MANHATTAN PHARMACEUTICALS INC
Form 424B3
July 06, 2010
Pursuant to Rule 424(b)(3)
File No. 333-157470

Prospectus

Manhattan Pharmaceuticals, Inc.

66,125,132 Shares
Common Stock

This prospectus relates to 66,125,132 shares of common stock of Manhattan Pharmaceuticals, Inc. for the sale from time to time by certain holders of our securities, or by their respective pledgees, assignees and other successors-in-interest. All of these shares are issuable upon exercise of warrants held by the selling securityholders. We will not receive any proceeds from the sales of the shares of common stock by the selling securityholders. We will receive the proceeds of any cash exercise of the warrants.

The distribution of securities offered hereby may be effected in one or more transactions that may take place on the Over the Counter Bulletin Board, including ordinary brokers' transactions, privately negotiated transactions or through sales to one or more dealers for resale of such securities as principals, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the selling securityholders.

The prices at which the selling securityholders may sell the shares in this offering will be determined by the prevailing market price for the shares or in negotiated transactions. Our common stock is traded on the Over the Counter Bulletin Board under the symbol “MHAN.” On June 18, 2010, the last reported sales price for our common stock on the Over the Counter Bulletin Board was $0.055 per share.

These securities involve a high degree of risk. See “Risk Factors” beginning on page 6 of this prospectus for factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is July 6, 2010.

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This prospectus contains service marks, trademarks and tradenames of Manhattan Pharmaceuticals, Inc.

PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus and may not contain all the information that is important to you. This prospectus includes information about the securities being offered as well as information regarding our business. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the section entitled "Risk Factors" beginning on page 5 and our financial statements and related notes. Unless the context otherwise requires, all references to "we," "us," "our company," or "the company" in this prospectus refer collectively to Manhattan Pharmaceuticals, Inc., a Delaware corporation.

Overview

We are a specialty healthcare product company focused on developing and commercializing innovative treatments for underserved patient populations. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either bringing the technologies to market or out-licensing. In the short term, we are focusing our efforts on the commercialization of the four product candidates we currently have in development: Hedrin™, a novel, non-insecticide treatment for pediculosis (head lice), which we are developing through a joint venture, AST-726, a nasally delivered form of hydroxocobalamin for the treatment of vitamin B12 deficiency, AST-915, an oral treatment for essential tremor and a topical product for the treatment of psoriasis. Longer term, we intend to acquire and commercialize low risk, quick to market products, specifically products that could be marketed over-the-counter, or OTC, treat everyday maladies, are simple to manufacture, and/or could be classified as medical devices by the FDA.

We have not received regulatory approval for, or generated commercial revenues from marketing or selling any drugs.

Recent Developments

2010 Private Placement

On April 8, 2010, we completed a private placement of approximately 121 units, which we refer to has the 2010 Private Placement, with each unit consisting of (i) 357,143 shares of our common stock, $0.001 par value per share and (ii) 535,714 common stock purchase warrants, each of which will entitle the holder to purchase one additional share of our common stock for a period of five years at an exercise price of $0.08 per share. The purchase price for each unit was $25,000. We received aggregate gross proceeds of $3,029,386 in connection with the private placement (including the conversion of a 12% original issue discount senior subordinated convertible debenture with a stated value of $400,000 and the interest accrued thereon into units).

The first closing of the private place was completed on March 2, 2010, at which we sold an aggregate of 101.9 units. In connection with the first closing, we issued a warrant to purchase 3,639,289 shares of our common stock at an exercise price of $0.08 per share to the placement agent as partial compensation for its services.

The final closing of the private placement was completed on April 8, 2010, at which we sold an aggregate of 2.4 additional Units. In connection with the final closing, we issued a warrant to purchase 12,857 shares of our common stock at an exercise price of $0.08 per share to the placement agent as partial compensation for its services. In addition, on April 8, 2010, the holder of an outstanding 12% original issue discount senior subordinated convertible debenture, dated October 28, 2009, with a stated value of $400,000 and $21,886 of accrued interest, exercised its option to convert such debenture (including all accrued interest thereon) into 16.88 units. The conversion price was equal to the per unit purchase price paid by the investors in the private placement.

Each of the investors in the private placement and the holder of the debenture represented that they were "accredited investors," as that term is defined in Rule 501(a) of Regulation D under the Securities Act, and the sale of the Units was made in reliance on exemptions provided by Regulation D and Section 4(2) of the Securities Act of 1933, as amended.

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In connection with the private placement, we entered into a registration rights agreement pursuant to which we agreed to file a registration statement to register the resale of the shares of our common stock issued in the private placement, within 60 days of the final closing date and to cause the registration statement to be declared effective within 150 days (or 180 days upon review by the SEC).

Acquisition of Ariston

On March 8, 2010, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Ariston Pharmaceuticals, Inc., a Delaware corporation ("Ariston") and Ariston Merger Corp., a Delaware corporation and our wholly-owned subsidiary (the "Merger Sub"). Pursuant to the terms and conditions set forth in the Merger Agreement, on March 8, 2010, the Merger Sub merged with and into Ariston, with Ariston being the surviving corporation of the merger. As a result of the merger, Ariston became a wholly-owned subsidiary of ours.

We merged with Ariston principally to add new products to our portfolio. Prior to the merger, Ariston was a private, clinical stage specialty biopharmaceutical company based in Shrewsbury, Massachusetts that in-licenses, develops and plans to market novel therapeutics for the treatment of serious disorders of the central and peripheral nervous systems.

Under the terms of the Merger Agreement, the consideration payable by us to the stockholders and note holders of Ariston consists of the issuance of 7,062,423 shares of our common stock at Closing (as defined in the Merger Agreement) plus the right to receive up to an additional 24,718,481 shares of our common stock (the “Ariston Milestone Shares”) upon the achievement of certain product-related milestones described below. In addition, we have reserved 38,630,723 shares of our common stock for possible future issuance in connection with the conversion of $15.45 million of outstanding Ariston convertible promissory notes. The note holders will not have any recourse to us for repayment of the notes (their sole recourse being to Ariston, which is our wholly-owned subsidiary), but the note holders will have the right to convert the notes into shares of our common stock at the rate of $0.40 per share. Further, we have reserved 5,000,000 shares of our common stock for possible future issuance in connection with the conversion of $1.0 million of an outstanding Ariston convertible promissory note issued in satisfaction of a trade payable. The note holder will not have any recourse to us for repayment of the note (their sole recourse being to Ariston, which is our wholly-owned subsidiary), but the note holder will have the right to convert the note into shares of our common stock at the rate of $0.20 per share.

Upon the achievement of the milestones described below, we would be obligated to issue portions of the Ariston Milestone Shares to the former Ariston stockholders and noteholders:

- Upon the affirmative decision of our Board of Directors, provided that such decision is made prior to March 8, 2011, to further develop the AST-914 metabolite product candidate, either internally or through a corporate partnership, we would issue 8,828,029 of the Ariston Milestone Shares.

- Upon the acceptance by the FDA of our filing of the first New Drug Application for the AST-726 product candidate, we would issue 7,062,423 of the Ariston Milestone Shares.

- Upon our receipt of FDA approval to market the AST-726 product candidate in the United States of America, we would issue 8,828,029 of the Ariston Milestone Shares.

Certain members of our board of directors and certain of our principal stockholders owned Ariston securities. Timothy McInerney, one of our directors, owned 16,668 shares of Ariston common stock which represented less than 1% of Ariston’s outstanding common stock as of the closing of the Merger. Neil Herskowitz, one of our directors, indirectly owned convertible promissory notes of Ariston with interest and principal in the amount of $192,739. Michael Weiser, who was serving as one of our directors at the time of the Merger, owned 117,342 shares of Ariston

common stock, which represented approximately 2.1% of Ariston's outstanding common stock as of the closing of the Merger. Lindsay Rosenwald, a more than 5% beneficial owner of our common stock, in his individual capacity and indirectly through trusts and companies he controls owned 497,911 shares of Ariston common stock, which represented approximately 8.9% of Ariston's outstanding common stock as of the closing of the Merger and indirectly owned convertible promissory notes of Ariston in the amount of $141,438.

Corporate History – Merger Transaction(s)

We were incorporated in Delaware in 1993 under the name “Atlantic Pharmaceuticals, Inc.” and, in March 2000, we changed our name to “Atlantic Technology Ventures, Inc.” In 2003, we completed a “reverse acquisition” of privately held “Manhattan Research Development, Inc.” In connection with this transaction, we also changed our name to “Manhattan Pharmaceuticals, Inc.” From an accounting perspective, the accounting acquirer is considered to be Manhattan Research Development, Inc. and accordingly, the historical financial statements are those of Manhattan Research Development, Inc.

During 2005, we merged with Tarpan Therapeutics, Inc., or Tarpan. Tarpan was a privately held New York based biopharmaceutical company developing dermatological therapeutics. This transaction was accounted for as a purchase of Tarpan by us.

During 2010, we completed a merger pursuant to which we acquired Ariston. We merged with Ariston principally to add new products to our portfolio. Prior to the merger, Ariston was a private, clinical stage specialty biopharmaceutical company based in Shrewsbury, Massachusetts that in-licenses, develops and plans to market novel therapeutics for the treatment of serious disorders of the central and peripheral nervous systems. For a more detailed discussion of the Merger, please see "Business - Recent Developments - Acquisition of Ariston".

Principal Executive Offices

Our executive offices are located 48 Wall Street, New York, NY 10005. Our telephone number is (212) 582-3950 and our internet address is www.manhattanpharma.com.

The Offering

Common Stock Offered by Selling Securityholders (1):	66,125,132 shares
Common Stock Issued and Outstanding prior to this Offering(2):	120,965,260 shares
Common Stock Issued and Outstanding after this Offering (3):	187,090,392 shares
Use of Proceeds:	We will not receive cash proceeds from the sale of shares of common stock by the selling securityholders. We will receive the proceeds of any cash exercise of the warrants.
Over the Counter Bulletin Board Symbol:	MHAN

(1) Consists of 66,125,132 shares of our common stock issuable upon exercise of outstanding warrants held by the selling securityholders.

(2) Based on the number of shares of our common stock outstanding as of June 18, 2010. Excludes approximately 171,905,717 shares of our common stock issuable upon exercise of outstanding warrants and options to purchase shares of our common stock (including the warrants held by the selling securityholders) and 71,428,571 shares of our common stock issuable upon exercise of a right to put, and our right to call, a 50% equity interest in H Pharmaceuticals K/S (formerly Hedrin Pharmaceuticals K/S) of the 52.38% equity interest currently held by Nordic Biotech Venture Fund II K/S.

(3) Consists of (i) 120,965,260 shares outstanding as of June 18, 2010 and (ii) 66,125,132 shares of our common stock issued assuming the exercise by the selling stockholders' of certain warrants to purchase shares of our common stock.

Summary Financial Information

The summary financial information for the fiscal years ended December 31, 2009 and 2008 was derived from our financial statements that have been audited by J.H. Cohn LLP for the fiscal years then ended. The summary financial information as of and for the three months ended March 31, 2010 and 2009 and for the cumulative period from August 6, 2001 (inception) to March 31, 2010 was derived from our unaudited financial data but, in the opinion of management, reflects all adjustments necessary for a fair presentation of the results of such periods. The summary financial information presented below should be read in conjunction with our financial statements and related notes appearing in this prospectus beginning on page F-1. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of our financial statements for the fiscal years ended December 31, 2009 and 2008 and for the three months ended March 31, 2010 and 2009.

	Three Months Ended March, 31		Years Ended December 31,		Cumulative period from August 6, 2001 (inception) to March 31, 2010
	2010 (unaudited)	2009 (unaudited)	2009	2010	(unaudited)
Statements of Operations Data:					
Revenue	$ -	$ -	$ -	$ -	$ -
Research and development expense	$ 17,767	$ 44,936	$ 40,376	$ 1,802,792	$ 28,349,978
General and administrative expense	$ 511,678	$ 512,400	$ 1,731,182	$ 2,609,910	$ 18,705,133
Net loss attributable to common shares	$ (1,633,169)	$ (761,844)	$ (2,793,285)	$ (4,268,858)	$ (63,566,604)
Net loss per common share	$ (0.02)	$ (0.01)	$ (0.04)	$ (0.06)	N/A
Statements of Cash Flows Data:					
Net cash used in operating activities	$ (604,827)	$ (645,797)	$ (1,049,799)	$ (4,444,009)	$ (40,274,191)
Net cash provided by financing activities	$ 2,084,746	$ 770,270	$ 961,772	$ 3,909,319	$ 41,401,806
Cash dividends declared	$ -	$ -	$ -	$ -	$ -

	At March 31, 2010 (unaudited)	At December 31, 2009
Balance Sheets Data:		
Total assets	$ 20,081,864	$ 365,662
Total liabilities	$ 27,599,378	$ 7,150,612
Total stockholders' deficiency	$ (7,517,514)	$ (6,784,950)

RISK FACTORS

An investment in our securities is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. You should carefully consider the following risk factors and the other information contained elsewhere in this prospectus before making an investment in our securities.

Risks Related to Our Business

We currently have no product revenues and will need to raise substantial additional funds in the future. If we are unable to obtain the funds necessary to continue our operations, we will be required to delay, scale back or eliminate one or more of our remaining drug development programs and may not continue as a going concern.

We have generated no product revenues to date and will not until, and if, we receive approval from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities for any of our four product candidates. We have already spent substantial funds developing our potential products and business, however, and we expect to continue to have negative cash flow from our operations for at least the next several years. As of December 31, 2009, we had $17,996 of cash and cash equivalents. We received additional funding of approximately $3.0 million from a financing transaction completed in April 2010. We expect that such financing shall be sufficient to fund our operations through the end of 2010. We will still have to raise substantial additional funds to complete the development of our product candidates and to bring them to market. Beyond the capital requirements mentioned above, our future capital requirements will depend on numerous factors, including:

- the results of any clinical trials;
- the scope and results of our research and development programs;
- the time required to obtain regulatory approvals;
- our ability to establish and maintain marketing alliances and collaborative agreements; and
- the cost of our internal marketing activities.

Our history of operating losses and lack of product revenues may make it difficult to raise capital on acceptable terms or at all. If adequate funds are not available, we will be required to delay, scale back or eliminate one or more of our drug development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or products that we would not otherwise relinquish. Our Independent Registered Public Accounting Firm has concluded that our net losses, negative cash flow, accumulated deficit and negative working capital as of December 31, 2009, raise substantial doubt about our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in the report of our Independent Registered Public Accounting Firm will make it more difficult for us to secure additional financing or enter into strategic relationships with distributors on terms acceptable to us, if at all, and likely will materially and adversely affect the terms of any financing that we may obtain.

We have incurred substantial losses and negative cash flow from operations and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. We have incurred losses in every period since our inception on August 6, 2001. For the three months ended March 31, 2010 and for the period from August 6, 2001

(inception) through March 31, 2010, we incurred net losses applicable to common shares of $1,633,169, and $63,566,604, respectively. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake nonclinical development and clinical trials for our product candidates;

- seek regulatory approvals for our product candidates;
- implement additional internal systems and infrastructure;
- lease additional or alternative office facilities; and
- hire additional personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

As a result of our continued losses, our Independent Registered Public Accounting Firm has included an explanatory paragraph in our financial statements for the fiscal years ended December 31, 2009 and 2008, expressing doubt as to our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph in the report of our Independent Registered Public Accounting Firm will make it more difficult for us to secure additional financing or enter into strategic relationships with distributors on terms acceptable to us, if at all, and likely will materially and adversely affect the terms of any financing that we may obtain. If we fail to generate revenues, or if operating expenses exceed our expectations or cannot be adjusted accordingly, we may not achieve profitability and the value of your investment could decline significantly.

We have a limited operating history upon which to base an investment decision.

We are a development-stage company and have not yet demonstrated any ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

- continuing to undertake nonclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Since inception as Manhattan Research Development, Inc., our operations have been limited to organizing and staffing, and acquiring, developing and securing our proprietary technology and undertaking nonclinical and clinical trials of principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

We did not engage financial advisors to evaluate the fairness of the consideration paid to the stockholders and noteholders of Ariston in connection with our merger with Ariston. We can provide no assurance that the fair value of the securities paid to the stockholders and noteholders of Ariston in the merger did not exceed the fair value of the assets acquired.

Ariston had approximately $16.5 million indebtedness prior to our merger with them. In connection with the merger, the merger subsidiary of the combined company assumed Ariston's indebtedness of approximately $16.5 million. Such indebtedness may negatively impact our ability to raise sufficient additional capital to fund our operations.

Ariston may have liabilities that were unknown at the time of the consummation of the merger that became our liabilities upon consummation of the merger with Ariston.

There may be liabilities of Ariston and/or its affiliates that were unknown at the time of the consummation of our merger with Ariston. As a result of our merger with Ariston, any such unknown liabilities may become our liabilities. In the event any such liabilities become known following such merger, they may lead to claims against Ariston, our wholly-owned subsidiary, including but not limited to lawsuits, administrative proceedings, and other claims. Any such liabilities may subject us to increased expenses for attorneys' fees, fines, litigation expenses, and expenses associated with any subsequent settlements or judgments. There can be no assurances that such unknown liabilities do not exist. To the extent that such liabilities become known following the merger with Ariston, any such liability-related expenses may materially impact our financial condition and results of operations.

We depend greatly on the intellectual capabilities and experience of our key executives and the loss of any of them could affect our ability to develop our remaining products.

We had only two full-time and two part-time employees as of June 18, 2010. The loss of either Michael G. McGuinness, our Chief Operating and Financial Officer, or Malcolm Morville, Chief Executive Officer of Ariston, could harm us. Mr. McGuinness' employment agreement with us expired in July 2009. Mr. Morville's employment agreement with Ariston expired upon consummation of the merger with Ariston. Messrs. McGuinness and Morville have been working for us and Ariston, respectively, on the same terms and conditions that were set forth in the employment agreements that expired. We cannot predict our success in hiring or retaining the personnel we require for continued operations.

We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our product candidates.

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must first submit to the FDA an IND, which will set forth our plans for clinical testing of our product candidates. We are unable to estimate the size and timing of the clinical and non-clinical trials required to bring our product candidates to market and, accordingly, cannot estimate the time when development of our product candidates will be completed.

When the clinical testing for our product candidates is complete, we will submit to the FDA a NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as nonclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject any or all of our future NDAs. We cannot be sure that we will ever obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We have not yet made any determination as to which foreign jurisdictions we may seek approval and have not undertaken any steps to obtain approvals in any foreign jurisdiction.

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Clinical trials are very expensive, time consuming and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials.

The results of our clinical trials may not support our product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims. Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and nonclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans or effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, we anticipate that our clinical trials will involve only a small patient population. Accordingly, the results of such trials may not be indicative of future results over a larger patient population.

Physicians and patients may not accept and use our products.

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our product will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
- cost-effectiveness of our product relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

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Our product-development program depends upon third-party researchers who are outside our control.

We currently are collaborating with several third-party researchers, for the development of our product candidates. Accordingly, the successful development of our product candidates will depend on the performance of these third parties. These collaborators will not be our employees, however, and we cannot control the amount or timing of resources that they will devote to our programs. Our collaborators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

We rely exclusively on third parties to formulate and manufacture our product candidates.

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We intend to contract with one or more manufacturers to manufacture, supply, store and distribute drug supplies for our clinical trials. If any of our product candidates receive FDA approval, we will rely on one or more third-party contractors to manufacture our drugs. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical needs and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

We have no experience selling, marketing or distributing products and no internal capability to do so.

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain such collaborative relationships, the collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with

third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product in the United States or overseas.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have product candidates that will compete with ours already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking nonclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

Developments by competitors may render our products or technologies obsolete or non-competitive.

Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel, parties for acquisitions, joint ventures or other collaborations.

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

See “Business – Intellectual Property and License Agreements”.

However, with regard to the patents covered by our license agreements and any future patents issued to which we will have rights, we cannot predict:

- the degree and range of protection any patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;

- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation, which could adversely affect our ability to execute our business plan.

Our business is substantially dependent on the intellectual property on which our product candidates are based. To date, we have not received any threats or claims that we may be infringing on another's patents or other intellectual property rights. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our drugs. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for any of our products, once approved, market acceptance of our products could be reduced.

Health care reform and restrictions on reimbursement may limit our returns on potential products.

Because our strategy ultimately depends on the commercial success of our products, we assume, among other things, that end users of our products will be able to pay for them. In the United States and other countries, in most cases, the volume of sales of products like those we are developing depends on the availability of reimbursement from

third-party payors, including national health care agencies, private health insurance plans and health maintenance organizations. Third-party payors increasingly challenge the prices charged for medical products and services. Accordingly, if we succeed in bringing products to market, and reimbursement is not available or is insufficient, we could be prevented from successfully commercializing our potential products.

The health care industry in the United States and in Europe is undergoing fundamental changes as a result of political, economic and regulatory influences. Reforms proposed from time to time include mandated basic health care benefits, controls on health care spending, the establishment of governmental controls over the cost of therapies, creation of large medical services and products purchasing groups and fundamental changes to the health care delivery system. We anticipate ongoing review and assessment of health care delivery systems and methods of payment in the United States and other countries. We cannot predict whether any particular reform initiatives will result or, if adopted, what their impact on us will be. However, we expect that adoption of any reform proposed will impair our ability to market products at acceptable prices.

Changes in laws affecting the health care industry could adversely affect our business.

In the U.S., there have been numerous proposals considered at the federal and state levels for comprehensive reforms of health care and its cost, and it is likely that federal and state legislatures and health agencies will continue to focus on health care reform in the future. Congress has passed legislation to reform the U.S. health care system by expanding health insurance coverage, reducing health care costs and making other changes. While health care reform may increase the number of patients who have insurance coverage for our products, it may also include cost containment measures that adversely affect reimbursement for our products. Congress has also considered legislation to change the Medicare reimbursement system for outpatient drugs, increase the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs and facilitate the importation of lower-cost prescription drugs that are marketed outside the U.S. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

We operate in a highly regulated industry. As a result, governmental actions may adversely affect our business, operations or financial condition, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, method of delivery and payment for health care products and services;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products;
- new laws, regulations and judicial decisions affecting pricing or marketing practices; and
- changes in the tax laws relating to our operations.

The enactment in the U.S. of health care reform, possible legislation which could ease the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business. In addition, the Food and Drug Administration Amendments Act of 2007 included new authorization for the FDA to require post-market safety monitoring, along with an expanded clinical trials registry and clinical trials results database, and expanded authority for the FDA to impose civil monetary penalties on companies that fail to meet

certain commitments.

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business may suffer.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in nonclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

If we are not successful in integrating Ariston's product development programs, we may not be able to operate efficiently after our merger with Ariston, which may have a material adverse effect on our results of operations and financial condition.

Achieving the benefits of our merger with Ariston will depend in part on the successful integration of Ariston's drug development programs and personnel in a timely and efficient manner. The integration process requires coordination of different development, regulatory, and manufacturing teams, and involves the integration of systems, applications, policies, procedures, business processes and operations. If we cannot successfully integrate Ariston's programs, we may not realize the expected benefits of the merger.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. We currently carry clinical trial insurance in an amount up to $5,000,000, which may be inadequate to protect against potential product liability claims or may inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. Although we intend to maintain clinical trial insurance during any clinical trials, this may be inadequate to protect us against any potential claims. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We are controlled by current officers, directors and principal stockholders.

As of June 18, 2010, our directors, executive officers and principal stockholders beneficially own approximately 6,877,851 shares of our common stock, which represents approximately 5.38% of our outstanding voting stock, including shares underlying outstanding options and warrants which are currently exercisable or exercisable within 60 days of June 18, 2010. In addition, Nordic Biotech Venture Fund II K/S, which we refer to herein as Nordic or the selling securityholder, as applicable, has the right to acquire up to 85,714,285 shares of our common stock which would result in Nordic beneficially owning approximately 41.47% of our common stock as of June 18, 2010 (although, as described in Note 18 to our financial statements at and for the years ended December 31, 2009 and 2008, and as described in an amendment to Nordic’s Schedule 13D filing with respect to ownership of our securities, Nordic disputes the anti-dilution method that we used to calculate the anti-dilution shares issuable to Nordic as a result of our

2010 Private Placement completed on April 8, 2010, which resulted in Nordic beneficially owning 85,714,285 shares as of June 18, 2010, and Nordic claims it acquired the right to purchase an additional 5,555,556 shares of our common stock upon exercise of the Nordic put as a result of Nordic's making an additional investment in the Hedrin JV of $500,000 in January 2010; as a result Nordic claims that it beneficially owns 216,666,666, or 65.5% of our common stock, which we dispute). Through its beneficial ownership of our common stock, its right to acquire additional shares, its substantial control over the management of the Hedrin JV (which includes the ability to terminate our management contract with the Hedrin JV), Nordic has the ability to exert substantial influence over the election of our Board of Directors, the outcome of issues submitted to our stockholders, the development of Hedrin and our ability, as a company, to benefit from the successful development of Hedrin. Accordingly, our directors, officers and principal stockholders, specifically Nordic, taken as a whole, have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

In April 2010, Nordic filed a Schedule 13D/A (the "Nordic Amended 13D"). We are not in agreement with the disclosure set forth in the Nordic Amended 13D and have written a letter to Nordic explaining our disagreements. The Nordic Amended 13D shows an aggregate number of shares of our common stock beneficially owned by Nordic as 216,666,666, or 65.5%. We believe the correct beneficial ownership is 85,714,285 shares, or 41.47%. The Nordic Amended 13D states that Nordic does not believe our determination of the anti-dilution shares accruing to Nordic as a result of the 2010 Private Placement was neither reasonable nor made in good faith. As we have previously stated we believe our determination was both reasonable and made in good faith. The Nordic Amended 13D further states that Nordic acquired the right to purchase an additional 5,555,556 shares of our common stock upon exercise of the Nordic put as a result of Nordic's making an additional investment in the Hedrin JV of $500,000 in January 2010. We are not in agreement with this claim, we do not believe that Nordic is required to any adjustment to Nordic's put as a result of Nordic making additional capital contributions to the Hedrin JV. In the letter to Nordic we note that Nordic's valuation suggestions for the warrants issued in the 2010 Private Placement ignores the concept of relative value inherent in the Hedrin JV Agreement.

Risks Related to Our Common Stock

Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.

During the last two fiscal years, our stock price has traded at a low of $0.007 in the fourth quarter of 2008 to a high of $0.23 in the first quarter of 2008. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- The global economic crisis, which affected stock prices of many companies, and particularly many small pharmaceutical companies like ours;
- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;