

foiapa

18-04189-E

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Sunday, April 29, 2018 1:34 PM
To: foiapa
Subject: FOIA Request

RECEIVED

APR 30 2018

Office of
FOIA Services

I would like to request access to Exhibit 10.6 to the Form S-1, as amended, filed by Women First Healthcare, Inc. on 5/24/1999. 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

May 22, 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. 18-04169-E

Dear Mr. Edwards:

This letter is in response to your request, dated April 29, 2018 and received in this office on April 30, 2018, for information regarding Exhibit 10.6 to the Form S-1, as amended, filed by Women First Healthcare, Inc. on May 24, 1999.

The search for responsive records has resulted in the retrieval of 22 pages of records that may be responsive to your request. They are being provided to you with this letter. Please note that this is the best available copy located from a thorough search of the various SEC systems of records.

No fees have been assessed for the processing of this request. If you have any questions, please contact me directly at andersonc@sec.gov or (202) 551-8315. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney 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,

A handwritten signature in cursive script that reads "Clarissa Anderson".

Clarissa Anderson
FOIA Research Specialist

Enclosure

10.6

Distribution Agreement

This Distribution Agreement (this "Agreement") made as of the 1st day of July, 1998 between Ortho-McNeil Pharmaceutical Corporation, a Delaware corporation ("Ortho"), and Women First HealthCare, Inc., a Delaware corporation ("WFH").

WITNESSETH:

WHEREAS, Ortho, among other business activities, is involved in the manufacture for sale of pharmaceutical products; and

WHEREAS, WFH, among other activities, is engaged in the marketing and distribution for sale of pharmaceutical products; and

WHEREAS, WFH has agreed to market and distribute generic estropipate manufactured by Ortho pursuant to that certain Distribution Agreement dated as of December 6, 1997 by and between the parties hereto; and

WHEREAS, Ortho and WFH wish to enter into this Agreement for the marketing and distribution by WFH of certain estropipate products supplied by Ortho or an Affiliate thereof and labeled under the name Ortho-Est and/or such other label as may be mutually agreed upon by Ortho and WFH and approved by the FDA.

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties hereto agree as follows:

ARTICLE I -- Definitions

As used in this Agreement, the following terms have the meanings specified or referred to in this Article I:

"Actual Net Sales" shall mean the amount invoiced by WFH for sales of Products, less estimates which will be adjusted to actual on a periodic basis of: (i) discounts, including cash discounts, discounts to managed care organizations, rebates paid, credited, accrued or actually taken (including government rebates such as Medicaid chargebacks), and retroactive price reductions or allowances actually allowed or granted from the billed amount, (ii) credits or allowances actually granted upon claims, rejections or returns of such sales of Products, and (iii) taxes, duties or other governmental charges levied on or measured by the billing amount when included in billing, as adjusted for rebates, chargebacks, and refunds.

"Affiliate" shall mean a person, firm or entity which directly or indirectly through one or more persons, firms or entities controls, is controlled by, or is under common control with such person, firm or entity.

"Claim(s)" shall mean claim(s) that a Product delivered to WFH does not conform to the Specifications or contains defects in design, material or workmanship.

"Equalization Payment" shall have the meaning set forth in Section 3.1(b)(ii) hereof.

"FDA" shall mean the United States Federal Food and Drug Administration.

"Fiscal Quarter" shall mean a fiscal quarter of WFH.

"Fiscal Year" shall mean a fiscal year of WFH.

"Forecasted Sales" shall mean, with respect to a given period, the amount of "Net Trade Sales" with respect to the Products for the applicable year as set forth in the P&L, multiplied by the appropriate fraction for such period (i.e., one-twelfth for a month, one-fourth for a quarter, etc.).

"Incremental Sales" shall mean, with respect to a given period, the Actual Net Sales of all Trade Units sold by WFH during such period, minus the Forecasted Sales for such period.

"Invoiced Amount" shall mean the amount invoiced by Ortho to WFH for Products shipped by Ortho to WFH in any given period with respect to such period.

"Inventory Base Amount" shall mean the amount determined by multiplying (i) the number of units of Product carried in WFH's inventory by (ii) the applicable transfer price (as set forth on Exhibit D).

"Inventory Payment" shall mean, with respect to a given period, the amount determined by multiplying the Prime Rate by [REDACTED] of the Inventory Base Amount for such period.

"P&L" shall mean the forecasted Income Statement (including forecasted Pre-Tax Profits) with respect to the Products as agreed upon by both WFH and Ortho and attached hereto as Exhibit B.

"Pre-Tax Profit" shall mean, with respect to a given period, the Income Before Tax with respect to the Products for the applicable year as set forth in the P&L, multiplied by the appropriate fraction for such period (i.e., one-twelfth for a month, one-fourth for a quarter, etc.).

"Prime Rate" shall mean the prevailing prime rate of interest (as published in the Wall Street Journal), as determined on the last date of the applicable Fiscal Month, divided by 12 (to reflect a monthly rate).

"Product" shall mean an estropiate product labeled and packaged under the name Ortho-Est and/or such other label as may be mutually agreed upon by Ortho and WFH and approved by the FDA, in one of the dosage forms listed in Exhibit C hereto, plus any additional dosage form for which Ortho subsequently receives approval from the FDA.

"Rebate Payment" shall have the meaning set forth in Section 3.1(b)(i) hereof.

"Royalty Payment" shall mean, with respect to a given period, an amount equal to [REDACTED] of the Incremental Sales for such period.

"Specifications" shall mean the USP specifications for estropiate in tablet form and the labeling and packaging specifications as defined in Exhibit E hereto.

"Territory" shall mean the United States of America (including Puerto Rico).

"Trade Unit" shall mean a unit of Product to be sold for commercial purposes and shall not include any sample Products.

"Transfer Price" shall mean with respect to a given year, the applicable transfer price for the Products as set forth on Exhibit D.

ARTICLE II – Description of Arrangement

2.1 Ortho hereby appoints WFH as the exclusive distributor of the Products throughout the Territory and shall sell to WFH WFH's requirements for Products and WFH shall purchase its requirements for Products, if any, from Ortho; provided, however, that nothing contained herein shall prevent or otherwise limit Ortho or any of its customers who purchase generic estropiate products from Ortho as of the date of this Agreement from performing under any such arrangements.

2.2 Ortho shall label or arrange for the labeling of Products sold hereunder upon receipt of camera-ready artwork from WFH to meet the specifications set forth on Exhibit E hereto; provided that prior to such time, Ortho may satisfy its obligations under Section 2.1 above by supplying WFH with its existing inventory of Ortho labeled Product. The parties shall consult concerning appropriate labeling upon execution of this Agreement. WFH shall not acquire any rights in or use any trademarks, trade names, service marks, or other identification owned or used by Ortho or any of its Affiliates in connection with the Products, except as contemplated by Section 2.8. The parties also each agree to keep a copy of this Agreement for at least two years after the final shipment or delivery of such Product labeled by or for WFH from

the WFH distribution facility. Further, each party agrees to make such copy available for inspection at any reasonable hour to any officer or employee of the Federal Department of Health and Human Services who requests it. Ortho shall not acquire any rights in or use any trademarks, trade names, service marks, or other identification owned or used by WFH or any of its Affiliates in connection with the Products.

2.3 WFH shall provide to Ortho on the first business day of each month a forecast of its orders for each of the Products for the then-following 12 months, along with requested shipment dates for such Products. Each forecast shall be binding upon WFH with respect to orders forecasted for the lesser of (i) the then-following three months, or (ii) the remaining term of this Agreement (the "Binding Forecast"). No change may be made in the Binding Forecast for Products or the shipment dates requested therefor without the prior consent of Ortho. Ortho shall use reasonable efforts to honor any increase in the amount of Product forecasted for any month, up to 25% of the amount originally forecasted for such month. In addition, in no event shall WFH provide less than 90 days' notice of a requested shipment date. All orders for Product shall be in whole number full batch lots.

2.4 Ortho agrees that it or its manufacturer of Products shall provide a certificate of conformance to WFH for its review and records with each shipment of Products to WFH. Ortho shall ship Products ordered by WFH via regular freight in accordance with the delivery instructions set forth in such order. All such shipments shall be FOB site of manufacture.

2.5 The terms and conditions of this Agreement shall supersede and control any inconsistent terms and conditions in any form of order, acknowledgment or invoice used by the parties.

2.6 Ortho shall use reasonable efforts to administer the current managed care contracts and any other discount arrangements between Ortho and stated customers as of the date hereof which relate to the Products until such contracts or arrangements expire by their terms. WFH shall reimburse Ortho for rebate amounts and any and all out-of-pocket costs associated or incurred with respect to the administration of such programs with respect to the Products within thirty (30) days of receipt of an invoice therefor. Ortho shall promptly inform WFH of any amendment, modification or supplement to any such contracts or arrangements and shall consult with WFH prior entering into any amendment, modification or supplement to any such contracts or arrangements which materially adversely affects the Products.

2.7 Ortho shall use reasonable efforts to maintain the patient assistance programs in which Ortho participates as of the date hereof with respect to the Products until such programs are transferred to WFH, provided that each party shall use its reasonable best efforts to consummate such transfer no later than six months from the date hereof; provided that any and all costs associated or incurred with respect to the administration of such programs with respect

to the Products shall be passed on to, and shall be the sole responsibility of, WFH (including without limitation, with respect to program administration, Product cost, shipping, etc.).

2.8 Advertising and other promotional materials created by WFH to promote sales of the Products, and any use of the ORTHO-EST Trademark, will be submitted to Ortho for its prior written approval which approval shall not be unreasonably withheld; provided that if no response is sent by Ortho within thirty (30) days after receipt of such request, approval shall be deemed to have been given. All promotional costs and expenses and all selling costs and expenses shall be borne by WFH.

2.9 WFH shall, subject to the terms and conditions of this Agreement, use commercially reasonable efforts to lawfully promote, distribute and market the Products so as to optimize sales and distribution of the Products, and shall do no act or thing to derogate from, diminish or injure the market for the Products. WFH shall only be authorized to promote, distribute, market and sell the Products within the Territory.

2.10 Ortho shall prepare and file at its expense all regulatory filings and perform any other regulatory compliance necessary to maintain all licenses, permits and approvals required by any government agency in connection with the manufacturing of the Products.

ARTICLE III -- Payments

3.1 (a) WFH shall pay for all Products shipped by Ortho to WFH at the applicable Transfer Price within thirty (30) days of the date of invoice therefor.

(b) Within (i) ten (10) business days following the end of each month which is not the final month of the Fiscal Year (i.e. December), and (ii) within thirty (30) calendar days following the end of the Fiscal Year, WFH shall prepare and deliver to Ortho (x) a report containing its sales data for such month on a month and year to date basis (including the number of units of Product sold and the respective prices therefor and such other information reasonably necessary to compute the payments contemplated in this Section 3.1), and (y) a payment reconciliation report, on a month to date and year to date basis, in substantially the form attached hereto as Exhibit A, which sets forth the calculation, among other things, regarding the net payments to be made by Ortho to WFH, or by WFH to Ortho, as the case may be, in connection with the following:

(i) if, on a year to date basis, the [REDACTED] with respect to such period, the [REDACTED] within ten (10) days after Ortho's receipt of the such report; and

3.4 (a) All payments by WFH shall be made via wire transfer to the account of Ortho as follows:

[Account Number: [REDACTED] ABA Number: [REDACTED]
JOM Pharmaceutical Services
c/o Harris Bank/Phone: [REDACTED]
; or as otherwise provided by notice from Ortho from time to time.

(b) All payments by Ortho shall be made via wire transfer to the account of WFH as follows:

Account Number: [REDACTED] ABA Number: [REDACTED]
Women First HealthCare, Inc.
c/o Republic National Bank/Phone: [REDACTED]

or as otherwise provided by notice from WFH from time to time.

ARTICLE IV – Claims for Nonconforming Product

4.1 During the First Contract Year, WFH shall have 45 days (and for each Contract Year thereafter, 30 days) after receipt of any shipment of products to examine such products to determine if they conform to the Specifications and if they are free from defects in design, material and workmanship, and, on the basis of such examination, to accept or reject such shipment. All Products shall have a shelf-life of at least two (2) years prior to the applicable expiration date at the time such Products are first received and accepted by WFH. Any Claims shall be made by WFH in writing to Ortho, indicating in detail the nonconforming characteristics of the Products. After the submission of a Claim by WFH, Ortho shall, at WFH's option, provide WFH with (i) a refund of the full amount paid by WFH for such Products, (ii) a credit against future billings equal to the full amount paid by WFH for such Products, or (iii) replacement for such Products. In no event shall Ortho be required to accept the return of any Products or provide reimbursement or credit for any Products to WFH solely because the expiration date for such Products shall have passed, provided that such Products have been received and accepted by WFH at least two (2) years prior to the applicable expiration date. Ortho shall pay for all shipping costs of returning the Products that are the subject of Claims. Ortho shall bear the risk of loss for such Products, beginning at such time as they are taken at WFH's premises for return delivery.

4.2 Any shipment of the Products to WFH for which WFH shall not submit a Claim within 45 days for the First Contract Year (or 30 days for any subsequent Contract Year) after delivery shall be deemed accepted. Upon acceptance, WFH shall release Ortho from all Claims for non-conformity or defects except Claims for latent defects which are not reasonably detectable at the time of acceptance.

ARTICLE V -- Warranties

5.1 Ortho warrants that any Products to be supplied to WFH hereunder will, upon shipment, comply in all respects with the Specifications and the specifications referred to in the Federal Food Drug and Cosmetic Act, and regulations issued pursuant to that Act, including but not limited to, regulations concerning current good manufacturing practices and the Quality System Regulations (as defined by the FDA) (the "QSR's"). The foregoing warranty shall not apply to any Products that after delivery to WFH (i) has been tampered with or otherwise altered; (ii) has been subjected to misuse, negligence or accident; or (iii) has been stored, handled or used in a manner contrary to FDA or other governmental requirements or Ortho's written instructions or applicable industry practices or standards. Subject to the first sentence of this Section 5.1 and except as otherwise expressly provided herein, ORTHO MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY OTHER MATTER WITH RESPECT TO THE PRODUCT WHETHER USED ALONE OR IN COMBINATION WITH ANY OTHER MATERIAL. Ortho agrees to bear the direct, incremental out-of-pocket costs reasonably incurred by WFH due to the recall of any Product or seizure of any Product by appropriate governmental authorities as a result of a wrongful act or omission by Ortho, including without limitation negligence in manufacture or failure to comply with applicable regulations concerning good manufacturing practices and the QSR's. Ortho further represents and warrants that to the best of its knowledge, (x) the Trademark and the Product do not infringe any patent, trademark, service mark, trade name, copyright, trade secret or other proprietary rights (collectively, Intellectual Property') of third parties in the Territory, and (y) it is the holder of all Intellectual Property necessary to perform its obligations hereunder. Ortho further agrees to notify WFH within twenty-four hours of receipt of notice from any source of any and all adverse reactions reported to Ortho and which were alleged to have been caused by any Product or similar products, or any other issues related to the design, materials or workmanship of the Product or similar products reported to Ortho.

5.2 WFH warrants that it will comply with all laws, regulations and orders in the United States, respecting sale of the Products. Without limiting the generality of the foregoing, WFH specifically warrants that as of the commencement of the First Contract Year and thereafter during the term of this Agreement it will have in place an effective system for tracking Products in the event a recall is necessary. WFH further agrees to use its reasonable best efforts in the event of a recall to notify all Product purchasers of the recall and to facilitate retrieval of Products recalled. WFH further agrees to notify Ortho within twenty-four hours of receipt of

notice from any source of any and all adverse reactions reported to WFH alleged to have been caused by any Product or similar products, or any other issues related to the design, materials or workmanship of the Product or similar products reported to WFH. WFH agrees to maintain (a) workers' compensation insurance for all of its employees, the limits of which shall be statutory, and (b) commercial general liability and automobile insurance with limits of not less than \$5,000,000 per occurrence.

5.3 Ortho hereby agrees to protect, indemnify, defend and hold harmless WFH, its officers, directors, shareholders, Affiliates, agents and employees from and against any and all claims, demands, actions, causes of action or judgments of any kind, nature and description for injury to or death of any person or persons whomsoever, together with costs and expenses thereto, including reasonable attorneys' fees, arising out of any product liability claims to the extent that Ortho has breached its warranties set forth in Section 5.1 hereof.

5.4 WFH hereby agrees to protect, indemnify, defend and hold harmless Ortho, its affiliates, officers, agents and employees from and against any and all claims, demands, actions, causes of action or judgments of any kind, nature and description as a result of WFH's breach of any of its warranties contained herein and for any statement, representation or warranty made by WFH or any of its agents with respect to a Product or its use that is not first approved by Ortho in writing or that is not consistent with the statements, representations or warranties contained in the Product labeling or package insert.

5.5 Ortho and WFH agree to promptly notify each other of and cooperate with and assist each other in investigating and answering any customer and regulatory complaints and inquiries concerning any of the Products without prejudice as to which party which might be ultimately liable or responsible therefor. In connection therewith, each party will comply with the current Ortho-McNeil Complaint Procedures, as may be amended from time to time.

5.6 Except as set forth in Section 5.3 hereof, neither party shall, in any case, be liable to the other party for special, incidental or consequential damages arising from breach of warranty, breach of contract, negligence or any other legal theory. Such damages include, but are not limited to, loss of profits or revenue, injury to business, cost of capital, cost of any substitute product, facilities or services, or claims of customers of either party for such damages.

5.7 The parties agree that WFH shall have no liability whatsoever for claims in respect of any Products sold by Ortho and its Affiliates prior to the date of this Agreement, including without limitation, any past or currently pending or threatened personal injury claims relating to the use of such products, and Ortho agrees to protect, indemnify, defend and hold harmless WFH, its officers, directors, shareholders, Affiliates, agents and employees from and against any and all claims, demands, actions, causes of action or judgments of any kind, nature and description arising from or relating to such matters.

5.8 (a) Subject to Section 6.2(a)(vi) hereof, Ortho agrees that it shall use its reasonable best efforts to correct process revalidation issues raised by the FDA related to the Products, including any reformulation of the Products if Ortho in its sole discretion determines such reformulation to be necessary; provided that Ortho shall be responsible for all costs associated therewith; and, provided further, that Ortho shall have no obligation with respect to the taking of such corrective action pursuant to this Section 5.8 or otherwise in the event that in the reasonable determination of Ortho the estimated cost of such corrective action would exceed \$3,000,000 in the aggregate; and, provided further, that in the event of any recall or failure to supply Product which is a result of Ortho's breach of any representation or warranty set forth in this Agreement, the parties shall agree to use good faith efforts to renegotiate the payments to be made under Section 3.1 hereof.

(b) Each of the parties hereby agrees and acknowledges that any failure to supply Products by Ortho to WFH as a result of the process revalidation issues raised by the FDA related to the Products set forth in Section 5.8(a) above, shall not be deemed a breach of Ortho's obligation to supply Product to WFH pursuant to Article 2 hereof or otherwise.

ARTICLE VI -- Term

6.1 The term of this Agreement shall commence on the date hereof and end on the date ten (10) years after the date hereof, unless sooner terminated as provided herein. The term of this Agreement shall automatically renew for one (1) year periods unless either party elects not to so renew the term which election shall be made by such party giving written notice to the other party of its election not to renew not less than 180 days prior to the end of the initial or renewal term. In the event of any renewal of this Agreement, the data set forth in the Exhibits attached hereto with respect to the year 2007 shall apply to any renewal term, unless otherwise agreed in writing by the parties. Notwithstanding any provision of this Agreement to the contrary, upon the expiration or termination of this Agreement, WFH shall have the right to sell all Products remaining in its inventory in the Territory in a manner consistent with its past sales practices during the term of this Agreement; provided that WFH shall pay to Ortho with respect to such Products sold from its inventory a royalty payment equal to [REDACTED] of the most current net trade sales price multiplied by the inventory on-hand.

6.2 (a) This Agreement may be terminated upon notice:

(i) by Ortho, in the event WFH shall have failed to pay any amount due under this Agreement when due, and WFH shall have failed to cure such failure within ten (10) days after receipt of written notice thereof; provided, however, that the right to so cure such failure within the periods provided above shall only be available once in any calendar year; or

(ii) by either party, in the event the other party shall have failed to a material extent to perform or materially breached any term, condition, representation or warranty herein, and such party shall have failed to cure such failure or breach within 30 days after notice thereof; provided, however, that in the event any such failure or breach cannot be cured within such 30 days it shall be sufficient if the party in default shall begin to cure such violation promptly after receipt of the aforesaid notice and shall complete such cure as soon as reasonably practicable; and, provided further, that the right to so cure such failure or breach within the periods provided above shall only be available once in any calendar year; or

(iii) by either party, in the event the other party makes an assignment for the benefit of creditors, is the subject of proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against such party, or has a receiver or trustee appointed for all or substantially all of its property; provided that in the case of an involuntary bankruptcy proceeding, such right to terminate shall only become effective if the other party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof; or

(iv) by either party, in the event the other party shall be subject to an action or proceeding (including without limitation seizure, criminal action, debarment or administrative or judicial actions seeking any of the foregoing) by the FDA or other applicable regulatory authority, except with respect to any issues described in Section 5.8(a) hereof, that might reasonably be expected to materially and adversely affect such party's ability to fulfill its obligations under this Agreement;

(v) by Ortho, upon one (1) years' notice: provided that upon WFH's request, Ortho shall (A) manufacture or have manufactured and provide or cause to be provided to WFH on substantially similar terms as set forth herein, a quantity of the Products sufficient to satisfy WFH's estimated sales of the Product for a one-year period following the effective date of such termination, and (B) use all reasonable commercial efforts to (i) transfer to WFH the rights to manufacture and sell the Products in the Territory for the term of this Agreement, including without limitation the New Drug Application and all other necessary permits, authorizations and approvals, and (ii) grant to WFH of a fully paid license to the ORTHO-EST trademark and all other intellectual property necessary to manufacture and sell the Products in the Territory for the term of this Agreement, and, provided further, that nothing contained herein shall limit Ortho from engaging a third party to manufacture the Products so long as Ortho continues to perform its obligations hereunder;

(vi) by Ortho, in the event that in the reasonable determination of Ortho (A) the estimated cost of taking the corrective action described in Section 5.8 above would exceed \$3,000,000, or (B) it would be impracticable to correct the process revalidation

issues raised by the FDA related to the Products described in Section 5.8(a) above without effecting Ortho's ability to supply Products to WFH in accordance herewith; or

(vii) by either party without cause, at any time after the expiration of the initial term, by giving 180 days prior written notice to the other party.

(b) All of the foregoing remedies set forth above in this Section 6.2 shall be alternative and not exclusive and exercise of any one such at any time shall not preclude or constitute a waiver of a further exercise at another time or times or the exercise of such other remedy or remedies as are provided herein or under applicable law. Termination for default or breach hereunder shall have no effect on performance obligations or amounts to be paid which have accrued up to the effective date of such termination.

6.3 The provisions of this Agreement set forth in Article V and Article VIII and any remedies for the breach thereof, shall survive the termination of this Agreement under the terms hereof.

ARTICLE VII -- Force Majeure

7.1 The performance of the obligations of either party hereunder shall be subject to any delays or non-performance caused by circumstances beyond the reasonable control of such party, including without limitation, requisition by any government authority or any other governmental order or regulation, wars, work stoppages due to strikes, lockouts or other labor disputes, riots, epidemic, disease, acts of God, civil commotion, fire, earthquake, storm, failure of public utilities or common carriers, shortage of or inability to obtain materials, equipment, supplies, utilities, labor or transportation from normal sources, breakdown of or injury to facilities or equipment used for production, transportation, receiving, manufacturing, processing, handling or delivery of Products, technical or other infeasibility of manufacturing any formulation which has been changed from the specifications therefor as a result of any governmental action, or any other circumstances whatsoever, whether similar to the above causes or not; provided, however, that a party excused from performance under this Section 7.1 shall provide prompt notice of any such event to the other party, that the duration of such excused performance shall be limited by the duration of such force majeure event plus ninety (90) days and the party affected shall use all reasonable efforts to resume performance under this Agreement as soon as reasonably practicable.

ARTICLE VIII -- Miscellaneous

8.1 Expenses. Expenses related to this Agreement and the transactions contemplated hereby, including without limitation the fees of counsel and accountants, shall be borne by the party incurring such expenses, except as expressly provided otherwise in this Agreement.

8.2 Modifications and Waivers. This Agreement may be modified and rights hereunder may be waived only by a writing executed and delivered on behalf of the party against whom such modification or waiver is asserted.

8.3 Governing Law. This Agreement and the transactions contemplated hereby shall be governed by and construed in accordance with the laws of the State of New York applicable to agreements made and to be performed entirely within such State, without regard to the conflicts of laws principles of such State.

8.4 Arbitration. Any controversy or claim arising out of or relating to this Agreement or the validity, inducement, or breach thereof, shall be settled by arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then pertaining, except where those rules conflict with this provision, in which case this provision controls. The parties hereby consent to the jurisdiction of the Federal District Court for the District of Delaware for the enforcement of these provisions and the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction shall enforce this clause and enter judgment on any award. The arbitrator shall be an attorney specializing in business litigation who has at least 15 years of experience with a law firm of over 25 lawyers or was a judge of a court of general jurisdiction. The arbitration shall be held in New York, New York and the arbitrator shall apply the substantive law of New York, except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. Within 30 days of initiation of arbitration, the parties shall reach agreement upon and thereafter follow procedures assuring that the arbitration will be concluded and the award rendered within no more than six months from selection of the arbitrator. Failing such agreement, the AAA will design and the parties will follow such procedures. Each party has the right before or during the arbitration to seek and obtain from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration. THE ARBITRATOR SHALL NOT AWARD ANY PARTY PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, AND EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT TO SEEK SUCH DAMAGES.

8.5 Notices. Any notice, request, instruction or other communication to be given by either party to the other party in connection with this Agreement or the transactions contemplated hereby shall be in writing and delivered by messenger, or sent by certified mail (postage prepaid) or telefax, to the address of such party set forth below or as changed by such party by notice given hereunder. Any notice hereunder shall be effective upon receipt at the indicated address. Such notices shall be

provided, if to Ortho, to:

Ortho-McNeil Pharmaceutical Corporation

U.S. Route #202 South
Raritan, New Jersey 08869
Attention: President
Fax: (908) 707-9757

with a copy (which copy shall not constitute notice) to:

Johnson & Johnson
Office of General Counsel
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
Fax: (732) 524-2788

and, if to WFH to:

Women First HealthCare, Inc.
12220 El Camino Real, Suite 400
San Diego, California 92130
Attention: President
Fax: (619) 509-1350

with a copy to:

Latham & Watkins
701 "B" Street, Suite 2100
San Diego, California 92101
Attention: Scott N. Wolfe, Esq.
Fax: (619) 696-7410

8.6 Section Headings. The section captions used in this Agreement and the index are for cross-reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. As used in this Agreement, the terms "hereof", "herein" and terms of like import shall refer to the entire agreement, including without limitation all schedules, exhibits and attachments hereto and thereto.

8.7 Accounting Terms. Each accounting term used herein and not otherwise defined shall have the respective meaning accorded it under generally accepted accounting principles, consistently applied on a year-to-year basis.

8.8 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original and all of which shall be deemed to constitute the same Agreement.

8.9 Integration. Before signing this Agreement the parties had numerous conversations, including preliminary discussions, formal negotiations and informal conversations, and generated correspondence and other writings in which the parties discussed the transactions contemplated hereby and their aspirations for success. In such conversations and writings, individuals representing the parties may have expressed their judgments and beliefs concerning the intentions, capabilities and practices of the parties, and may have forecasted future events. The parties recognize that such conversations and writings often involve an effort by both sides to be positive and optimistic about future prospects. However, it is also recognized that all business transactions contain an element of risk, as do the transactions contemplated hereby, and that it is normal business practice to limit the legal obligations of contracting parties to only those promises and representations which are essential to their transactions so as to provide certainty as to their respective future rights and remedies. Accordingly, this Agreement is intended to define the full extent of the legally enforceable undertakings of the parties hereto, and no promise or representation, written or oral, which is not set forth explicitly in this Agreement is intended by either party to be legally binding. Both parties acknowledge that in deciding to enter into this Agreement and to consummate the transactions contemplated hereby neither has relied upon any statements or representations, written or oral, other than those explicitly set forth in this Agreement.

8.10 Confidentiality; Publicity. All written information marked as confidential and exchanged between WFH and Ortho while this Agreement is in effect shall be treated as confidential information unless one of the exceptions set out below applies. The party receiving such confidential information shall not, for so long as that information retains its character as confidential information, use (other than in the performance of its obligations or the exercise of its rights hereunder) or disclose such information to any third party (except any Affiliates or those consultants of the receiving party that have an obligation of confidentiality to the receiving party) without the prior written approval of the disclosing party. Information will be deemed nonconfidential at such time as such information either has become public knowledge through no fault of the party receiving such information, or comes to such party from a third party under no obligation of confidentiality with respect to such information, or was in the possession of such party prior to the date of disclosure, or is developed by or on behalf of such party without any reliance on confidential information received hereunder or is otherwise required to be disclosed in compliance with an order by a court or other regulatory body having competent jurisdiction. The obligations of the parties set forth in this Section shall survive termination of this Agreement until the third anniversary of the effective date of such termination. Upon termination of this Agreement, all Confidential Information of a disclosing party that is held by a receiving party shall be returned to the disclosing party except that one copy of such Confidential Information shall be retained by counsel for the receiving party to ensure compliance with this Section. Neither party shall originate any publicity, news release or public announcement, written or oral, whether to the public or press, stockholders or otherwise, relating to this Agreement, to any amendment or performances under the Agreement, without the prior written consent of the other which consent shall not be unreasonably withheld, except for such announcements as in the opinion of counsel for

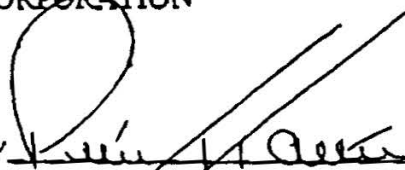
the party making such announcement is required by law to be made. If a party decides to make an additional announcement required by law under this Agreement, it shall give the other party thirty (30) days advance written notice, or any shorter notice period otherwise required by law, of the text of the announcement so that the other party shall have an opportunity to comment upon the announcement.

8.11 WFH Acknowledgment. WFH hereby acknowledges that nothing expressed or implied in this Agreement shall prevent, prohibit or otherwise restrict the ability of Ortho or any of Ortho's Affiliates from promoting, selling or otherwise distributing any other product on a brand name or generic basis or any other basis that may compete with, or is substantially similar to, any or all of the Products; provided that in no event shall Ortho or any of its Affiliates promote, sell or distribute any estropiate product sold as a single ingredient product in an oral formulation nor shall it enter into any arrangement with any third party with respect to the promoting, selling or distributing any estropiate product sold as a single ingredient product in an oral formulation, except as contemplated in Section 2.1 hereof.

8.12 Assignment. This Agreement, or any of the rights and obligations created herein, shall not be assigned or transferred, in whole or in part, by either party hereto without the prior written consent of the other party, which consent shall not be unreasonably withheld; provided, however, that Ortho shall have the right to assign any or all of its rights or obligations under this Agreement to any Affiliate, or a successor to that part of its business to which this Agreement relates, without such prior written consent. Nothing contained in this Section 8.12 shall restrict or limit in any manner Ortho's ability to have the Products manufactured by a third party; provided that Ortho remains bound by its obligations hereunder. Any attempted assignment or transfer of such rights or obligations without such consent, except as provided herein, shall be void. Subject to the foregoing sentence, this Agreement shall bind and inure to the benefit of the parties hereto and their respective successors and assigns.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representative.

ORTHO-MCNEIL PHARMACEUTICAL
CORPORATION

By 
Name: PETER T. TATTLE
Title: CHAIRMAN

WOMEN FIRST HEALTHCARE, INC.

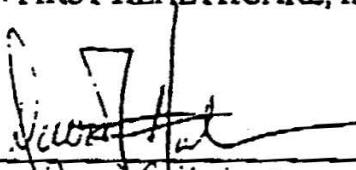
By 
Name: David F. White
Title: President & CEO

Exhibit A

**Ortho-Est
Payment Reconciliation - Trade Product**

1. No Reconciliation Payment Due

<u>Actual Trade Units Shipped</u>	<u>Transfer Price</u>	<u>Total</u>
.625 MG	\$ 2,000	\$ 1,250.00
1.25 MG	\$ 3,000	\$ 3,750.00
Total invoiced product		\$ 5,000.00
Total forecasted IBT (\$6,637 divided by 12)		\$ 553.08
Total invoiced Product over IBT forecast		\$ 4,446.92
Actual Net Sales		\$ 5,000.00
Forecasted Net Sales		\$ 5,000.00
Actual Incremental Sales (Assumes no incremental sales)		\$ -
Royalty payment of 15% on incremental sales		\$ -
Actual Manufacturing Cost		\$ -
.625 MG	\$ 2,000	\$ 1,250.00
1.25 MG	\$ 3,000	\$ 3,750.00
Actual Manufacturing Cost due to OMP		\$ 5,000.00
Equalization Payment Due/(Rebate Payment Due)		\$ -

2. Equalization Payment Due

<u>Actual Trade Units Shipped</u>	<u>Transfer Price</u>	<u>Total</u>
.625 MG	\$ 2,616	\$ 1,635.00
1.25 MG	\$ 3,637	\$ 4,546.25
Total invoiced product		\$ 6,181.25
Total forecasted IBT (\$6,637 divided by 12)		\$ 553.08
Total forecasted IBT over total invoiced product		\$ 508.23
Actual Net Sales		\$ 6,181.25
Forecasted Net Sales		\$ 6,181.25
Actual Incremental Sales (Assumes no incremental sales)		\$ -
Royalty payment of 15% on incremental sales		\$ -
Actual Manufacturing Cost		\$ -
.625 MG	\$ 2,616	\$ 1,635.00
1.25 MG	\$ 3,637	\$ 4,546.25
Actual Manufacturing Cost due to OMP		\$ 6,181.25
Equalization Payment Due/(Rebate Payment Due)		\$ 508.23

3. Rebate Payment Due

<u>Actual Trade Units Shipped</u>	<u>Transfer Price</u>	<u>Total</u>
.625 MG	\$ 2,616	\$ 1,635.00
1.25 MG	\$ 7,366	\$ 9,001.25
Total invoiced product		\$ 10,636.25
Total forecasted IBT (\$6,637 divided by 12)		\$ 553.08
Total forecasted IBT over total invoiced product		\$ (83,894)
Actual Net Sales		\$ 10,636.25
Forecasted Net Sales		\$ 612,583
Actual Incremental Sales		\$ 10,636.25
Royalty payment of 15% on incremental sales		\$ 1,595.44
Actual Manufacturing Cost		\$ -
.625 MG	\$ 2,616	\$ 1,635.00
1.25 MG	\$ 7,366	\$ 9,001.25
Actual Manufacturing Cost due to OMP		\$ 10,636.25
Equalization Payment Due/(Rebate Payment Due)		\$ 1,595.44

**Ortho-Est
Income Statement
(Dollars In Thousands)**

[illegible]

Exhibit C

Products-Ortho-Est (Estropipate)

Dosage

Trade Product:

.625 mg Bottles of 100 tablets

1.250 mg Bottles of 100 tablets

Sample Product:

.625 mg Bottles of 30 tablets

1.250 mg Bottles of 30 tablets

Transfer Prices

[illegible]

Exhibit E
Labeling Specifications

Dispense in child-resistant container.
Store below 30°C (86°F).
Dispense in a tight, light-resistant
container as defined in the USP.

PHARMACIST'S NOTE: Include one
patient package insert with each
prescription dispensed.

100 Tablets NDC 0062-1801-01

ORTHO
Estropipate
ORTHO
tablets USP, 0.75 mg



Caution: Federal law prohibits
dispensing without prescription.

ORTHO PHARMACEUTICAL
CORPORATION
Raritan, New Jersey 08869



Each tablet contains: Estropipate
0.75 mg calculated as sodium
estrone sulfate 0.625 mg.

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0062-1801-01

Dispense in child-resistant container.
Store below 30°C (86°F).
Dispense in a tight, light-resistant
container as defined in the USP.

PHARMACIST'S NOTE: Include one
patient package insert with each
prescription dispensed.

100 Tablets NDC 0062-1800-01

ORTHO
Estropipate
ORTHO
tablets USP, 1.5 mg



Caution: Federal law prohibits
dispensing without prescription.

ORTHO PHARMACEUTICAL
CORPORATION
Raritan, New Jersey 08869



Each tablet contains: Estropipate
1.5 mg calculated as sodium
estrone sulfate 1.25 mg

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0062-1800-01