foiapa

From:

Mark Edwards < medwards@biosciadvisors.com>

Sent:

Friday, May 18, 2018 8:24 PM

To:

foiapa

Subject:

FOIA Request

RECEIVED

MAY 2 1 2018

Office of FOIA Services

would like to request access to Exhibit 10.21 to the Form 8-K filed by Foxhollow Technologies, Inc. on 9/28/2006. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to \$61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

STATION PLACE 100 F STREET, NE WASHINGTON, DC 20549-2465

Office of FOIA Services

June 04, 2018

Mr. Mark G. Edwards Bioscience Advisors 2855 Mitchell Dr., Suite 103 Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552

Request No. 18-04381-E

Dear Mr. Edwards:

This letter is in response to your request, dated and received in this office on May 21, 2018, for information regarding Exhibit 10.21 to the Form 8-K filed by Foxhollow Technologies, Inc., on September 28, 2006.

The search for responsive records has resulted in the retrieval of 16 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at smithLR@sec.gov or (202) 551-8328. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

La Kisha R. Smith

FOIA Research Specialist

Enclosure

Full Version

FOXHOLLOW TECHNOLOGI

FORM 8-K

RR Donnelley Profile

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SUPPLIER AGREEMENT

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Norman Noble, Inc.

Fox Hollow Technologies, Inc.

AMENDED SUPPLIER AGREEMENT

10.21 10109

This Amended Supplier Agreement ("Agreement"), dated September 26, 2006, replaces in its entirety the Supplier Agreement entered into between the parties dated effective as of March 25, 2005 (the "Effective Date"). This Amended Supplier Agreement is, by and between Norman Noble, Inc., an Ohio corporation, having its offices at 5507 Avion Park Drive, Highland Heights, Ohio 44143("NNI") and Fox Hollow Technologies, Inc. a Delaware corporation, having offices at 740 Bay Road, Redwood, California 94063 ("FHT").

WITNESSETH:

WHEREAS, the parties entered into a long-term supply contract for the purchase by FHT from NNI of certain Products dated March 25, 2005;

WHEREAS, the parties desire to amend and replace the March 25, 2005 Agreement with this Agreement, as if it had been effective March 25, 2005;

NOW, THEREFORE, FHT and NNI hereby agree as follows:



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ARTICLE 1. PRODUCTS

Section 1.1 Products

- (a) For purposes of this Agreement, the term Product or Products shall mean the items listed on Schedule I, as amended by the parties from time to time.
- (b) FHT shall offer NNI the option to submit a quotation to manufacture any new products developed by FHT, including, any catheter products in the coronary market. The parties shall negotiate in good faith the pricing for such products and they shall then be added as Products on Schedule I if a mutually acceptable agreement is reached.

Section 1.2 Specifications

For purposes of this Agreement, the term Specifications shall mean the items detailed on Schedule III.

ARTICLE 2. PURCHASE AND SUPPLY COMMITMENT

Section 2.1 FHT's Purchase Obligation

- (a) During the initial Term of this Agreement, and any extended Term, FHT shall purchase from NNI at least 80% of FHT's annual unit requirements of each Product listed on Schedule I (the "Requirements Purchase Obligation"). In addition, during the first 18 months of the initial Term of this Agreement, FHT shall purchase from NNI at least \$5,700,000 worth of Products (the "Initial Volume Purchase Obligation"). During the second 18 months of the initial Term of this Agreement, FHT shall purchase from NNI a total additional revenue generation of \$11,400,000 consisting of:
 - (i) All production related components;
 - (ii) All Research and Development related components,
 - (iii) All new components that meet NNI capabilities
- (b) Each quarter during the Term, FHT shall provide NNI with a rolling six month forecast with respect to FHT's anticipated requirements for the Products (the "Forecast"). FHT shall be required to purchase the quantity of Products specified in the first two months of the Forecast. NNI will rely on the Forecasts to purchase raw materials to be used in the manufacture of the Products.
- (c) FHT shall not be required to purchase any particular mix of Products, provided that it meets the Requirements Purchase Obligation and both Volume Purchase Obligations. FHT shall be excused from complying with the Requirements Purchase Obligation and the Volume Purchase



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Obligations if NNI is unable to meet the Specifications, technical requirements or reasonable quality standards set forth by FHT after notice and an opportunity to cure or if NNI is in material breach of this Agreement.

- (d) At the end of each year during the Term or extended term, FHT shall examine its expenditures for purchasing the Products paid by FHT to third parties. If FHT did not meet the Requirements Purchase Obligation during the preceding year, then FHT shall be required to pay to NNI as liquidated damages an amount equal to 0% of the unit number of Products procured from third parties that should have been procured from NNI multiplied by the applicable price as if the Products were purchased from NNI. FHT shall pay the amount due within 30 days of the end of the year.
- (e) If FHT fails to meet the Initial Volume Purchase Obligation, then FHT shall be required to pay to NNI as liquidated damages an amount equal to 50% of the difference between the amount of FHT's actual purchases from NNI and the Initial Purchase Volume Obligation. Payment shall be due within 30 days of the end of the first 18 months of the initial Term of this Agreement.
- (f) At the end of the initial Term of this Agreement, if FHT has not met the Second Volume Purchase Obligation, then FHT shall be required to pay to NNI as liquidated damages an amount equal to 25% of the difference between the amount of FHT's actual purchases from NNI during the second 18 months of the initial Term and the Second Purchase Volume Obligation. Payment shall be due within 30 days of the end of the second 18 months of the initial Term of this Agreement. FHT's actual purchases during the second 18 months shall include
 - Products included in Schedule I
 - (ii) Revisions of Products in Schedule I
 - (iii) New Products not included in Schedule I
- (g) If this Agreement is terminated other than by FHT in accordance with the terms of Section 4.2 below, then FHT shall pay to NNI as liquidated damages an amount equal to (i) the sum of the Initial Volume Purchase Obligation and the Second Volume Purchase Obligation, less its FHT's actual purchases through the date of termination, (ii) multiplied by 80% If this Agreement is terminated other than by FHT in accordance with the terms of Section 4.2 below prior to the end of the first 18 months of the Initial Term, then the Second Volume Purchase Obligation shall be calculated by assuming that FHT would have continued to purchase Products during the time period between termination and the end of the first 18 months at the same rate as it had averaged for each Product during the time period preceding termination. The payment to be made by FHT pursuant to this subparagraph shall be paid no later than 30 days following termination.
- (h) During any extended Term of this Agreement, NNI may, at its expense, have an independent public accounting firm audit FHT's purchasing and other records to determine whether FHT has complied with the Requirements Purchase Obligation. The accounting firm must execute a reasonable confidentiality agreement to protect the confidentiality of the records to which it will be



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given access by FHT. FHT will use its best efforts to accommodate the accounting firm during such audit by providing all documents reasonably requested to determine compliance. The accounting firm will report to NNI only whether or not FHT has complied with the Requirements Purchase Obligation, and, if not, sufficient information about the non-compliance to enable NNI to calculate the amount of liquidated damages to which it is entitled pursuant to this Section 2.1 of this Agreement. NNI will be entitled to one audit per year.

(i) NNI will use commercially reasonable efforts to provide FHT's requirements of the Products.

Section 2.2 Orders

FHT may place purchase orders with NNI for Products using FHT's standard forms, but no terms and conditions on those standard forms shall apply or vary the terms of this Agreement unless NNI has agreed to those separate or additional terms in writing.

Section 2.3 Product Improvements, Design Modifications and other Changes

Either party may request a change to any mechanical, component, material, packaging or process ("Engineering Changes"). No Engineering Change shall become effective unless FHT and NNI agree in writing as to any price change due to the implementation of the Engineering Change.

ARTICLE 3. TERMS

The following terms shall apply to sales of Products by NNI to FHT during the Term or any extended Term of this Agreement.

Section 3.1 Pricing and Payment

- (a) Products pricing shall be as set forth in the attached Schedule II.
- (b) NNI shall mail invoices to FHT immediately upon shipment of Products. FHT shall pay the NNI invoices within 30 days of invoice date ("Due Date"). If invoices are not paid in full by the Due Date, then a finance charge of 1.5% per month (18%) annual) shall be added to any outstanding balances.
- (c) All shipments are FOB NNI's manufacturing facility. FHT may select transportation modes and carriers. FHT is liable for all Product freight charges. If FHT does not specify the carrier, NNI may select the carrier, but FHT is still liable for freight charges. If FHT does not arrange to prepay for the freight charges, or provide NNI with an account number against which to charge the freight charges, NNI may prepay the freight charges and add the cost to the invoice.
- (d) NNI shall not be considered late in deliveries of the Products or in any way in breach of this agreement if the raw materials needed to make the Products are unavailable due to the fault of the supplier of such raw materials. NNI shall protect against this by carrying a two month inventory of raw material that, should FHT default on this agreement, will be the responsibility of FHT. NNI



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shall make good faith efforts to utilize such leftover material but to the extent such alternative uses are not found, FHT shall (at its option) either purchase said materials from NNI at NNI's actual cost or reimburse NNI and allow NNI to keep or dispose of said materials.

Section 3.2 Warranty

- (a) NNI warrants that all Products shall meet the Specifications. NNI warrants that it shall comply with all present and future statutes, laws, ordinances and regulations relating to the manufacture and supply of the Products. NNI MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, AND NNI EXPRESSLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES ARE HEREBY EXPRESSLY EXCLUDED.
- (b) The exclusive remedy for breach of the foregoing warranty Agreement shall be repair or replacement of the defective Products or, at NNI's option, refund of the purchase price paid for the defective Products.
- (c) UNDER NO CIRCUMSTANCES SHALL NNI BE LIABLE TO FHT FOR INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES OR DAMAGES FOR LOSS OF USE ARISING DIRECTLY OR INDIRECTLY FROM ANY BREACH OF WARRANTY, BREACH OF CONTRACT, MATERIAL OR OTHERWISE, OR FROM ANY ACTS OR OMISSIONS OF NNI'S EMPLOYEES OR AGENTS, TORTIOUS OR OTHERWISE, IN NO EVENT SHALL NNI'S LIABILITY FOR ANY CLAIM BROUGHT BY FHT EXCEED THE PRICE OF THE DEFECTIVE PRODUCT.

Section 3.3 Indemnification

FHT shall defend and indemnify NNI from all claims arising from NNI's manufacture and sale of the Products, whether for personal injury, property damage or otherwise, including any claims premised on negligence, strict liability, breach of warranty or infringement of a third party's intellectual property rights (provided that the accused infringement is solely caused by NNI's compliance with FHT's specifications); provided, however, that FHT shall not be liable for any award of damages which results from NNI's failure to manufacture the Products in conformance with specifications. NNI shall cooperate with the defense of any claim for which it seeks indemnification and may, at its expense, retain counsel of its choice to serve as co-counsel for its defense. NNI and FHT shall be entitled to recover any costs, including attorneys' fees, incurred in connection with enforcing its rights under this Section.

Section 3.4 Force Majeure

Neither party shall be liable to the other if its performance is hindered, delayed or prevented as a result of (i) acts of God; (ii) expropriation, confiscation or requisitioning of facilities or compliance with any law, decree, regulation, order, directive or request of any governmental authority or person(s) purporting to act therefore that affects to a degree not presently existing the supply, availability or use of materials, equipment or labor; (iii) acts or inaction on the part of any



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governmental authority or person purporting to act therefore; (iv) acts of war or the public enemy whether war be declared or not; (v) public disorders, insurrection, rebellion, sabotage, riots or violent demonstrations; (vi) explosions, fires, earthquakes or other natural calamities; (vii) strikes or lockouts or other industrial action by workers or employees of the NNI. Notwithstanding the foregoing, no event of Force Majeure shall excuse the payment of money when it is due.

Section 3.2 Quality and Records

- (a) NNI will maintain quality assurance and quality controls as appropriate. NNI presently is ISO 9002-2000, DS/EN 4602 and ISO 13485:2003 certified and will maintain such certifications during the Term and any extended Term. NNI shall be responsible for the traceability of the Products 7 years after date of manufacture.
- (b) NNI will at its cost, take samples, perform inspections and issue certificates as required by the Specifications. NNI will provide FHT with current Materials Safety Data Sheets for the Products, certificates of analysis, identification of materials covered by Prop. 65, and other related information; such as toxicological data that FHT may reasonably request to enable FHT to comply with all applicable federal, state and municipal statutes, regulations, rules and ordinances relating to FHT's use of Products. NNI will maintain and make available to FHT a Device History Record for the production of the Products, including all documents required by the FDA, by applicable law or regulation, or reasonably requested by FHT, for example: (1) process specifications; (2) In process controls; (3) Quality Control test specifications; (4) Release Specifications; (5) Production schedules; (6) Environmental Controls; (7) Material History Records for each lot; (8) Equipment maintenance and calibration records; (9) Process validation procedures and data; (10) Quality audits; (11) Defect analysis and Corrective Action; and (12) Change histories for documents generated by NNI. NNI will promptly provide FHT with copies of correspondence regarding any regulatory actions, including for example 483's and warning letters.

ARTICLE 4. TERM; TERMINATION

Section 4.1 Duration

(a) This Agreement shall be effective on the Effective Date and, subject to earlier termination as provided in Section 4.2 or extension as provided in Section 4.1(b), shall continue in effect for three years after the Effective Date (the "Term").

Section 4.2 Right to Terminate

The parties may terminate this Agreement for the reasons and as provided in this section.

(a) Default

If a party fails to observe or perform any of its material promises, agreements or undertakings under this Agreement, and fails to remedy any such breach within 90 days of notice to



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do so from the other party, then the aggrieved party may; upon expiration of the 90-day notice period, give written notice of termination of this Agreement either forthwith or at a future date designated by the aggrieved party. Notwithstanding the foregoing, the non-payment of money when due shall be a material breach of this Agreement if not cured within ten days of notice of the non-payment.

(b) Bankruptcy, Liquidation

If either of the parties shall become voluntarily or involuntarily the subject of proceedings under any bankruptcy or insolvency law, or other law or procedure for the relief of financially distressed debtors, or is unable, or admits in writing its inability, to pay its debts as they mature, or takes or suffers any action for its liquidation or dissolution other than in the context of a merger of consolidation, or has a receiver or liquidator appointed for all or any part of its assets and, in the event any act of the aforesaid character is involuntary, the consequences thereof are not cured within 60 days, the party not affected by such circumstances may give to the affected party written notice of its decision immediately to terminate this Agreement. In the event that such notice is not given for any reason, the affected party shall remain fully responsible for its obligations set forth in this Agreement at the times required.

Section 4.3 Survival

The provisions of Articles 5 and 6 shall survive any termination of this Agreement.

ARTICLE 5. GOVERNING LAW; DISPUTES

Section 5.1 Governing Law

This Agreement shall be governed by the laws of the State of Ohio, without reference to its conflict of laws principles,

Section 5.2 Resolution of Disputes

- (a) All disputes arising under this Agreement, or in any way related to the parties' business relationship, shall first be submitted to mediation in accordance with the then current Mediation Procedure of the CPR Institute for Dispute Resolution. Any statute of limitations defense shall be tolled until resolution of the mediation. If the Parties cannot agree on the selection of a mediator, one shall be selected according to CPR rules. Except as permitted by subsection (b), no party shall institute any lawsuit, arbitration or other formal claim resolution procedure without first submitting the dispute to mediation pursuant to this Section.
- (b) In the event of a breach, or threatened breach of any provision of this Agreement, that poses a threat of immediate and irreparable harm, a party may seek temporary or preliminary injunctive relief in a court of competent jurisdiction. Following a ruling on any such request for temporary or interim relief, the action will be stayed pending completion of the dispute resolution procedures in this paragraph. Participation in any such preliminary judicial proceedings in no way waives the rights and obligations of this Section.



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(c) If mediation is unsuccessful, and the amount in controversy is less than \$100,000 the parties shall submit their dispute to binding arbitration pursuant to the then current CPR Rules for Non-Administered Arbitration ("CPR Rules"). The Parties shall select a single arbitrator to resolve the dispute. If the Parties are unable to agree on the selection of an arbitrator within 30 days of the notice of arbitration first being served, the arbitrator shall be selected in accordance with the CPR Rules. To the fullest extent allowed by law, damages shall be limited to compensatory damages, and the arbitrator has no jurisdiction to award damages in excess of compensatory damages, or any amount in excess of a total of \$100,000 including any costs awarded pursuant to the CPR Rules. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. \$1, et. seq., to the exclusion of any state laws inconsistent therewith. Judgment upon the award may be entered by any court of competent jurisdiction.

(d) If mediation is unsuccessful, and the amount in controversy is \$100,000 or more, then the aggrieved party may file suit in any California or Ohio court having jurisdiction. The Parties waive any right to a jury trial. The Parties further waive any right to seek enhanced or punitive damages and will limit their claims to compensatory damages only.

ARTICLE 6. MISCELLANEOUS

Section 6.1 Assignment

This Agreement shall be binding upon and shall inure to the benefit of and be enforceable by the parties hereto and their respective successors and duly permitted assigns. Neither FHT nor NNI may assign their rights and/or obligations under this Agreement other than with the express written consent of the other party, which consent will not be unreasonably withheld. Nothing in this Section 6.1 shall be deemed to prohibit a merger, consolidation or conversion of FHT or NNI or a sale of all or substantially all of the business operations of FHT or NNI as long as the successor to the obligations of FHT or NNI assumes FHT's or NNI's, as the case may be, obligations hereunder.

Section 6.2 Waiver

The failure of either party to insist upon strict adherence to any term of this Agreement on any occasion shall not be considered a waiver of any right thereafter to insist upon strict adherence to that term or any other term of this Agreement. Any waiver must be made in writing.

Section 6.3 Notices

All notices required by this Agreement shall be in writing and shall be either (a) delivered with signed receipt obtained acknowledging delivery; (b) transmitted by facsimile; or e-mailed to a party at the address set out below (or at such other address as it may have specified):



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If to NNI: Norman Noble, Inc.

5507 Avion Park Drive

Highland Heights, Ohio 44143 Fax Number: (216) 761-0455 Attention: Mr. Chris Noble

With a copy to:

Scott Noble

5507 Avion Park Drive

Highland Heights, Ohio 44143 Fax Number: (216) 373-6579

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If to FHT: FoxHollow Technologies, Inc.

300 Saginaw Dr.

Redwood City, California 94063 Attention: Ronald T. Steckel

With a copy to:

Section 6.4 Severability

Any provision of this Agreement that is determined by an arbitration panel or a court of competent jurisdiction to be invalid. illegal or unenforceable shall be ineffective to the extent of such invalidity, illegality or unenforceability, without affecting in any way the remaining provisions hereof in such jurisdiction or rendering that or any other provision of this Agreement invalid, illegal or unenforceable, so long as the material purposes of this Agreement can be determined and effectuated. Should any provision of this Agreement be so declared invalid, illegal or unenforceable, the parties shall agree on a valid provision to substitute for it.

Section 6.5 Entire Agreement

This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes any existing agreements between them whether oral or written. In case of a conflict between this Agreement and a purchase order or purchase order confirmation contemplated hereunder, the terms of this Agreement shall govern unless the parties otherwise agree in writing. The terms of this Agreement shall only be amended, modified or supplemented as set forth herein or in writing signed by or on behalf of each party.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement to be effective as of the date and year first above written.

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NORMAN NOBLE, INC.

By: /s/ Christopher L. Noble

By: /s/ John Fraboni

Name: John Fraboni

Title: Senior Director of Materials

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Name: Christopher L. Noble Title: Chief Operating Officer

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Schedule I-Products

Products

Product	Part Number	
Peripheral Standard tip w/ plat.housing (LS)	SA05355-	
Peripheral Flush Tip w/ plat. Housing (LS-F)	SA06655-	
Peripheral Ex. Tip w/ plat. Housing (LX)	SA05354-	
Peripheral Compact w/plat Housing (LC)	SA07950-	
Housing and tip, ALL Platinum per. PSV (SX)	MS05386-	
Plat. Housing w/SS Coil Cor. Cath Ass'y (SS)	MS03426-	
ALL Plat, housing Cor. Small vessel (ES)	MS02941-	35
Small Vessel Housing, BTK (SS+)	MS07724 /	
Extra Small Vessel, BTK (ES+)	MS07725	



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Schedule II-Pricing

Product	Part Number	Price Per Unit
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During the initial Term of this Agreement, the price per u	than 10 000 22 12 12 12 12 12 12 12 12 12 12 12 12	7 S F 2 3 3 3 1
	s than 137,500:)	\$ 42.11
For all units purchased in excess of (64,999 units:		\$ 40.79
During the initial Term of this Agreement, the price per u	unit shall be priced as follows:	120
For all units purchased in excess of 65,999 units, but less		\$ 51.49
For all units purchased in excess of 98,999 units:		
	MS05386-S	1 1 1 1 1 1 1
During the initial Term of this Agreement, the price per u	init shall be priced as follows:	



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	For all units purchased in ex For all units purchased in ex	cess of 32,999 unit	which is the confidence of			\$44.8° \$43.40	
	During the initial Term of the state of the	nis Agreement, the	orice per unit shall be prices, but less than 44,000:)		Branisla.	\$22.4	
(During the initial Term of the form of the	is Agreement, the page 18 of 32,999 units	price per unit shall be price to the state of the state o		TO PROBLEM STORY OF THE STORY O	\$11.36 \$11.36 \$11.01	

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Prices do not include freight or other delivery charges, or any applicable sales, excise, use or ad valorem taxes. Prices shall remain firm during the initial Term of this Agreement, provided, however, that if NNI's raw material costs increase from the raw material costs in effect as of the date of this Agreement, NNI may invoice FHT for the increased raw material costs of all Products sold to FHI pursuant to this Agreement. If NNI's raw material costs decrease from the raw material costs in effect as of the date of this Agreement, NNI will issue FHT a credit for the decreased raw material costs of all Products sold to FHT pursuant to this Agreement, NNI shall invoice or credit FHT on a quarterly basis for all increased or decreased raw material costs incurred during the previous calendar quarter. FHT shall pay such invoices within 30 days. The parties will attach as Schedule IV to this agreement a copy of the most recent pricing for Platinum on the U.S. commodity index.

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Schedule III - Specifications

Document Number	Document Name	
LMS 04802	Housing with Jacket	
LMS 04838	Housing with Jacket, Ex-Tip	
MPI 03281	Tip to Housing Weld, Standard Peripheral	
MPI 03710	Housing Edge Weld, Standard Peripheral	
MPI 04246	Tip to Housing Weld, Extended Peripheral	
MPI 04916	Housing Edge Weld, Extended Peripheral	
MPI 04801	Laser Welding, Jacket and Housing	
MPI 04917	Laser Welding, Housing to Jacket Extended	
MPI 05353	Laser Welding Housing to Tip, LV Peripheral, Mid	
LMS 05336	Standard Tip and Housing, LV Peripheral, Mid	
LMS 05324	Extended Tip and Housing, LV Peripheral, Mid	
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Schedule IV - Raw Material Pricing as of Effective Date of Agreement

