within days of each other in and around April 2024.

6. During her tenure as Chief Regulatory Officer of ExThera, Ilic did not report the declining health and two deaths to the FDA, or alternatively, document any findings that these events were unrelated to the Device, though she was required to take one of those courses of action under the FDA's regulations and ExThera's own policies and procedures.

7. Ilic intentionally concealed the declining health and deaths of the two American patients with the specific intent to defraud and mislead the FDA. Ilic understood that disclosure would have triggered regulatory scrutiny from the FDA, caused clinical trial partners to potentially withdraw their participation, and jeopardized ExThera's and Ilic's potential, future financial prospects. Rather than comply with her legal obligation to report the events (or document medical findings that the declining health and deaths were unrelated to the Device), Ilic chose to suppress this critical information to defraud and mislead the FDA and keep the agency unaware of these adverse events.

II. Relevant Agencies, Entities, and Individuals

8. The FDA played a critical role in protecting the health and safety of the American public by ensuring that, among other things, medical devices intended for use in the treatment of human beings were safe and effective.

9. ExThera was a Delaware corporation with its principal place of business in Martinez, California. ExThera was a medical device manufacturer and, as such, was fully subject to the FDA's comprehensive oversight and regulatory requirements. Among other things, ExThera was required to promptly report to the FDA any adverse events involving its devices where the device may have caused or contributed to serious death or injury.

10. Ilic was employed by ExThera in or around November 2021 through January 2025. During 2024 through her termination from ExThera in January 2025, Ilic was the Chief Regulatory Officer, as well as Vice President of Regulatory Affairs, Vice President of Clinical Affairs, and Vice President of Medical Affairs. Ilic was a salaried employee and held stock options in ExThera that linked her own future financial prospects to ExThera's.

11. Private Equity Firm referred to a group of affiliated entities (including Distributor) organized and existing under the laws of the Delaware, the British Virgin Islands, and elsewhere, and with principal places of business in New York, Florida, and elsewhere.

12. Consulting Entity was a limited liability company operating as a consulting firm with a business address in Carlsbad, California—the same address as Ilic's home address. Ilic owned and controlled Consulting Entity.

13. Executive 1 was the Director of Medical Affairs and subsequently the Vice President of Medical Affairs for ExThera. Executive 1 resigned from ExThera on or about June 3, 2024.

14. Executive 2 had a long-standing relationship with Private Equity Firm and was a member of ExThera's Board of Directors until on or about September 9, 2024. Executive 2 was involved in fostering the relationship between Private Equity Firm and ExThera.

15. Patient 1 was a resident of Panama City, Florida, who was diagnosed with Stage III esophageal cancer in or around March 2022. Patient 1 passed away on or about April 18, 2024.

16. Family Member 1 was the spouse of Patient 1. Family Member 1 had a background in nursing and maintained a multi-state registered nurse license. For 25 years she worked in occupational health for the roofing company she started with her husband, Patient 1.

17. Individual 1 was a physician based in the United States.

18. Patient 2 was diagnosed with Stage IV liposarcoma in or around December 2023. Patient 2 passed away on April 19, 2024.

19. Family Member 2 was the spouse of Patient 2. Family Member 2 was a registered nurse who previously worked in pediatrics.

20. Individual 2 was a physician based in the United States.

III. Relevant Laws and Regulations

21. The Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations provided a mechanism that allowed the FDA and others to identify and monitor adverse events (deaths and serious injuries) and certain malfunctions involving medical devices. *See* 21 U.S.C. §§ 331(q)(1)(B), 360i; 21 C.F.R. Part 803—Medical Device Reporting. Specifically, the FDCA prohibited the failure or refusal to furnish any notification or other material or information required by or under 21 U.S.C. § 360i, pursuant to 21 U.S.C. § 331(q)(1)(B).

22. Pursuant to 21 U.S.C. § 360i(a) and 21 C.F.R. Part 803, medical device manufacturers were required to (1) develop, maintain, and implement written procedures for the

identification and evaluation of all malfunctions, serious injuries, and deaths to determine whether a Medical Device Report ("MDR") was required for an event; (2) submit MDR reportable events involving their medical devices to the FDA; and (3) establish and maintain complete files for all MDR events. These requirements applied to all manufacturers of medical devices in the United States, regardless of where in the world the device is used.

23. MDRs were one of the post-market surveillance tools that the FDA used to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of devices.

24. Manufacturers were required to file an MDR with the FDA within thirty (30) days of receiving or otherwise becoming aware of information that reasonably suggested that a device the manufacturer marketed (a) may have caused or contributed to a death or serious injury or (b) had malfunctioned and the device or a similar device the manufacturer marketed would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.20(b)(3); 21 C.F.R. § 803.50(a). Such reports were referred to as "initial reports." Manufacturers were required to submit relevant information that was "reasonably known" to it, including information that could be obtained by contacting a user facility, importer, or other initial reporter, 21 C.F.R. § 803.50(b)(1)(i), information that was in its possession, 21 C.F.R. § 803.50(b)(1)(ii), and information that it could obtain by analysis, testing, or other evaluation of the device, 21 C.F.R. § 803.50(b)(1)(iii).

25. The standard for filing an adverse event report was low. The applicable regulations required a report of "any information, including professional, scientific, or medical facts, observations, or opinions, [that] may reasonably suggest that a device has caused or may have caused or contributed to . . . a death, a serious injury, or . . . a malfunction that would be likely to

cause or contribute to a death or serious injury if the malfunction were to recur." 21 C.F.R. § 803.20(c)(1).

26. Manufacturers who subsequently obtained information about the event that was not known or was not available when the initial report was submitted, but which would have been required to be submitted as part of the initial report had that additional information been known or available, were required to file a supplemental report or "supplemental MDR" with the FDA within thirty (30) days of receiving the additional information. 21 C.F.R. § 803.10(c)(3); 21 C.F.R. § 803.50(b)(3).

27. Manufacturers had additional duties in connection with these requirements. They were responsible for obtaining and submitting to the FDA information that was incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. 21 C.F.R. § 803.50(b)(2). And they were responsible for conducting an investigation of each event and evaluating the cause of each event. 21 C.F.R. § 803.50(b)(3). If a manufacturer could not submit complete information that was not available at the time it filed its initial report, it was required to provide a statement explaining why this information was incomplete and the steps it took to obtain the information. 21 C.F.R. § 803.50(b)(3). If the manufacturer later obtained any required information that was not available at the time it filed its initial report, it was required to submit this information in a supplemental report under the applicable regulations. 21 C.F.R. § 803.50(b)(3).

28. Not all events needed to be reported to the FDA. A manufacturer did not have to report an adverse event if it had information that would lead a person who was qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to have caused or contributed to a death or serious injury if it were to recur. 21 C.F.R. § 803.20(c)(2). Persons qualified to make a medical

judgment included physicians, nurses, risk managers, and biomedical engineers. 21 C.F.R. § 803.20(c)(2). However, the manufacturer was required to keep in its MDR event files (described in 21 C.F.R. § 803.18) the information that the qualified person used to determine whether or not an event was reportable. 21 C.F.R. § 803.20(c)(2).

29. Adverse events that were reported to the FDA were also published in the FDA's Manufacturer and User Facility Device (MAUDE) Database. The MAUDE Database allowed patients, medical providers, and other members of the public to learn about adverse events.

IV. ExThera's Blood Filtering Device

30. ExThera developed and manufactured the Device that removed pathogens from the bloodstream of patients. The Device was designated a "Class III" device, which was the FDA's highest risk category for human use. The Device worked in tandem with a dialysis machine, which pumped blood from a patient through a cylinder to be filtered of pathogens before returning to the patient's body. ExThera had not obtained FDA premarket approval for commercial distribution of the Device or use on patients in the United States. Depending on its intended use and labeling, the Device had multiple names, including the Seraph® 100 Microbind® Affinity Blood Filter (Seraph 100) and the ONCObind™ Procedure Hemoperfusion Filter.

31. In April 2020, ExThera received an Emergency Use Authorization ("EUA") from the FDA to treat certain patients with confirmed COVID-19 infections who were (i) "admitted to the intensive care unit (ICU) with" (ii) "confirmed or imminent respiratory failure." The FDA's EUA for the Device reflected conclusions that the Device "may be effective at treating certain patients with confirmed COVID-19" and "may provide clinical benefit." The EUA expressly prohibited ExThera from stating or suggesting that the Device was "safe or effective for the prevention and treatment of COVID-19." ExThera agreed to withdraw the EUA in or around

October 2025. ExThera also obtained Investigational Device Exemptions allowing for certain limited clinical study uses, including treating sepsis and a certain form of pancreatic cancer. In Europe, the Device had received CE mark authorization for removal of blood-borne pathogens.

Background

32. Distributor and its affiliates established a clinic in Antigua to treat patients using the Device, including patients with cancer. The first treatments were provided in or around early/mid-January 2024.

33. In and around December 2023, Private Equity Firm obtained equity in ExThera, and ExThera and the Distributor entered into a distribution agreement under which the Distributor would purchase Devices, including through an upfront payment of $10 million, $3,676,111.93 of which was returned by ExThera when the parties' agreement was terminated in October 2024.

34. When the Antigua Clinic first opened in and around January 2024, ExThera personnel, including Ilic, traveled to the site to train clinic personnel and observe the use of the Device on American cancer patients. ExThera personnel—including Ilic—also spoke directly with patients and their family members about treatments with the Device, as well as with physicians who referred those patients to the Antigua Clinic.

35. Some patients, many of whom were United States residents, agreed to pay, and did pay, up to approximately $45,000 to Distributor per trip for treatment with the Device.

Adverse Events

36. Although Ilic knew and understood the requirements for adverse event reporting, she intentionally failed to report adverse events associated with the Device for patients treated at the Antigua Clinic.

A. Ilic's Background and Knowledge

37. As part of her job duties and responsibilities as the Chief Regulatory Officer, Vice President of Regulatory, Clinical, and Medical Affairs, Ilic was tasked with ensuring that ExThera's products complied with the regulations of the FDA.

38. For example, ExThera's Medical Device Reporting Policy identified the Vice President of Regulatory and Clinical Affairs as the responsible official for evaluating adverse events or complaints against appropriate logic trees, determining whether an event was reportable, and if so, completing and submitting the appropriate reports.

39. Ilic worked for more than twenty years in regulatory affairs, clinic development and full product life cycle management. She described herself as an internationally recognized expert in the field of regulatory and clinical development strategy.

40. Ilic had been credentialed with a Regulatory Affairs Certification (RAC) since 2004 and was recertified multiple times.

41. During 2024, including while patients were being treated at the Antigua Clinic, Ilic was directly involved in advancing a U.S.-based clinical research study into the use of the Device in patients with cancer. That clinical study was permitted under an Investigational Device Exemption issued by the FDA on or about July 13, 2023. The clinical study required oversight by the FDA, as well as oversight and approval by the U.S. clinical cancer center hosting the study.

42. Shortly before the Antigua Clinic began to treat patients with the Device, when experience with the Device in cancer patients was limited, Ilic documented her knowledge about potential Device-related adverse events in an email to some members of ExThera senior management. On or about December 18, 2023, she explained in an email how side effects and/or adverse reactions could theoretically occur during use of the Device itself, as well as other related

procedures. These potential events included hypersensitivity reactions, hypotension, anemia/decreased hematocrit, hypovolemia, thrombocytopenia, cardiac dysrhythmia, hemolysis, hematoma formation at the venipuncture site, chest pain, and dyspnea. Patients, including Patient 1 and Patient 2, or their family members, reported that they experienced some of these medical events after being filtered with the Device at the Antigua Clinic.

43. Nevertheless, despite her experience, training, and knowledge of FDA adverse event reporting, Ilic did not properly address potentially reportable adverse events, including the deaths of two patients treated with the Device at the Antigua Clinic.

B. Ilic Concealed Patient 1's Post Filtration Experiences and Death from the FDA

44. Despite repeated contact with Family Member 1 over several months about Patient 1's status and issues related to Patient 1's treatment, Ilic intentionally failed to notify the FDA regarding adverse events following Patient 1's use of the Device at the Antigua Clinic. Among other events, Ilic intentionally failed to report to the FDA Patient 1's death, acting with intent to defraud and mislead the agency.

i. Ilic Learned of Patient 1's Negative Experiences

45. On or about February 7, 2024, Family Member 1 began communicating with Ilic about using the Device to treat Patient 1, who was battling advanced cancer.

46. After speaking with Ilic, Patient 1 and Family Member 1 traveled to Antigua for filter treatments in February 2024. Patient 1 received filter treatments between on or about February 28, 2024, and March 3, 2024.

47. Following the procedures, Family Member 1 updated Ilic about Patient 1's status, explaining that Patient 1 "felt worse" and experienced "more pain" in the first week following treatment at the Antigua Clinic.

48. Ilic told Family Member 1 that Patient 1 was feeling worse because the filtering at the Antigua Clinic had caused "strong immune activation"—*i.e.*, it was effective—and that increases in cancer detection testing indicated cancer die-off. Family Member 1 sent subsequent text messages in and around March 2024 to Ilic informing her that Patient 1's tumor markers were increasing and that Patient 1 "continued to feel bad." In addition, Family Member 1 told Ilic that Patient 1 had a "severe pleural effusion" and was "extremely short of breath." Family Member 1 continued to provide information to Ilic on Patient 1's bloodwork and reports.

49. On or about March 13, 2024, Individual 1 emailed Executive 2 seeking additional information stating, "I am worried that two of my patients are getting worse after their filter treatment and I don't have enough information to deliver optimal care to those patients." Executive 2 forwarded this email to Ilic and others, stating Individual 1 "is worried that both patients are showing evidence that the cancer is spreading and is considering [the] best path forward on their treatment."

50. On or about March 14, 2024, Family Member 1 texted Ilic stating, "[Family Member 1] wanted to ask [Ilic] about tumor markers. [Patient 1's] CEA [which is a carcinoembryonic antigen, a protein that can be found in higher amounts in individuals with certain types of cancer] before filtering was 25. This week it was 338."

51. In and around late March 2024, in a telephone conversation about Patient 1's treatments, Family Member 1 asked Ilic if she was "strongly opposed to doing anything else to boost immune response like immunotherapy or chemo in between the filters." Ilic replied that "chemo will totally destroy him." Family Member 1 reported that she relied on Ilic's recommendation for Patient 1 not to use chemotherapy treatments.

52. On or about April 6, 2024, Family Member 1 updated Ilic on the procedures in Antigua. Family Member 1 wrote to Ilic that a filter had clogged and asked Ilic for her thoughts on why it clogged. Ilic advised that Patient 1 should not get any additional filtering "knowing [Patient 1's] labs from last month."

53. Approximately three days later, on or about April 9, 2024, Family Member 1 urgently wrote to Ilic, "This is an emergency and I need help. Please call me[.]" Family Member 1 sent multiple reports accompanied by the message "What does this mean??!!!!" and a sad emoji. Family Member 1 texted that Patient 1's "scan was horrible and . . . clinical picture doesn't look good." Ilic did not respond.

54. Patient 1 died on or about April 18, 2024, after returning to the United States from the Antigua Clinic because of Patient 1's deteriorating health. Family Member 1 sent Ilic a link to Patient 1's obituary on or about April 21, 2024. Ilic did not respond.

ii. Despite Awareness of Adverse Events Concerning Patient 1, Ilic Intentionally Failed to Report to FDA

55. Executive 1 reported that on or about April 26, 2024, Ilic informed Executive 1 about Patient 1's death, that Ilic and Executive 1 discussed reporting requirements to the FDA of any serious adverse events, and that Ilic refused to report, despite her awareness of Patient 1's complications and death in the United States and her knowledge and experience with adverse event reporting. Ilic similarly did not document in ExThera's MDR files any reason why she concluded Patient 1's death was not reportable pursuant to FDA requirements.

56. In 2025, following public reporting about the Device and after Ilic was terminated, ExThera filed several adverse event reports with the FDA related to Patient 1's use of the Device to treat cancer outside the United States. Among other things, ExThera reported to the FDA that Patient 1 "saw progression of . . . cancer after treatment" and aggressive tumor growth, as well as

a pleural effusion, trouble breathing, and other experiences following Patient 1's use of the Device at the Antigua Clinic.

57. When Ilic chose to conceal the death of Patient 1 from FDA, she was acting within the scope of her employment and with intent to benefit herself and ExThera.

C. Ilic Concealed Patient 2's Post Filtration Experiences and Death from the FDA

58. In March and April 2024, Ilic was also informed about Patient 2's treatment in Antigua. Despite her knowledge and awareness of Patient 2's status, Ilic failed to notify the FDA regarding adverse events following Patient 2's use of the Device at the Antigua Clinic. Among other events, Ilic intentionally failed to report to the FDA Patient 2's death, acting with intent to defraud and mislead the agency.

i. Ilic Learned of Patient 2's Negative Experiences

59. Patient 2 was diagnosed with liposarcoma in and around December 2023. According to Family Member 2, Patient 2's initial treatment plan was to try conventional chemotherapy and radiation treatment, with a plan to begin radiation on or about January 5, 2024, to attempt to shrink a tumor and relieve pain, followed by chemotherapy to begin on or about January 25, 2024. But in and around January 2024, Patient 2 and Family Member 2 learned of the Device and decided to try it.

60. Patient 2's filter treatment timeline was pushed back multiple times. When they arrived at the clinic in Antigua on or about February 21, 2024, Family Member 2 stated that the treatment center was run down, had paint peeling down the walls, and dimly lit. Family Member 2 reported that Patient 2 underwent filtration using the Device three times over the next several days.

61. Individual 2, the United States-based physician handling Patient 2's care, was in contact with Ilic and others about Patient 2's status.

62. Individual 2 wrote an email to Ilic on or about April 15, 2024. In the message, Individual 2 reported that Patient 2 was "doing very poorly, quite critical condition" and "decided to be comfortable." Individual 2 passed on a message from Patient 2's father, stating that, among other things, Patient 2's internist reported Patient 2 was experiencing tumor lysis syndrome, a potentially life-threatening complication of cancer treatment. Patient 2's father stated that Patient 2's "heart was also acting up with really high brats to compensate for the really low blood pressure," had left leg pain, and was put on oxygen.

63. Later that day, Individual 2 sent an email to Ilic and others. Individual 2 reported that the tumor was "50% larger" and Patient 2 moved to hospice care.

64. Patient 2 died on April 19, 2024, within days of Patient 1 passing away.

ii. Despite Awareness of Adverse Events Concerning Patient 2, Ilic Intentionally Failed to Report to FDA.

65. Despite awareness of Patient 2's deteriorating condition and death, Ilic failed to report any adverse events to the FDA. Ilic similarly did not document in ExThera's MDR files any reason why the deteriorating condition and death were not reportable pursuant to FDA requirements.

66. In 2025, following public reporting about the Device and after Ilic was terminated, ExThera filed several adverse event reports with the FDA related to Patient 2's use of the Device to treat cancer outside the United States. Among other things, ExThera reported to the FDA that Patient 2's tumor had grown significantly and that Patient 2 was diagnosed with tumor lysis syndrome following Patient 2's use of the Device at the Antigua Clinic. When Ilic chose to conceal

the death of Patient 2 from the FDA, she was acting within the scope of her employment and with intent to benefit herself and ExThera.

Financial Benefit

67. By choosing not to report the deaths of Patient 1 and Patient 2 to the FDA, Ilic intended to defraud and mislead the FDA. At the start of the Antigua Clinic, the stakes were high for both Ilic and ExThera. ExThera stood on the brink of major financial success, having just secured $10 million and the potential for millions more in future distribution agreements.

68. Around this time, Ilic was shepherding ExThera's first U.S. clinical study involving the treatment of cancer patients with the Device. This clinical trial was potentially critical not only to Ilic's and ExThera's financial future, but also to securing FDA approvals for the Device, which would have opened the door to a much larger market.

69. In addition to her salary and stock options for equity in ExThera, Ilic separately received payments from ExThera through another corporate entity under Ilic's control, which Ilic used to bill for consulting services provided to ExThera. This provided Ilic with an additional, direct financial interest in suppressing adverse event reports that could threaten this lucrative arrangement, which personally benefited Ilic. Ilic and ExThera potentially stood to lose financially if negative adverse event reports related to the Antigua Clinic were filed with the FDA.

70. Although Ilic became aware of potentially reportable adverse events relating to Patients 1 and 2 in or about March 2024, she did not take steps to report those events or otherwise evaluate them for potential reportability to the FDA. Between March 2024 and January 2025, ExThera paid Ilic approximately $661,563.48 in payroll, cash distributions, and payments to Consulting Entity, which Ilic owned and controlled.

71. In total, ExThera's sales of Devices to the Distributor between May 2024 and December 2024 totaled $6,327,500. When the agreement between the Distributor and its affiliates and ExThera was terminated in October 2024, ExThera returned $3,676,111.93 to the Distributor.

ATTACHMENT B

CERTIFICATE OF CORPORATE RESOLUTIONS

WHEREAS, EXTHERA MEDICAL CORPORATION (the "Company") has been engaged in discussions with the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section") and the United States Attorney's Office for the District of Massachusetts (the "Office") (collectively, the "Offices") regarding issues arising in relation to the failure to file adverse event reports with the intent to defraud or mislead the FDA; and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a certain agreement with the Offices; and

WHEREAS, the Company's General Counsel, together with outside counsel for the Company, have advised the Board of Directors of the Company of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Offices;

Therefore, the Board of Directors has RESOLVED that:

1. The Company (a) acknowledges the filing of the one-count Information charging the Company with one count of failure to file adverse event reports with the intent to defraud or mislead, in violation of Title 21, United States Code, Sections 331(q)(1)(B), 333(a)(2), and 360i, as well as a criminal forfeiture allegation; (b) waives indictment on such charges and enters into a deferred prosecution agreement with the Offices; and (c) agrees to accept a monetary penalty against Company totaling $750,000, and to pay such penalty to the United States Treasury with respect to the conduct described in the Information;

2. The Company accepts the terms and conditions of this Agreement, including, but not limited to, (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) a knowing waiver for purposes of this Agreement and any charges by the United States arising out of the conduct described in the attached Statement of Facts of any objection with respect to venue and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the District of Massachusetts; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to the conduct described in the attached Statement of Facts or relating to conduct known to the Offices prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement;

3. The Chairman and President of the Company, Robert Ward, is hereby authorized, empowered and directed, on behalf of the Company, to execute the Deferred Prosecution Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the Chairman and President of the Company, Robert Ward, may approve;

4. The Chairman and President of the Company, Robert Ward, is hereby authorized, empowered and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. All of the actions of the Chairman and President of the Company, Robert Ward, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: March 5, 2026

By: _____
Corporate Secretary
ExThera Medical Corporation

ATTACHMENT C

CORPORATE COMPLIANCE PROGRAM

In order to address any deficiencies in its internal controls, compliance code, policies, and procedures regarding compliance with U.S. fraud laws and the federal Food, Drug, and Cosmetic Act's adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i, EXTHERA MEDICAL CORPORATION (the "Company") agrees to continue to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, policies, and procedures.

Where necessary and appropriate, the Company agrees to modify its compliance program, including internal controls, compliance policies, and procedures in order to ensure that it maintains: (a) an effective system of internal controls designed to ensure the making and keeping of fair and accurate records; and (b) a rigorous anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance program that incorporates relevant internal controls, as well as policies and procedures designed to effectively detect and deter violations of U.S. fraud laws and the federal Food, Drug, and Cosmetic Act's adverse event reporting law (collectively, the "Subject Laws"). At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company's existing internal controls, compliance code, policies, and procedures:

Commitment to Compliance

1. The Company will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to compliance with its corporate policy against

violations of the Subject Laws, its compliance policies, and its Code of Conduct, and demonstrate rigorous support for compliance principles via their actions and words.

2. The Company will ensure that mid-level management throughout its organization reinforce leadership's commitment to compliance policies and principles and encourage employees to abide by them. The Company will create and foster a culture of ethics and compliance with the law in their day-to-day operations at all levels of the Company.

Periodic Risk Assessment and Review

3. The Company will implement a risk management process to identify, analyze, and address the individual circumstances of the Company, in particular the fraud and adverse reporting compliance risks facing the Company.

4. On the basis of its periodic risk assessment, the Company shall take appropriate steps to design, implement, or modify each element of its compliance program to reduce the risk of violations of the Subject Laws, its compliance policies, and its Code of Conduct.

Policies and Procedures

5. The Company will develop and promulgate a clearly articulated and visible corporate policy against violations of the Subject Laws, which shall be memorialized in a written compliance policy or policies.

6. The Company will develop and promulgate compliance policies and procedures designed to reduce the prospect of violations of the Subject Laws and the Company's compliance policies and Code of Conduct, and the Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures against violation of the Subject Laws by personnel at all levels of the Company. These policies and procedures shall apply

to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of the Company, including all agents and business partners. The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the company.

7. The Company will ensure that it has a system of internal controls, reasonably designed to ensure the completeness and accuracy of records pertaining to compliance with the Subject Laws.

8. The Company shall review its anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance policies and procedures as necessary to address changing and emerging risks and update them as appropriate to ensure their continued effectiveness, taking into account relevant developments in the field and evolving international and industry standards.

Independent, Autonomous, and Empowered Oversight

9. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance policies and procedures. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including internal audit, the Company's Board of Directors, or any appropriate committee of the Company's Board of Directors, and shall have an adequate level of autonomy from management as well as sufficient resources, authority, and support from senior leadership to maintain such autonomy.

Training and Guidance

10. Company will implement mechanisms designed to ensure that its Code of Conduct and anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance policies and procedures are effectively communicated to all directors, officers, employees, and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors and officers, all employees in positions of leadership or trust, positions that require such training (e.g., internal audit, sales, legal, compliance, finance), or positions that otherwise pose a fraud or federal Food, Drug, and Cosmetic Act adverse event reporting risk to the Company, and, where necessary and appropriate, agents and business partners; and (b) metrics for measuring knowledge retention and effectiveness of the training. The Company will conduct training in a manner tailored to the audience's size, sophistication, or subject matter expertise and, where appropriate, will discuss prior compliance incidents.

11. The Company will maintain, or where necessary establish, an effective system for providing guidance and advice to directors, officers, employees, and, where necessary and appropriate, agents and business partners, on complying with the Company's anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance policies and procedures, including when they need advice on an urgent basis or in any foreign jurisdiction in which the Company operates.

Confidential Reporting Structure and Investigation of Misconduct

12. The Company will maintain, or where necessary establish, an effective system for internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners concerning violations of the

Company's Code of Conduct or anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance policies and procedures and protection of directors, officers, employees, and, where appropriate, agents and business partners who make such reports.

13. The Company will maintain, or where necessary establish, an effective and reliable process with sufficient resources for responding to, investigating, and documenting allegations of violations of the Subject Laws or the Company's anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance policies and procedures.

Compensation Structures and Consequence Management

14. The Company will implement clear mechanisms amongst all directors, officers, employees, and, where necessary and appropriate, parties acting on behalf of the Company, to incentivize behavior that complies with the Company's corporate policy against violations of the Subject Laws, its compliance policies, and its Code of Conduct. These incentives shall include, but shall not be limited to, the implementation of criteria related to compliance in the Company's compensation and bonus system.

15. The Company will institute appropriate disciplinary procedures to address, among other things, violations of the Subject Laws and the Company's Code of Conduct and anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance policies and procedures by the Company's directors, officers, and employees. Such procedures should be applied consistently and fairly, regardless of the position held by, or perceived importance of, the director, officer, or employee. The Company shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are taken to prevent further similar misconduct,

including assessing the internal controls, Code of Conduct, and compliance policies and procedures and making modifications necessary to ensure the overall anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance program is effective.

Third-Party Management

16. The Company will institute appropriate risk-based due diligence and compliance requirements pertaining to the retention and oversight of all agents and business partners, including:

a. properly documented due diligence pertaining to the hiring and appropriate and regular oversight of agents and business partners;

b. informing agents and business partners of the Company's commitment to abiding by the Subject Laws, and of the Company's Code of Conduct and anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance policies and procedures; and

c. seeking a reciprocal commitment from agents and business partners.

17. The Company will engage in ongoing monitoring and risk management of third-party relationships through updated due diligence, training, audits, and/or annual compliance certifications by the third party.

18. Where necessary and appropriate, the Company will include standard provisions in agreements, contracts, and renewals thereof with all agents and business partners that are reasonably calculated to prevent violations of the Subject Laws, which may, depending upon the circumstances, include: (a) representations and undertakings relating to compliance with the Subject Laws; (b) rights to conduct audits of the books and records of the agent or business partner to ensure compliance with the foregoing; and (c) rights to terminate an agent or business partner

as a result of any breach Subject Laws, the Company's Code of Conduct or compliance policies, or procedures, or the representations and undertakings related to such matters.

Mergers and Acquisitions

19. The Company will develop and implement policies and procedures for mergers and acquisitions requiring that the Company conduct appropriate risk-based due diligence on potential new business entities, including appropriate anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting due diligence by legal, accounting, and compliance personnel.

20. The Company will ensure that the Company's Code of Conduct and compliance policies and procedures regarding the Subject Laws apply as quickly as is practicable to newly acquired businesses or entities merged with the Company and will promptly:

a. train the directors, officers, employees, agents, and business partners consistent with Paragraph 10 above on the Subject Laws and the Company's compliance policies and procedures regarding the Subject Laws;

b. where warranted, conduct an anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting -specific audit of all newly acquired or merged businesses as quickly as practicable;

c. where warranted, establish a plan to integrate the acquired businesses or entities into the Company's enterprise resource planning systems as quickly as practicable.

Monitoring and Testing

21. The Company will conduct periodic reviews and testing of all elements of its compliance program to evaluate and improve their effectiveness in preventing and detecting

violations of Subject Laws and the Company's Code of Conduct and anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance policies and procedures, taking into account relevant developments in the field and evolving international and industry standards.

22. The Company will ensure that compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing of transactions.

Analysis and Remediation of Misconduct

23. The Company will conduct a root cause analysis of misconduct, including prior misconduct, to identify any systemic issues and/or any control failures. The Company will timely and appropriately remediate the root causes of misconduct. The Company will ensure that root causes, including systemic issues and controls failures, and relevant remediation are shared with management as appropriate.

ATTACHMENT D

COMPLIANCE REPORTING REQUIREMENTS

EXTHERA MEDICAL CORPORATION (the "Company") agrees that it will report to the United States Department of Justice, Criminal Division, Fraud Section and the United States Attorney's Office for the District of Massachusetts (collectively, the "Offices") periodically. During the Term, the Company shall review, test, and update its compliance program and internal controls, policies, and procedures described in Attachment C. The Company shall be required to: (i) conduct an initial ("first") review and submit a first report and (ii) conduct and prepare at least two follow-up reviews and reports, as described below. Prior to conducting each review, the Company shall be required to prepare and submit a workplan for the review.

In conducting the reviews, the Company shall undertake the following activities, among others: (a) inspection of relevant documents, including the Company's current policies, procedures, and training materials concerning compliance with U.S. fraud laws and the federal Food, Drug, and Cosmetic Act's adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i; (b) inspection and testing of the Company's systems procedures, and internal controls, including record-keeping and internal audit procedures at sample sites; (c) meetings with, and interviews of, relevant current and, where appropriate, former directors, officers, employees, business partners, agents, and other persons; and (d) analyses, studies, and comprehensive testing of the Company's compliance program.

Written Work Plans, Reviews and Reports

a. The Company shall conduct a first review and prepare a first report, followed by at least two follow-up reviews and reports.

b. Within sixty (60) calendar days of the date this Agreement is executed, the Company shall, after consultation with the Offices, prepare and submit a written work plan to address the Company's first review. The Offices shall have thirty (30) calendar days after receipt of the written work plan to provide comments.

c. With respect to each follow-up review and report, after consultation with the Offices, the Company shall prepare a written work plan within forty-five (45) calendar days of the submission of the prior report, and the Offices shall provide comments within thirty (30) calendar days after receipt of the written work plan.

d. All written work plans shall identify with reasonable specificity the activities the Company plans to undertake to review and test each element of its compliance program, as described in Attachment C.

e. Any disputes between the Company and the Offices with respect to any written work plan shall be decided by the Offices in their sole discretion.

f. No later than one year from the date this Agreement is executed, the Company shall submit to the Offices a written report setting forth: (1) a complete description of its remediation efforts to date; (2) a complete description of the testing conducted to evaluate the effectiveness of the compliance program and the results of that testing; and (3) its proposals to ensure that its compliance program is reasonably designed, implemented, and enforced so that the program is effective in deterring and detecting violations of U.S. fraud laws and the federal Food, Drug, and Cosmetic Act's adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i. The report shall be transmitted to:

Deputy Chief – Health Care Fraud Unit
Deputy Chief – CEC Unit
Criminal Division, Fraud Section
U.S. Department of Justice

1400 New York Avenue, NW
Bond Building
Washington, DC 20005

Chief – Health Care Fraud Unit
U.S. Attorney's Office for the District of Massachusetts
John Joseph Moakley Federal Courthouse
One Courthouse Way
Boston, MA 02210

The Company may extend the time period for issuance of the first report with prior written approval of the Offices.

Follow-up Reviews and Reports

g. The Company shall undertake at least two follow-up reviews and reports, incorporating the views of the Offices on the Company's prior reviews and reports, to further monitor and assess whether the Company's compliance program is reasonably designed, implemented, and enforced so that it is effective at deterring and detecting violations of U.S. fraud laws and the federal Food, Drug, and Cosmetic Act's adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i.

h. The first follow-up ("second") review and report shall be completed by no later than one year after the first report is submitted to the Offices.

i. The second follow-up ("third") report shall include a plan for ongoing improvement, testing, and review of the compliance program to ensure the sustainability of the program. The third report shall be completed and delivered to the Offices no later than thirty (30) days before the end of the Term.

j. The Company may extend the time period for submission of any of the follow-up reports with prior written approval of the Offices.

Confidentiality of Submissions

g. Submissions by the Company, including the work plans and reports will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the submissions could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the submissions and the contents thereof are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent the Offices determine in their sole discretion that disclosure would be in furtherance of the Offices' discharge of their duties and responsibilities or is otherwise required by law.

ATTACHMENT E

CERTIFICATION

To: United States Department of Justice
Criminal Division, Fraud Section
Attention: Chief of the Fraud Section

United States Department of Justice
United States Attorney's Office for the District of Massachusetts
Attention: United States Attorney for the District of Massachusetts

Re: Deferred Prosecution Agreement Disclosure Certification

The undersigned certify, pursuant to Paragraph 24 of the deferred prosecution agreement ("the Agreement") filed on _____ in the United States District Court for the District of Massachusetts, by and between the United States of America and EXTHERA MEDICAL CORPORATION (the "Company"), that undersigned are aware of the Company's disclosure obligations under Paragraph 6 of the Agreement, and that the Company has disclosed to the United States Department of Justice, Criminal Division, Fraud Section and the United States Attorney's Office for the District of Massachusetts (collectively, the "Offices") any and all evidence or allegations of conduct required pursuant to Paragraph 6 of the Agreement, which includes evidence or allegations of any violation of U.S. fraud laws or violations of the federal Food, Drug, and Cosmetic Act's adverse event reporting requirements under 21 U.S.C. §§ 331(q)(1)(B), 333(a)(2), 360i committed by the Company's employees or agents ("Disclosable Information"). This obligation to disclose information extends to any and all Disclosable Information that has been identified through the Company's compliance and controls program, whistleblower channel, internal audit reports, due diligence procedures, investigation process, or other processes. The undersigned further acknowledge and agree that the reporting requirements contained in Paragraph

6 and the representations contained in this certification constitute a significant and important component of the Agreement and of the Offices' determination whether the Company has satisfied its obligations under the Agreement.

The undersigned hereby certify that they are the Chief Executive Officer and the Chief Financial Officer of the Company, respectively, and that each has been duly authorized by the Company to sign this Certification on behalf of the Company.

This Certification shall constitute a material statement and representation by the undersigned and by, on behalf of, and for the benefit of, the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001, and such material statement and representation shall be deemed to have been made in the District of Massachusetts. This Certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. § 1519, and such record, document, or tangible object shall be deemed to have been made in the District of Massachusetts.

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Executive Officer
EXTHERA MEDICAL CORPORATION

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Financial Officer
EXTHERA MEDICAL CORPORATION

ATTACHMENT F

COMPLIANCE CERTIFICATION

To: United States Department of Justice
Criminal Division, Fraud Section
Attention: Chief of the Fraud Section

United States Department of Justice
United States Attorney's Office for the District of Massachusetts
Attention: United States Attorney for the District of Massachusetts

Re: Deferred Prosecution Agreement Compliance Certification

The undersigned certify, pursuant to Paragraph 17 of the Deferred Prosecution Agreement filed on _____, in the United States District Court for the District of Massachusetts, by and between the United States of America and EXTHERA MEDICAL CORPORATION (the "Company") (the "Agreement"), that the undersigned are aware of the Company's compliance obligations under Paragraphs 14-16 of the Agreement, and that, based on a review of the Company's reports submitted to the Department of Justice, Criminal Division, Fraud Section and U.S. Attorney's Office for the District of Massachusetts pursuant to Paragraph 16 of the Agreement, the reports are true, accurate, and complete.

In addition, the undersigned certify that, based on the undersigned's review and understanding of the Company's anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance program, the Company has implemented an anti-fraud and federal Food, Drug, and Cosmetic Act adverse event reporting compliance program that meets the requirements set forth in Attachment C to the Agreement. The undersigned certifies that such compliance program is reasonably designed to detect and prevent violations of U.S. fraud laws and the federal Food, Drug, and Cosmetic Act's adverse event reporting law throughout the Company's operations.

The undersigned hereby certify that they are respectively the Chief Executive Officer ("CEO") of the Company and the Chief Compliance Officer ("CCO") of the Company and that each has been duly authorized by the Company to sign this Certification on behalf of the Company.

This Certification shall constitute a material statement and representation by the undersigned and by, on behalf of, and for the benefit of, the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001, and such material statement and representation shall be deemed to have been made in the District of Massachusetts. This Certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. § 1519, and such record, document, or tangible object shall be deemed to have been made in the District of Massachusetts.

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Executive Officer
EXTHERA MEDICAL CORPORATION

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Compliance Officer
EXTHERA MEDICAL CORPORATION