January 15 2018

US Securities & Exchange Commission Office of FOIA and Privacy Act Operations 100 F Street, NE Mail Stop 5100 Washington, DC 20549-5100 18-01948]-E

RECEIVED

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Office of FOIA Services

Dear FOIA Office:

Under the Freedom of Information Act (FOIA), please send a copy of the following: A copy of:

Exhibit: 10.1 to the form 8-K filed by PediatRx Inc. on September 14, 2011 In the event confidential

treatment has not expired provide the specific date for which confidential treatment is still in

effect. I do not need a copy of the order. We authorize up to \$61.00 in processing fees.

Thank You,

**Christopher Dalziel** 

Editor - Deals

Clarivate Analytics Friars House, 160 Blackfriars Road London, UK SE1 8EZ

Phone: +44-2074334789 paul.dsouza@clarivate.com



# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

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

Office of FOIA Services

February 15, 2018

Mr. Paul D'Souza Clarivate Analytics 160 Blackfriars Road London, SE18EZ United Kingdom

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

Request No. 18-01948-E

Dear Mr. D'Souza:

This letter is in response to your request, dated January 15, 2018 and received in this office on January 16, 2018, for access to Exhibit 10.1 to the Form 8-K filed by PediatRx, Inc. on September 14, 2011.

The search for responsive records has resulted in the retrieval of 9 pages of records that may be responsive to your request. They are being provided to you with this letter.

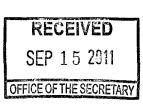
No fees have been assessed for the processing of this request. If you have any questions, please contact me at <a href="mailto:taylorf@sec.gov">taylorf@sec.gov</a> or 202-551-8349. You may also contact me at <a href="mailto:foiapa@sec.gov">foiapa@sec.gov</a> or (202) 551-7900. You also have the right to seek assistance from Dave Henshall 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 <a href="mailto:Archives.gov">Archives.gov</a> or via e-mail at <a href="mailto:ogis@nara.gov">ogis@nara.gov</a>.

Sincerely,

Felecia Taylor

FOIA Lead Research Specialist

Enclosure



#### **CO-PROMOTION AGREEMENT**

THIS CO-PROMOTION AGREEMENT (the "Agreement") is made as of September 12, 2011 (the "Effective Date"), between:

**BI-COASTAL PHARMACEUTICAL CORP.**, a New Jersey corporation ("Company"), with an office located at 130 Maple Avenue, Red Bank, New Jersey 07701 USA; and

PEDIATRX, INC., a Nevada corporation ("PediatRx"), with an office located at 405 Trimmer Road, Suite 200, Califon, NJ 07830 USA.

BACKGROUND: Company is the owner of the pharmaceutical product known as AQUORAL<sup>TM</sup>, U.S. NDC No. NHRIC 8546.0001.40 (the "<u>Product</u>") which has been approved for sale in the United States of America (the "<u>Territory</u>"). PediatRx desires to Promote (defined below) the Product on a non-exclusive basis in the Territory, in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, the parties hereto hereby agree as follows:

### 1. <u>CO-PROMOTION SERVICES</u>

- Engagement of PediatRx. During the term of this Agreement (the "Term"), and subject to the terms and conditions of this Agreement, Company hereby grants to PediatRx the non-exclusive right to Promote the Product under the Company Trademark in the Territory. As used in this Agreement, "Promote" or "Promotion" shall mean promotion of the Product through PediatRx sales forces, including telemarketing efforts as carried out by contracted telemarketing groups when available, in the Territory with detailing activities in at least a secondary detail position, ordinarily and customarily undertaken by a sales representative during a face-to-face sales call on medical professionals, excluding dental care professionals, with prescribing authority to provide information on the use, safety, effectiveness, contraindications, side effects, warnings and other relevant characteristics of the Product and using, as necessary or desirable, Promotional Materials (defined below) provided by Company. PediatRx shall include such Product details in no less than 85% of the sales calls made by its sales and telemarketing forces. PediatRx shall include the Product in no less than 85% of appropriate trade presentations and meetings that it attends within the Territory.
- Non Exclusivity. No exclusive rights are provided to either party by this Agreement. Company may appoint other representatives for the Promotion of the Product in the Territory. PediatRx may market products similar to or competitive with the Product in the Territory. This Agreement does not provide for any minimum efforts or minimum sales obligations for PediatRx with the exception of the detailing of the Product in at least a secondary position in no less than 85% of the sales calls made by its sales and telemarketing forces.

## 2. PEDIATRX OBLIGATIONS

2.1 General. PediatRx shall collaborate jointly with Company in order to train, deploy, supervise, motivate and direct the PediatRx sales force to Promote the Product using Promotional Materials supplied by Company in accordance with this Agreement provided such Promotional Materials meet FDA and other regulatory and compliance standards.

- 2.2 <u>Not Company Employees</u>. None of the PediatRx employees or contractors shall represent or hold themselves out as employees of the Company at any time.
- 2.3 Approval of Promotional Materials. Except as required by law or regulation, any Promotional Materials or other material information mentioning the Product (i) by name, (ii) by describing the Product, or (iii) via an internet link to the Product, which PediatRx intends to publish, disclose or otherwise distribute must be approved in advance by Company, which approval may or may not be granted at sole discretion of the Company and will not be unreasonably withheld by the Company.
- 2.4 <u>Costs of Sales Force</u>. Except as expressly provided herein, PediatRx shall pay all costs associated with managing the Promotion of the Product by its sales force.
- 2.5 Records. PediatRx shall maintain records of all sales calls made by its sales force to Promote the Product that will accurately represent the number of calls made for the Product and the number of samples of the Product, if any, left with medical professionals.

#### 3. COMPANY OBLIGATIONS

- 3.1 Promotional Materials. Company, at its cost shall develop, reproduce and deliver to PediatRx sufficient quantities of all Promotional Materials needed to Promote the Product. Company shall own all right, title and interest in and to the Promotional Materials, including all copyrights therein, but excluding any rights in or to trademarks owned by PediatRx and all copyrighted material related to products marketed and sold by PediatRx other than the Product. Company hereby grants to PediatRx a non-exclusive license to use the Promotional Materials and Company trademarks in connection with the Promotion of the Product under the terms of this Agreement in the Territory during the Term.
- Product Samples. Company at its cost shall source and deliver to PediatRx sufficient quantities of samples of the Product needed to Promote the Product, appropriately labeled as required by law, in accordance with a mutually agreed sampling plan. However, if samples are used to demonstrate the use of the Product, then PediatRx will not need to maintain a record of demonstrations made to customers. Initially 100 samples of the Product will be allocated to each PediatRx representative supporting the Product per annum.
- Training. Company at its cost shall provide (i) a trainer and any other pertinent experts for the training of the PediatRx sales, including for the launch meeting and for additional training support reasonably requested by PediatRx from time to time, and (ii) home study training materials for the PediatRx sales force. PediatRx shall pay for any travel and lodging costs associated with training of PediatRx employees as necessary.
- 3.4 Commercialization of the Product. Company shall offer the Product for sale throughout the Territory and shall ensure that there is a continuous supply of sufficient quantities of the Product in wholesale distribution so as to fill all orders for the Product and otherwise fully supply the market. Company shall have the sole responsibility, at its sole cost and expense, with respect to the Product for (i) manufacture, packaging, labeling, shipping, distribution and warehousing; (ii) trade relations and stocking at the retail level; (iii) pricing; (iv) booking sales, order processing, invoicing and collection of receivables; (v) customer support; (vi) medical inquiries; (vii) product and medical complaints; (viii) returns; (ix) recalls and market withdrawals; (x) reporting adverse reactions as required by applicable law or regulation. PediatRx will be informed in a timely fashion of such activities. Negotiating agreements with managed care organizations, payers,

wholesalers, other distribution organizations and Group Purchasing Organizations will be done in collaboration with PediatRx.

3.5 Regulatory Matters. To Company's knowledge, there are no investigations, adverse third party allegations, claims or actions against Company, including any proceedings or any pending or threatened action against Company by or before the U.S. Food and Drug Administration ("FDA") or any other governmental authority, relating to the Product or Company's intellectual property. Company at its cost shall have the sole right and responsibility to handle all recalls and market withdrawals of the Product. Company shall notify PediatRx immediately of (i) any recall or market withdrawal of any lot of a Product, or (ii) any Warning Letter, Notice of Violation letter, or other communication from FDA or any other governmental agency related to the marketing, advertising, promotion, sales or education efforts related to the Product. Company shall determine in its discretion any response to any communication from FDA or any other governmental agency related to the Product; provided, however, that to the extent that any such matter involves or relates to PediatRx sales representatives or other PediatRx actions, the Company shall immediately alert PediatRx of such matter and cooperate in good faith to agree on an appropriate response or other course of action.

### 4. MUTUAL OBLIGATIONS

- 4.1 Compliance with Laws and Guidelines. Each party hereto shall in all material respects conform its practices and procedures relating to the marketing, detailing and Promotion of the Product in the Territory to all applicable laws, regulations and guidelines, including, but not limited to, the Federal Food, Drug and Cosmetic Act, as amended, the Prescription Drug Marketing Act, as amended, The Medicare and Medicaid Patient Protection Act of 1987, as amended, 42 U.S.C. §1320a-7b, State and Federal False Claims acts, the Generic Drug Enforcement Act of 1992 (the "Debarment Act"), as the same may be amended from time to time, and any regulations with respect to the accounting of samples of the Product, and shall immediately notify the other party of and provide the other party with a copy of any correspondence or other reports with respect to the marketing, detailing and Promotion of the Product submitted to or received from the U.S. Department of Health and Human Services or its components (including the FDA and the Office of the Inspector General), PhRMA or the AMA relating to such laws and regulations. Each party has not used and will not use, in any capacity associated with or related to the Product, the services of any persons who have been, or are in the process of being, debarred under the Debarment Act.
- 4.2 Non-Solicitation. During the Term and for one (1) year after the Term, each party agrees that it will not, without the other party's prior written consent, knowingly recruit, solicit or induce any employee or contractor of the other party or any of its affiliates to terminate his or her employment or contract and become employed by or consult for the other party or any of its affiliates. For purposes of the foregoing, "recruit," "solicit" or "induce" shall not be deemed to mean general solicitations of employment. Notwithstanding the foregoing a party shall be free to recruit, solicit or induce an employee or contractor of the other party if such other party took action that terminated the employment or contract of such person.

#### 5. COMPENSATION TO PEDIATRX

5.1 <u>Compensation.</u> In consideration of the services provided by PediatRx hereunder, Company shall compensate PediatRx as specified in Exhibit A hereto.

Audit Right. Company shall keep accurate books of account and records reasonably sufficient to determine the amounts payable to PediatRx pursuant to this Agreement until two (2) years following the relevant Contract Year (as such term is defined in Exhibit A hereto) to which such records pertain, which may be audited by PediatRx or its representative not more than once in any Contract Year with PediatRx to bear cost of audit if conducted.

#### 6. ALLOCATION OF LIABILITIES

- 6.1 Representation and Warranties. Each party represents and warrants to the other party as follows:

  (i) it is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization; (ii) it has the legal power and authority to enter into and be bound by the terms and conditions of this Agreement and to perform its obligations under this Agreement; (iii) it has taken all necessary action on its part to authorize the execution and delivery of this Agreement; (iv) this Agreement has been duly executed and delivered on behalf of such party; and (v) it is not subject to any legal, contractual or other restrictions, limitations or conditions which conflict with its rights and obligations under this Agreement or which might affect adversely its ability to perform under this Agreement.
- 6.2 <u>PediatRx Indemnification</u>. PediatRx shall indemnify and defend Company and its affiliates and their directors, officers, employees and representatives against any third party claims, demands, suits or proceedings arising out of or related to: (i) breach of this Agreement by PediatRx; or (ii) the negligence or willful misconduct of PediatRx, provided that this Section 6.2 shall not cover any matter which is the subject of indemnification by Company under Section 6.3.
- 6.3 Company Indemnification. Company shall indemnify and defend PediatRx and its affiliates and its directors, officers, employees and representatives against any third party claims, demands, suits or proceedings arising out of or related to: (i) breach of this Agreement by Company; (ii) the negligence or willful misconduct of Company; or (iii) the research, development, manufacture, distribution, sale or use of the Product, including without limitation products liability claims and claims for infringement of third party intellectual property rights related to the Product.
- 6.4 Procedure. A party seeking indemnification under Sections 6.2 or 6.3 shall provide the indemnifying party with prompt written notice of any such claim. The indemnifying party shall have sole control and authority with respect to the defense and settlement of any such claim. The indemnified party shall cooperate fully with the indemnifying party, at the indemnifying party's sole cost and expense, in the defense of any such claim. The indemnifying party shall not agree to any settlement of any such claim that does not include a complete release of the indemnified party from all liability with respect thereto or that imposes any liability, obligation or restriction on the indemnified party with the prior written consent of the indemnified party. The indemnified party may participate in the defense of any claim through its own counsel, and at its own expense.
- 6.5 Insurance. Each party agrees to maintain: (i) workers' compensation insurance for all of its employees, the limits of which shall be in statutory compliance with the applicable compensation laws, and employer's liability of not less than \$1,000,000 per accident; and (ii) commercial general liability, including product liability and automobile insurance with limits of not less than \$5,000,000 per occurrence for bodily injury and property damage for commercial general liability, including product liability and \$1,000,000 per occurrence, combined single limit for bodily injury and property damage for automobile insurance, coverage extends to owned, hired, and non-owned vehicles. Neither party's liability under this Agreement shall be limited by the amount of insurance that it maintains. Each Party shall add the other Party as an additional insured on their respective insurance policies and shall provide the other Party with the relevant

documentation of such coverage. For avoidance of doubt, PediatRx representatives are contractors and PediatRx will take reasonable measures to ensure representatives maintain adequate automobile insurance.

- 6.6 <u>Limitation of Remedies</u>. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY UNDER THIS AGREEMENT FOR INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS, BUSINESS OPPORTUNITY OR ENTERPRISE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
- 6.7 <u>Force Majeure</u>. Neither party shall be in default hereunder by reason of any failure or delay in the performance of any obligation under this Agreement where such failure or delay arises out of any cause beyond the reasonable control and without the fault or negligence of such party.

## 7. CONFIDENTIALITY AND PROPRIETARY RIGHTS

- Confidentiality. Each party shall not disclose and shall only use for purposes of this Agreement all information received from the other party and marked or identified as "confidential" during the Term. Notwithstanding the foregoing, information exchanged by the parties shall not be subject to the foregoing restriction on disclosure and use if such information: (i) is or becomes publicly available from a source other than the disclosing party; (ii) is obtained by the receiving party from a third party not subject to confidentiality; (iii) was known by the receiving party at the time of disclosure by the disclosing party, or (iv) is required to be disclosed under applicable laws. In addition, PediatRx shall request that the Securities and Exchange Commission (the "SEC") permit it to keep confidential, for a period of at least two years from the date of this Agreement, any information in this Agreement and in Exhibit A to this Agreement disclosing (i) the amount of the commission to be paid per unit of the Product sold, (ii) the number of samples that will be allocated to each PediatRx representative, and (iii) the home location and sales territory of sales representatives. In the event that the SEC grants this request, the Parties hereto agree to keep this information confidential for a period of two years.
- 7.2 Protection of Proprietary Rights. Each party agrees to cooperate with and assist the other party, at the other party's expense, in the protection of trademarks, patents or copyrights owned by or licensed to the other party, and shall inform the other party promptly of any infringements or other improper action with respect to such trademarks, patents or copyrights that shall come to the attention of such party.

## 8. TERM AND TERMINATION

- 8.1 Term. The Term shall be for an initial term of two (2) years, commencing on the Effective Date and ending on September 12 2013. The Term shall automatically renew for an additional twelve (12) months unless either party provides notice of non-renewal at least six (6) months prior to the end of the initial term or then-current renewal term.
- 8.2 <u>Termination Without Cause</u>. This Agreement may be terminated prior to expiration by either party, without cause and without liability, upon not less than six (6) months prior notice to the other party.
- 8.3 <u>Termination for Cause</u>. This Agreement may be terminated prior to expiration by either party, if the other party (i) materially breaches any of its obligations or provisions of this Agreement;

provided, however, that the defaulting party will be given not less than thirty (30) days prior written notice of such breach and the opportunity to cure the breach during such period; or (ii) is unable to pay its debts, becomes insolvent, makes an assignment for the benefit of creditors, or is the subject of proceedings in bankruptcy, reorganization or receivership.

- Further Diligence. The Agreement is subject to further diligence to be conducted on the market for the Product and other financial data to be received by PediatRx and supplied by the Company. Notwithstanding such diligence, PediatRx agrees to commence co-promotion no later than the Effective Date. Should said diligence indicate that the Product is unsuitable for co-promotion, PediatRx may immediately terminate the Agreement by giving notice to the Company.
- 8.5 <u>Effect of Termination</u>. The rights and obligations of the parties pursuant to Sections 4.2 (Non-Solicitation), 5.2 (Audit Right), 6 (Allocation of Liabilities), 7 (Confidentiality and Proprietary Rights) and 9.2 (General Provisions) shall survive the expiration or termination of this Agreement for any reason.

## 9. MISCELLANEOUS

- 9.1 <u>Independent Contractors.</u> Company and PediatRx are independent parties, and nothing contained herein shall be construed to create a joint venture, partnership or similar relationship. Neither party is authorized to, nor shall it, make any statements, claims, representations, warranties or otherwise act in any way so as to incur any liability whatsoever for which the other may become directly, indirectly or contingently liable.
- 9.2 General Provisions. This Agreement shall be governed by the laws of the State of New Jersey without regard to the choice-of-law principles thereof, and is the entire agreement of the parties related to the subject matter hereof. No amendment or waiver of any provision of this Agreement will be effective unless in writing signed by the parties. Neither party shall assign its rights or delegate its duties hereunder without the written consent of the other party. The illegality or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any legal and enforceable provisions hereof. All notices under this Agreement shall be in writing and given in person, first class registered mail or by reputable delivery service, delivery costs prepaid, addressed to the parties at the addresses specified above, or to such other address of which either party may notify the other pursuant to this sentence. Any headings used herein are for convenience of reference only and are not a part of this Agreement, nor shall they affect the interpretation hereof. This Agreement may be executed in multiple counterparts, each of which is an original, true and correct version hereof, and shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors, and assigns.

IN WITNESS WHEREOF, the parties have executed this Agreement.

<b>BI-COASTAL</b>	PHARMACEU	TICAL
CORP		

PEDIATRX, INC..

By:

Name:

Title:

Ralph Massa, Jr.

President and COO

Date: September 12, 2011

Ву:

Name: Cameron Durrant

Title: President and CEO

Date: September 12, 2011

#### **EXHIBIT A: COMPENSATION**

#### CONFIDENTIAL TO PEDIATRX, INC..

## **Commission Rates**

In consideration of the services provided by PediatRx pursuant to the Agreement, Company shall pay to PediatRx a commission for each unit of the Product as follows:

Product sold by Company in the Territory in the relevant time frame	Commission per unit of the Product
Between September 12, 2011 and December 31, 2011	US\$25.00 per unit
From January 1, 2012 through Term of Agreement US\$20.00 per unit	

"Contract Year" shall mean a twelve (12) month period beginning on September 12 and ending on September 12 the subsequent calendar year during the Term of the Agreement. For avoidance of doubt, unit sales reset to zero at the completion of each Contract Year.

Each commission rate shall only apply to the number of units of the Product sold which related to that rate per the above table. Such commission rates are not cumulative for all units of the Product sold. Payment

On a monthly basis, within thirty (30) days after the close of the first month of the Term and within fifteen (15) days after the close of each month thereafter, Company shall provide PediatRx with a detailed report calculating commissions due to PediatRx hereunder. Payments to PediatRx shall be made with each such report (within fifteen (15) days after the close of each month after the first month) during the Term for sales of the Product in such month. Interest on late payments shall accrue at the rate of one percent (1%) per month. Payments shall be made in U.S. dollars by check or wire transfer to a bank and account designated in writing by PediatRx.

Commissions shall accrue and shall be payable for all units sold by PediatRx in areas covered by its representatives in the Territory during the Term. Representatives and the areas covered will be submitted to Company on a monthly basis or on a representative-by-representative basis upon contracting such representatives. In addition, and subject to PediatRx ability to secure contracts with distributors, Group Purchasing Organizations and other organizations responsible for distribution of Product (referred to collectively as 'Distribution Entities') and such Distribution Entities to be specified by PediatRx to Company with copies of relevant contracts specifying Product, PediatRx will be compensated for Product sales from the Company to those Distribution Entities.

As of Effective Date, representatives home location in:

California - to cover S. California, Arizona, Nevada

California - to cover N. California

New Hampshire – to cover New Hampshire, Massachusetts, Connecticut, Rhode Island, Maine, Vermont

Florida - to cover South and Central Florida

Florida - to cover N. Florida

Florida – to cover Texas, Virginia

Georgia - to cover Georgia, Alabama, Mississippi

TO ADD REP TERRITORY DETAILS ON ROLLING BASIS AS TAKEN ON BOARD

\* \* \* \* \*