

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the “United States”), Diopsys, Inc. (“Diopsys”), and Atul Jain (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Diopsys is a medical device company headquartered in Middletown, PA, which produced and marketed in the U.S. eye devices used for Visual Evoked Potential (VEP) and electroretinography (ERG) vision testing, including the Diopsys Nova, Diopsys Argos, and Diopsys Retina Plus devices. On or about March 1, 2022, Diopsys was acquired by and became a wholly-owned subsidiary of LumiThera, Inc., a commercial-stage medical device company headquartered in Poulsbo, Washington, focused on treating people affected by ocular damage and disease including dry age-related macular degeneration.

B. On October 6, 2021, Atul Jain filed a qui tam action in the United States District Court for the District of New Jersey captioned *United States ex rel. Jain v. Diopsys, Inc., et al.* (2:21-cv-18151 (ES/LDW)), pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action).

C. The United States contends that Diopsys submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”) and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”).

D. The United States contends that it has certain civil claims against Diopsys arising from Diopsys’ marketing of the NOVA system during the period from January 1, 2015 through

March 1, 2022. Specifically, on or about May 9, 2011, Diopsys obtained FDA 510(k) clearance of its NOVA medical device, an electrophysiological device that ophthalmologists could use to conduct visual evoked potential (VEP) testing. By June 2012, Diopsys had made substantial changes to the NOVA device, enabling it to conduct electroretinography (ERG) testing, but Diopsys did not seek further clearance from FDA for the changes to the NOVA device despite knowing that VEP and ERG testing were substantially different tests and that FDA had not cleared the NOVA device with the ERG component. Over time, Diopsys added three different types of ERG tests to the device (full-field ERG, pattern ERG, and multi-focal ERG). Diopsys sales representatives promoted the ERG features of NOVA as “completely new” and advised customers on how to maximize reimbursement for tests conducted using the device. Internal Diopsys records referred to “new” electrodes being added to device to conduct ERG testing, along with a “new manufacturing process.” Diopsys knew, or was reckless in not knowing, that the changes to the NOVA device were substantial and required submission to the FDA for clearance or approval. Diopsys sales personnel described how doctors could maximize their financial return on NOVA and further marketed NOVA for medically unnecessary uses causing physicians to submit false claims to federal and state health care programs. This conduct is referred to below as the “Covered Conduct.”

E. Diopsys has entered into or will be entering into one or more separate settlement agreements (hereinafter referred to as the “Medicaid State Settlement Agreement”) with certain states (the “Medicaid Participating States”) in settlement of the conduct described in the Medicaid State Settlement Agreement, and will pay to the Medicaid Participating States in connection with the agreement the sum of One Hundred Five Thousand Three Hundred Fifty Seven Dollars and Twenty Five Cents (\$105,357.25) for the “Fixed Medicaid Settlement

Amount” and an apportioned amount as detailed herein as the “Contingent Medicaid Settlement Amount.”

F. This Agreement is neither an admission of liability by Diopsys nor a concession by the United States that its claims are not well founded.

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator’s reasonable expenses, attorneys’ fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Diopsys agrees to collectively pay the United States and the Medicaid Participating States: (1) the fixed sum of one million two-hundred twenty-five thousand dollars (\$1,225,000) (the “Fixed Settlement Amount”), of which six-hundred twelve thousand, five-hundred dollars (\$612,500) is restitution, and (2) a percentage of its total annual gross revenue not to exceed a total of thirteen million, twenty-five thousand dollars (\$13,025,000), of which 50% shall be restitution (the “Contingent Settlement Amount,” and, together with the Fixed Settlement Amount, the “Settlement Amount”). With \$105,357.25 of the Fixed Settlement Amount being paid to the Medicaid Participating States, the United States shall be paid a total of \$1,119,642.75 plus interest for the Fixed Settlement Amount, according to the following terms:

A. Fixed Settlement Amount. Within 10 days of the Effective Date of this Agreement, Diopsys will make a payment to the United States in the amount of forty five thousand six hundred ninety nine dollars and seventy cents (\$45,699.70). Over a period of 5 years, Diopsys will pay the remaining one million one-hundred seventy three

thousand nine hundred forty three dollars and five cents (\$1,073,943.05), plus interest at 4.5% per annum from July 1, 2024, pursuant to the following payment schedule:

- i. Six months after the Effective Date: \$45,699.70
- ii. One year after the Effective Date: \$91,399.41
- iii. Two years after the Effective Date: \$137,099.11
- iv. Three years after the Effective Date: \$228,498.52
- v. Four years after the Effective Date: \$274,198.22
- vi. Five years after the Effective Date: \$297,048.08

B. Contingent Settlement Amount. Each year for six years, beginning with 2025, Diopsys will pay to the United States and the Medicaid Participating States a percentage of its total annual gross revenue for the preceding calendar year. It will make that payment by March 31 of the following year . This Contingent Settlement Amount shall be paid according to the following schedule:

- i. Year 1 [2025]: 5%
- ii. Year 2 [2026]: 5%
- iii. Year 3 [2027]: 10%
- iv. Year 4 [2028]: 15%
- v. Year 5 [2029]: 20%
- vi. Year 6 [2030]: 20%

The amount of each annual payment shall be calculated using the financial data from the preceding fiscal year. Thus, the first annual payment, due in 2025, shall be a percentage of Diopsys's gross revenue as measured for the calendar year ending December 31, 2024. Diopsys shall provide the United States with annual financial statements, and upon the request of the United States other documents and information reasonably necessary to

substantiate the calculation of each of the annual Contingent Settlement Amounts. For each annual payment calculated pursuant to the schedule above, an amount of 18.48% shall be apportioned as the Contingent Medicaid Settlement Amount, of which Diopsys shall pay to the Medicaid Participating States 46.54% of the 18.48% Contingent Medicaid Settlement Amount, and 53.46% of the 18.48% Contingent Medicaid Settlement Amount to the United States, in addition to all other amounts due to the United States pursuant to the Federal Settlement Agreement.¹

C. The Fixed Settlement Amount and any accrued Contingent Settlement Amount shall be secured pursuant to a consent judgment in the form of Exhibit A.

D. Interest shall accrue on the Fixed Settlement Amount as set forth in Paragraph 1(A), above.

E. If Diopsys is sold, merged, or transferred, or a significant portion of the assets of Diopsys (including, but not limited to, the NOVA device) is sold, merged, or transferred into any other entity, Diopsys shall promptly notify the United States, and (1) all remaining payments owed pursuant to the Fixed Settlement Amount shall be accelerated and become immediately due and payable, as well as (2) any Contingent Settlement Amount accrued and owed at that time shall be due and payable. All future Contingent Settlement Amounts shall not be affected by this section and shall still be owed by the acquiring entity according to the payment schedule provided above.

2. Conditioned upon the United States receiving the Settlement Amount payments, the United States agrees that it shall pay to Relator by electronic funds transfer 18.5% percent of

¹ For example, if 5% of Year 1 gross annual revenue equates to \$1,000,000.00, the 18.48% Contingent Medicaid Settlement Amount would equate to \$184,800.00. As a result, \$86,005.92 (46.54%) would be paid to the Medicaid Participating States and the balance of \$98,794.08 (53.46%) would be paid to the United States for the Contingent Medicaid Settlement Amount portion of the overall \$1,000,000.00.

each such payment received under the Settlement Agreement (Relator's Share) as soon as feasible after receipt of the payment.

3. Diopsys shall pay to Relator \$240,000, over five years, with 4.5% interest per annum from July 1, 2024, on the following schedule:

- within ten days of the effective date of this Settlement Agreement: \$10,000;
- within six months of the effective date of this Settlement Agreement: \$15,000;
- within one year of the effective date of this Settlement Agreement: \$25,000;
- within two years of the effective date of this Settlement Agreement: \$40,000;
- within three years of the effective date of this Settlement Agreement: \$45,000;
- within four years of the effective date of this Settlement Agreement: \$50,000; and
- within five years of the effective date of this Settlement Agreement: \$55,000

to fully and finally resolve Relator's claim for expenses, attorneys' fees and costs (the "Fee Settlement Amount"). Payments shall be made by electronic funds transfer pursuant to written instructions from Relator's counsel.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and subject to Paragraph 9 (concerning disclosure of assets), Paragraph 18 (concerning default), and Paragraph 19 (concerning bankruptcy) below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases Diopsys together with its current and former parent corporations, direct and indirect subsidiaries, brother or sister corporations, divisions, current or former corporate owners, and the corporate predecessors, successors and assigns of any of them, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil

Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and subject to Paragraph 9 (concerning disclosure of assets), Paragraph 18 (concerning default), and Paragraph 19 (concerning bankruptcy) below, and upon the United States' and Medicaid Participating States' receipt of the Settlement Amount, plus interest due under Paragraph 1, and Relator's receipt of the full Fee Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Diopsys, together with its current and former parent corporations, direct and indirect subsidiaries, brother or sister corporations, divisions, current or former corporate owners, and the corporate successors and assigns of any of them from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, and from all liability, claims, demands, actions, or causes of action whatsoever, under any federal or state statute or regulation, or in common law, that Relator, his heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement.

6. Notwithstanding the releases given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;

- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals.

7. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and subject to Paragraph 9 (concerning disclosure of assets), Paragraph 18 (concerning default), and Paragraph 19 (concerning bankruptcy) below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, and Relator's receipt of the full Fee Settlement Amount, Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases Diopsys, together with its current and former parent corporations, direct and indirect subsidiaries, brother or sister corporations, divisions, current or former corporate owners, and the corporate successors and assigns of any of them, and their officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

9. Diopsys has provided sworn financial disclosures and supporting documents (together "Financial Disclosures") to the United States, and the United States has relied on the

accuracy and completeness of those Financial Disclosures in reaching this Agreement. Diopsys warrants that the Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which Diopsys had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy Diopsys's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by Diopsys on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by \$500,000 or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of Diopsys's previously undisclosed assets. Diopsys agrees not to contest any collection action undertaken by the United States pursuant to this paragraph, and agrees that it will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected in the collection action, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States, pursuant to this paragraph rescinds this Agreement, Diopsys waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to Diopsys that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on November 10, 2021.

10. Diopsys waives and shall not assert any defenses Diopsys may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based

in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

11. Diopsys fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Diopsys has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution of the Civil Action.

12. Diopsys fully and finally releases the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Diopsys has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof.

13. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Diopsys agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

14. Diopsys agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395III and 1396-1396w-5; and the regulations and official

program directives promulgated thereunder) incurred by or on behalf Diopsys, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Diopsys' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Diopsys makes to the United States pursuant to this Agreement and any payments that Diopsys may make to Relator, including costs and attorneys' fees.

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Diopsys, and Diopsys shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Diopsys or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Diopsys further agrees that within 90 days of the Effective Date of this Agreement it shall

identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Diopsys or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Diopsys agrees that the United States, at a minimum, shall be entitled to recoup from Diopsys any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Diopsys or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Diopsys or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Diopsys's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

15. Diopsys agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Diopsys shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of

former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Diopsys further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

16. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 17 (waiver for beneficiaries paragraph), below.

17. Diopsys agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

18. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due in part to Diopsys's financial condition as reflected in the Financial Disclosures referenced in Paragraph 9.

a. In the event that Diopsys fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above, Diopsys shall be in Default of Diopsys' payment obligations ("Default"). The United States will provide a written Notice of Default, and Diopsys shall have an opportunity to cure such Default within thirty (30) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Diopsys's counsel that signs this agreement, or to such other representative as Diopsys shall designate in advance in writing. If Diopsys fails to cure the Default within thirty (30) calendar days of receiving the Notice of Default and in the

absence of an agreement with the United States to a modified payment schedule (“Uncured Default”), the remaining unpaid balance of the Fixed Settlement Amount as well as any accrued and owed Contingent Settlement Amount at the time of Default shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

b. In the event of Uncured Default, Diopsys agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against Diopsys for the claims that would otherwise be covered by the releases provided in Paragraph 4 above, with any recovery reduced by the amount of any payments previously made by Diopsys to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to Diopsys and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Diopsys agrees immediately to pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States’ reasonable attorneys’ fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, Diopsys waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims

that are (i) filed by the United States against Diopsys within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on November 10, 2021. Diopsys agrees not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

c. In the event of Uncured Default, OIG-HHS may exclude Diopsys from participating in all Federal health care programs until Diopsys pays the Settlement Amount, with interest, as set forth above (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Diopsys. Diopsys waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Diopsys wishes to apply for reinstatement, it must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Diopsys will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

19. In exchange for valuable consideration provided in this Agreement, Diopsys and Relator acknowledge the following:

a. Diopsys has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous

exchange for new value given to Diopsys, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which Diopsys was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If any of Diopsys' payments or obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, Diopsys or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Diopsys' debts, or to adjudicate Diopsys as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Diopsys or for all or any substantial part of Diopsys' assets; and (i) any such case, proceeding, or action under any law described herein is not dismissed within thirty (30) calendar days and (ii) a determination has been made that Diopsys is unable to pay the Settlement Amount in full in such case, proceeding, or action:

(i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Diopsys for the claims that would otherwise be covered by the releases provided in Paragraph 4 above or the United States has an undisputed, noncontingent, and liquidated allowed claim against Diopsys in the amount of \$14,250,000, less any payments received pursuant to Paragraph 1 of this Agreement,

provided, however, that such payments are not otherwise avoided and recovered from the United States by Diopsys, a receiver, trustee, custodian, or other similar official for Diopsys;

(ii) if any payments are avoided and recovered by a receiver, trustee, creditor, custodian, or similar official, the United States shall not be responsible for the return of any amounts already paid by the United States to the Relator; and

(iii) if, notwithstanding subparagraph (iii), any amounts already paid by the United States to the Relator pursuant to Paragraph 2 are recovered from the United States in an action or proceeding filed by a receiver, trustee, creditor, custodian, or similar official in or in connection with a bankruptcy case that is filed within two years of the Effective Date of this Agreement or of any payment made under Paragraph 1 of this Agreement, Relator shall, within thirty days of written notice from the United States to the undersigned Relator's counsel, return to the United States all amounts recovered from the United States.

f. Diopsys agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 24.e is not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States' police and regulatory power. Diopsys shall not argue or otherwise contend that the United States' claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Diopsys waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to Diopsys that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on July 1, 2024.

20. Upon receipt of the first payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Stipulation of Dismissal of the Civil Action as to Diopsys pursuant to Rule 41(a)(1). Relator's dismissal shall be with prejudice as to Diopsys. The United States' dismissal shall be with prejudice as to the Covered Conduct and without prejudice as to any other claims.

21. Except as provided in Paragraph 3, above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

22. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

23. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the District New Jersey. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

24. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

25. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

26. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

27. This Agreement is binding on Diopsys' successors, transferees, heirs, and assigns.

28. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.


29. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

30. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[SIGNATURE PAGES FOLLOW]

THE UNITED STATES OF AMERICA

DATED: 3/19/2025

BY: 


Daniel Meyler
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: DAVID  Digitally signed by DAVID
SIMUNOVICH
Date: 2025.03.19 16:02:48
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David Simunovich
Assistant United States Attorney
District of New Jersey

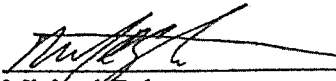
DATED: 3/19/25

BY: **SUSAN GILLIN**  Digitally signed by SUSAN
GILLIN
Date: 2025.03.19 14:47:53
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SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

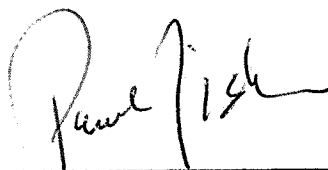
DIOPSYS - DEFENDANT

DATED: 3/11/25

BY: 

Michael Egleston
Chief Financial Officer
Diopsys, Inc.
1000 Kreider Dr., STE 700
Middletown, PA 17057
Defendant

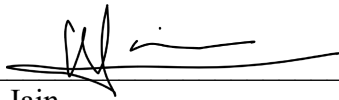
DATED: 3/11/25

BY: 

Paul Fishman, Esq.
Arnold & Porter Kaye Scholer LLP
One Gateway Center, Suite 1025
Newark, NJ 07102
Counsel for Diopsys, Inc.

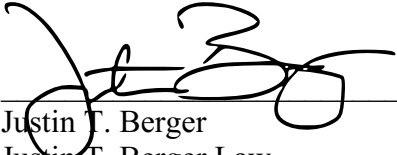
ATUL JAIN - RELATOR

DATED: 3/13/2025

BY: 

Atul Jain

DATED: 3/12/2025

BY: 

Justin T. Berger
Justin T. Berger Law
Counsel for Atul Jain