**PRODUCT DEVELOPMENT AGREEMENT**

**Featured Drug Development Agreements**

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.   
  
Exhibit 10.11   
  
PRODUCT DEVELOPMENT AGREEMENT   
  
  
THIS PRODUCT DEVELOPMENT AGREEMENT is made and entered into this 24 th day of January, 2003 (the " Effective Date" ) between Respirics, Inc., a Delaware corporation having an address at 6008 Triangle Drive, Suite 101, Raleigh, NC 27617 (hereinafter referred to as " Respirics" ), and TEAMM Pharmaceuticals, a Delaware corporation and a wholly owned subsidiary of Accentia, Inc., a Florida corporation, having a primary address at 3000 Aerial Center Parkway, Suite 110, Morrisville, North Carolina 27560 (" TEAMM" ).   
  
WITNESSETH   
  
WHEREAS, Respirics has exclusive rights to, and is currently developing, the MD-Turbo99 inhaled drug delivery device, as described in the patents and patent applications listed on Exhibit A attached hereto and incorporated herein by reference (the " Product" );   
  
WHEREAS, TEAMM wishes to fund the further development of the Product in order to enable its approval by the U.S. Food and Drug Administration (" FDA" ), in exchange for Respirics entering into an exclusive distribution arrangement with TEAMM for the sale of Products in the United States; and   
  
WHEREAS, Respirics wishes to accept such funding on the terms described herein and enter into such an arrangement with TEAMM.   
  
NOW, THEREFORE, for and in consideration of the covenants, conditions, and undertakings hereinafter set forth, it is agreed by and between the parries as fellows:   
  
1. Definitions   
  
For purposes of this Agreement, and in addition to those terms defined elsewhere in this Agreement, the following terms shall have the meanings set forth below unless the context dictates otherwise.   
  
1.1 " Confidential Information" means all proprietary or confidential information of Respirics, including all information concerning the Product, Product Improvements (as defined below), or Product Know-How (as defined below), any data derived there from, or any other trade secrets, information, technical data, know-how, and other confidential and proprietary information, including, but not limited to, that which relates to research, products, services, customers, markets, software, product plans, protocols, methods, developments, inventions (whether patentable or not), chemical compounds, mixtures, formulas, formulations, manufacturing processes, strategies, processes, designs, drawings, engineering information, marketing or finances. Specifically excluded from " Confidential Information" shall be information which: (a) is or becomes part of the public domain, through no fault of either party; (b) is lawfully disclosed without limitation to TEAMM by a third party who is not obligated to retain such information in confidence; or (c) is required to be disclosed by law, regulation, or order of a court or other tribunal of   
  
competent jurisdiction, provided that TEAMM provides Respirics with (i) prior written notice of such proposed disclosure, in order to allow Respirics to take reasonable and lawful actions to avoid and/or minimize the extent of such disclosure and (ii) reasonable assistance in minimizing the extent of such disclosures, as requested by Respirics.   
  
  
1 .2 " Product Improvements" shall mean any inventions, discoveries, information, knowledge, improvements or modifications related to the practice of the Product which come into the possession of Respirics during the term of this Agreement.   
  
  
1.3 " Product Know-How" shall mean any research and development information, un-patented inventions, preclinical and/or clinical data, technical data, or knowledge related to the practice of the Product or Product Improvements in the possession of or which comes into the possession of Respirics.   
  
  
1.4 For the purposes of this agreement, " TEAMM" shall mean Teamm Pharmaceuticals, Inc., a wholly-owned subsidiary of Accentia, Inc., a Florida corporation, Biotech Specialty Partners, IXC, or other subsidiaries or affiliates of Accentia, Inc.   
  
  
2. Development Program .   
  
  
2.1 Conduct of Research . Research shall use commercially reasonable efforts to perform the Development Program as set forth in Exhibit B, attached hereto and incorporated herein by reference (the " Development Program" ), according to the specifications and schedule set forth therein.   
  
  
2.2 Compliance . The Development Program shall be performed by Respirics in accordance with all applicable laws, rules, and regulations.   
  
  
2.3 Funding . TEAMM shall pay Respirics a total of $1,070,000, in accordance with the budget and payment schedule attached hereto as Exhibit C, attached hereto and incorporated herein by reference, for the conduct of the Development Program, provided that, in the event TEAMM fails to provide funding on the terms required by this Agreement, TEAMM shall, in addition to any other remedies available to Respirics, be liable to Respirics for any unpaid amounts. Payments are to be made within ten (10) days of receipt of an invoice for the initiation of each Phase of the Development Program (each, a " Phase" ) prior to the beginning of such Phase. Respirics shall not commence work on a particular Phase until the funding for such Phase has been received by Respirics, and Respirics shall not be responsible or liable for any delays in performing the Development Program caused by delays in payment by TEAMM.   
  
  
2.4 Development Reporting . During the term of this Agreement, Respirics shall (i) provide monthly status reports via teleconference with TEAMM regarding Respirics'   
  
  
progress with respect to the Development Program and (ii) furnish written reports regarding the progress of the Development Program within thirty (30) days of the completion of each Phase of the Development Program. A final written report setting forth the results of the Development Program shall be prepared by Respirics and submitted to TEAMM within thirty (30) days following the sooner of (i) completion of the Development Program or (ii) the effective date of any early termination pursuant to Section 5. In addition, during Phases TV and V of the Development Program, Respirics shall keep TEAMM periodically informed as to the progress of the regulatory approval process with respect to the Product, and, to the extent reasonably possible, shall provide TEAMM with advance notice of any pending approval in order to provide sufficient time to prepare for the initiation of TEAMM' s marketing and sales efforts pursuant to the Distribution Agreement (as defined below).   
  
  
2.5 Intellectual Property Rights . All Products, Product Improvements, Product Know-How, all intellectual property rights related to Products, Product Improvements, and Product Know-How, regulatory approvals, and related rights and/or documentation shall be the property of Respirics. TEAMM shall not acquire any rights of any kind whatsoever with respect to the Product, Product Improvements, or Product Know- How. Respirics shall have complete, sole, and unfettered discretion regarding all matters related to the development, regulatory approval, and protection of all technology and rights thereto with respect to the Product and Product Improvements.   
  
  
2.6 Warrants . If TEAMM provides all funding to Respirics required by this Agreement on or before the required due dates, but Respirics does not obtain final EDA clearance and approval of a 510(k) submission made with respect to the Product by January 24, 2005, Respirics shall issue TEAMM a warrant to purchase 164,249 shares of Common Stock of Respirics, exercisable at $1.00 per share, in the form set forth at Exhibit D hereof, provided that Respirics shall have no such obligation if (i) it has submitted a 510(k) application to FDA by July 24, 2004, (ii) such failure to obtain regulatory approval results from circumstances beyond Respirics' reasonable control, or (iii) TEAMM has not provided funding on or before each specified funding date.   
  
  
If, prior to Respirics receiving all funding from TEAMM, as required by this Agreement, (i) the parties mutually agree to terminate this Agreement due to a reasonable expectation that final FDA clearance and approval of a 510(k) submission made with respect to the Product will not be obtained by January 24, 2005 or (ii) TEAMM terminates this Agreement pursuant to Section 5.2(c) in conjunction with a reasonable expectation that final FDA clearance and approval of a 510(k) submission made with respect to the Product will not be obtained by January 24, 2005, Respirics shall issue TEAMM a warrant to purchase shares of Common Stock of Respirics, exercisable at $1.00 per share, in the form set forth at Exhibit C hereof, in the amounts described in the table below, provided that Respirics shall have no such obligation if (i) such expectation results from circumstances beyond Respirics' reasonable control or (ii) TEAMM has not provided funding on or before each specified funding date.   
  
  
Total Funding Provided to Respirics by TEAMM/Hopkins   
  
  
Number of Shares For Which  
  
  
Warrant May Be Exercised $0 0 $200,000 30,701 $550,000 84,427 $950,000 145,829  
  
  
In any event, any warrant issued pursuant to this Section 2.6 shall be considered liquidated damages, and TEAMM' s sole and exclusive remedy, with respect to any failure by Respirics to complete the Development Program in a timely fashion pursuant to the terms of this Agreement.   
  
  
3. Distribution Agreement . Upon execution of this Agreement by all three parties, Respirics shall enter into a Distribution Agreement with TEAMM, in the form attached hereto as Exhibit E (the " Distribution Agreement" ), providing the terms and conditions upon which TEAMM shall market and sell Products on behalf of Respirics. The Distribution Agreement shall only become effective and binding upon Respirics' successful completion of the Development Program within its prescribed budget and schedule, as defined in this Agreement, and final clearance and approval by the FDA of Respirics' 510(k) submission with respect to the Product.   
  
  
4. Confidential Information . TEAMM shall keep in strict confidence, using commercially reasonable measures at least as strict as applies to their own proprietary and/or confidential information of a similar nature, and not disclose or make available to third parties, nor make any use of, Confidential Information except (i) with the prior written consent of Respirics or (ii) for purposes of preparing to perform or performing under the Distribution Agreement. The parties recognize and agree that remedies at law for breach of the provisions of this Section 4 may be inadequate and Respirics, shall, in addition to any other rights, which it might have, be entitled to seek injunctive relief. The obligations of this paragraph shall survive termination of this Agreement.   
  
  
5. Term and Termination .   
  
  
5.1 Unless terminated earlier in accordance with Sections 5.2 or 5.3 below, this Agreement shall terminate on the completion of the Development Program.   
  
  
5.2 Without prejudice to any other rights it may have hereunder or at law or in equity, TEAMM may terminate this Agreement immediately by written notice to Respirics upon the occurrence of any of the following:   
  
  
(a) Respirics becomes insolvent, an order for relief is entered against Respirics under any bankruptcy or insolvency laws or laws of similar import; (b) Respirics makes an assignment for the benefit of its creditors or a receiver or custodian is appointed for it or its business is placed under attachment, garnishment or other process involving a significant portion of its business; or   
  
  
(c) after thirty (30) days' written notice from the terminating party without cure by Respirics of any material breach of this Agreement by Respirics.   
  
  
5.3 Without prejudice to any other rights it may have hereunder or at law or in equity, Respirics may terminate this Agreement, the Distribution Agreement, and/or the exclusivity of the Distribution Agreement, as determined by Respirics in its sole discretion, immediately by written notice to TEAMM upon the occurrence of any of the following:   
  
  
(a) TEAMM becomes insolvent, an order for relief is entered against TEAMM under any bankruptcy or insolvency laws or laws of similar import; (b) TEAMM makes an assignment for the benefit of its creditors or a receiver or custodian is appointed for it or its business is placed under attachment, garnishment or other process involving a significant portion of its business;   
  
  
(c) after thirty (30) days' written notice from Respirics without cure by TEAMM of any material breach of this Agreement by TEAMM (d) TEAMM fails to provide funding when due as required by Section 2.3.   
  
  
5.4 Any termination under any provision of this Agreement shall not relieve TEAMM of its obligation to pay any amounts due or owing at the time of such cancellation or termination.   
  
  
5.5 Upon the termination of this Agreement pursuant to Sections 5.2 or 5.3, TEAMM shall immediately return all Confidential Information, reports provided pursuant to Section 2.4, any other documents provided to TEAMM, and any copies of the foregoing to Respirics.   
  
  
6. Use of Respirics' Name . The use of the name of Respirics, or any contraction thereof, in any manner in connection with the exercise of this Agreement is expressly prohibited except with prior written consent of Respirics. The foregoing notwithstanding, TEAMM shall have the right to identify Respirics and to disclose the terms of this Agreement in any prospectus, offering memorandum, or other document or filing required by applicable securities laws or other applicable law or regulation.   
  
  
7. Waiver . It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default.   
  
  
8. Assignment . This Agreement is binding upon and shall inure to the benefit of Respirics and TEAMM, and their successors and assigns. This Agreement shall not be assignable or otherwise transferable by either party without the prior written consent of the other, which consent shall not be unreasonably withheld, except that Respirics may assign or otherwise transfer its rights under this Agreement to the following parties without obtaining consent: (1) a successor to Respirics' business, or a successor to that portion of Respirics' business that pertains to the Product, and (2) any entities controlled by, controlling, or under common control with Respirics.   
  
  
9. Independent Contractor Status . Respirics, for all purposes related to this Agreement, shall be deemed an independent contractor of TEAMM, and nothing in this Agreement shall be deemed to create a relationship of employment or agency or to constitute the parties as partners or joint venture partners.   
  
  
10. Notices . Any notice required or permitted to be given to the parties hereto shall be deemed to have been properly given when received by means of confirmed facsimile transmission, recognized national overnight courier, or first-class certified mail to the other party at the appropriate address or facsimile number as set forth below or to such other addresses or facsimile numbers as may be designated in writing by the parties from time to time during the term of this Agreement   
  
  
TEAMM   
  
  
TEAMM Pharmaceuticals, Inc. 3000 Aerial Center Parkway, Suite 110   
  
  
Morrisville, North Carolina 27560   
  
  
Attn: President   
  
  
Fax: 919 481 9300   
  
  
Respirics   
  
  
Respirics, Inc.   
  
  
6008 Triangle Drive Suite 101   
  
  
Raleigh NC 27617   
  
  
Attn: President   
  
  
Fax: 919 789 4254   
  
  
11. Governing Law: Jurisdiction . This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of North Carolina, excluding that body of law known as choice of law, and shall be binding upon the parties hereto in the   
  
  
United States and worldwide. All disputes with respect to this Agreement shall be brought and heard either in the North Carolina state courts located in Wake County, North Carolina, or the federal district court for the Eastern District of North Carolina located in Raleigh, North Carolina. The parties to this Agreement each consent to the jurisdiction and venue of such courts. The parties agree that service of process upon them in any such action may be made if delivered in person, by courier service, by telegram, by telefacsimile or by first class mail, and shall be deemed effectively given upon receipt.   
  
  
12. Complete Agreement . This Agreement and the Exhibits hereto (including the Distribution Agreement) contain the entire agreement between the parties. No amendments or modifications to this Agreement shall be effective unless made in writing and signed by authorized representatives of both parties.   
  
  
13. Force Majeure . Neither party will be responsible for delays resulting from acts beyond the reasonable control of such party, provided that the non-performing party uses reasonable commercial efforts to avoid or remove such causes of nonperformance and continues performance hereunder with reasonable dispatch whenever such causes are removed.   
  
  
14. Survival of Terms . Sections 1,2.5, and 4-14 shall survive the expiration or termination of this Agreement.   
  
  
[Signature page to follow.]   
  
  
IN WITNESS WHEREOF, TEAMM Pharmaceuticals, Inc., and Respirics have executed this Agreement, by their respective officers hereunto duly authorized, the day and year first above written.   
  
  
TEAMM PHARMACEUTICALS, INC. Respirics, Inc.  
  
  
By:   
  
  
/s/ Martin G. Baum   
  
  
By:   
  
  
/s/ Gilbert S. Mott, Jr.   
  
  
Martin G. Baum   
  
  
Gilbert S. Mott, Jr.   
  
  
President and CEO   
  
  
President and CEO  
  
  
  
EXHIBIT A   
  
  
PRODUCT PATENTS   
  
  
Title   
  
  
Serial Numbers and Dates Device For Use With Metered Dose-Inhalers (MDIs)   
  
  
Patent No. 5,826,571  
  
  
Patent Issued: October 27, 1998 Device For Use With Metered Dose Inhalers (MDIs)   
  
  
Patent No. 6,357,442  
  
  
Patent Issued: March 19, 2002  
  
  
Inhalation Actuated Device For Use With Metered  
  
  
Dose Inhalators (MDIs)   
  
  
Patent Pending  
  
  
Serial No. 09/535,097 Filed March 24, 2000  
  
  
Inhalation Actuated Device For Use With Metered  
  
  
Dose Inhalators (MDIs)   
  
  
Patent Pending  
  
  
Serial No. 10/074,27 1 Filed February 11, 2002  
  
  
  
EXHIBIT B   
  
  
DEVELOPMENT PROGRAM   
  
  
BACKGROUND   
  
  
The MD (metered dose) Turbo device market advantage is that a multiplicity of currently approved ethical and generic metered dose inhalers (" MDIs" ) can be inserted in the device and be breath activated. This will be the only low-cost device that offers this capability when commercialized. Most importantly, the breath-triggering mechanism offers a significant market advantage over the use of standard MDIs since it eliminates the coordination issue experienced by patient' s when they attempt to coordinate inhalation and pressing of the MDI canister. It has been reported in the literature that 50-70% of the patients are unable to coordinate their inhalation with " firing" of the MDI canister. As a result, the MD Turbo99 was developed to eliminate the issue of patients being unable to coordinate this activity.   
  
  
Respirics' MD Turbo possesses the following features:   
  
  
(1) a breath-actuated triggering mechanism (set at a pre-determined inspiratory air flow rate, typically 30-60L/min) which automatically depresses the MDI canister for release of a dose;   
  
  
(2) the ability to incorporate a multiplicity of commercially available innovator or generic MDI products, representing approximately 80 % of the medications currently used to treat asthma;   
  
  
(3) the ability to accept replacement MDI products. The device is anticipated to be reusable for at least one year, e.g., Ventolin canister of 200 doses with one can used per month, i.e., 2400 delivered doses;   
  
  
(4) an electronic dose-counting mechanism for tracking the number of doses used from the MDI canister; i.e., a countdown of doses available; and (5) a mechanical override button which automatically depresses the MDI canister for release of a dose as the patient inhales, i.e., only for those patients (young children less than 6 years of age, elderly or very severe asthmatic) who may have difficulty achieving the required inspiratory effort necessary to automatically trigger firing of the device.   
  
  
In addition to the above features, the MD Turbo is patent protected. There are two issued United States patents, one issued Canadian patent, and one issued Australian patent on the MD Turbo device. Additional CIPs are pending and foreign patent filings have been initiated covering the seventeen EPO States, Japan, Australia and Canada. All of these patents are either owned or exclusively licensed by Respirics.   
  
  
  
Objectives   
  
  
The following objectives (within each defined phase of the Development Program' s research activities) have been established for the MD Turbo development program:   
  
  
(1) Phase I - to finalize the design of the MD Turbo device; to prepare SLA prototype models of this design; and, to perform preliminary in vitro experiments with the prototype model   
  
  
(2) Phase II - to obtain single cavity tooling and stamping of the components for the MD Turbo device; and, to perform preliminary in vitro tests with the injection molded and stamped assembled components   
  
  
(3) Phase III - to manufacture sufficient devices to complete the 510(k) in vitro testing program; and, to perform a failure effect and mode analysis (FEMA) on assembled MD Turbo devices   
  
  
(4) Phase IV - to collate the results obtained in the 510(k) testing program and to prepare the 510(k) application for submission to the FDA (5) Phase V - FDA review of 510(k) pre-market notification application   
  
  
Each of the above phases is briefly described below as to the research activities that will be performed:   
  
  
PHASE I   
  
  
During this phase of the program, the MD Turbo design will be finalized. The exterior of the device will be modified to provide a more ergonomic presentation. After the design is " locked-in" , stereo lithography will be used to produce plastic components and " working" models will be constructed and subjected to a battery of laboratory tests to verify the performance of the models using currently marketed MDIs. Any final adjustments in the MD Turbo will be made at this time. The final design will be subject to approval by TEAMM, which approval shall not be unreasonably withheld.   
  
  
PHASE II   
  
  
Following completion of Phase I, the engineering design files will be provided to a qualified injection molding facility, single-cavity molds will be designed and fabricated for all plastic components, and the molds will be qualified for production. Plastic components will then be produced from these molds.   
  
  
Metal stamped and machined parts will also be fabricated during this phase and these components, along with the molded plastic components, will be used to assemble working devices.   
  
  
The final task in Phase II will be to perform laboratory testing on these working devices to verify drug delivery performance prior to initiating Phase III.   
  
  
PHASE III   
  
  
During this phase, Respirics will manufacture and assemble a reasonably sufficient number of devices (estimated to be 25-50 devices) to complete the 510(k) testing program. The 510(k) testing program will entail the comparison of the MD Turbo device to (1) the standard MDI and (2) a predicate device (spacer), using a minimum of three drug products. Presently, Respirics plans to use those products that are generating the most revenues in the open market, i.e., Sereventae , Floventae , Ventolinae (both HFA and CFC products), Combiventae , Atroventae and several generic CFC MDI products. Some of the 510 (k) tests that will need to be performed include emitted dose delivery, dose through canister life, shot weight, particle/droplet sizing, cascade impaction, spray pattern, and plume geometry. Respirics plans to confirm the required tests with the FDA prior to conducting these studies.   
  
  
PHASE IV   
  
  
During this phase, the data generated in the 510(k) testing will be collated into the correct format for submission of the 510(k) application. Respirics anticipates using an outside consultant to facilitate this activity.   
  
  
PHASE V   
  
  
There are no research activities planned during this phase as the FDA is reviewing the 510(k) submission. However, there will need to be planning and activities performed during this phase so that an orderly launch of the product can take place. These activities should be discussed as we enter Phase TV so that we have sufficient time and resources to plan the potential launch.   
  
  
Respirics shall use commercially reasonable efforts to complete the Development Program within eighteen (18) months following execution of the Development Agreement, according to the schedule established on Exhibit C , provided that, if Respirics has submitted a 510(k) application within eighteen (18) months of the Effective Date, Respirics' shall have satisfied its obligation to exercise commercially reasonable efforts to complete the Development Program.   
  
  
Deliverables   
  
  
The Respirics deliverables will include monthly teleconferences on the status of the research activities plus a summary report upon completion of each phase of the program. The summary reports will be due thirty (30) days after completion of the research activities for each phase as outlined in the Development Program.   
  
  
EXHIBIT C   
  
  
DEVELOPMENT BUDGET AND PAYMENT SCHEDULE   
  
  
PHASE COST  
  
ESTIMATED  
  
TIME  
  
  
  
I. Finalize design; create SLA prototype models; perform preliminary testing with the SLA prototype model $ [ \*] [\*]  
  
  
II. Mold tooling and stamping; limited device assembly; and preliminary in vitro testing on the assembled devices $ [ \*] [\*]  
  
  
III. Manufacture of MD Turbo devices for 510(k) testing; perform 510(k) in vitro tests; device FEMA analysis $ [ \*] [\*]  
  
  
IV. Preparation of 510(k) application for FDA submission $ [ \*] [\*]  
  
  
V. FDA review of 510(k) application $ [ \*] [\*]   
  
  
TOTAL COSTS [ \*] [\*]   
  
  
The total payments for the Development Program are $[\*]. Payments are to be made within ten (10) days of receipt of an invoice for the initiation of each Phase prior to the beginning of such Phase; Respirics shall not commence work on a particular development Phase until the funding for such Phase has been received by Respirics, and shall not be responsible or liable for any delays in performing caused by delays in payment by TEAMM. The amount for each phase is as follows:   
  
  
Phase I = $[\*] Phase II = $[\*]   
  
  
Phase III = $[\*]   
  
  
Phase IV = $[\*] Phase V = $[\*]   
  
  
  
EXHIBIT D   
  
  
FORM OF WARRANT   
  
  
EXHIBIT E   
  
  
DISTRIBUTION AGREEMENT   
  
  
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