

MANHATTAN PHARMACEUTICALS INC

Form 424B3

July 06, 2010

Pursuant to Rule 424(b)(3)

File No. 333-150580

Prospectus

Manhattan Pharmaceuticals, Inc.

33,928,571 Shares

Common Stock

This prospectus relates to 33,928,571 shares of common stock of Manhattan Pharmaceuticals, Inc. for the sale from time to time by a certain holder of our securities, or by its pledgees, assignees and other successors-in-interest. Of these shares, (i) 26,785,714 shares of common stock (the "Original Put Shares") are issuable upon exercise of the selling securityholder's right to put up to a 50% equity interest in a limited partnership out of the 52.38% equity interest currently held by the selling securityholder of which we and the selling securityholder are partners and (ii) 7,142,857 shares of common stock (the "Original Warrant Shares") are issuable upon exercise of an outstanding warrant held by the selling securityholder. We will not receive any proceeds from the sales of the shares of common stock by the selling securityholder. We will not receive cash proceeds from the exercise of all or any portion of the put right exercisable for shares of common stock being registered in this offering; however, in the event of any such exercise, we will receive up to a 50% equity interest in the limited partnership of the 52.38% equity interest currently held by the selling stockholder. We will receive the proceeds of any cash exercise of the warrant.

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 securityholder.

The prices at which the selling securityholder 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 5 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.

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## 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 as 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 placement 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.

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](http://www.manhattanpharma.com).

The Offering

|   |                    |
|---|--------------------|
| Common Stock Offered by Selling Securityholder (1):             | 33,928,571 shares  |
| Common Stock Issued and Outstanding prior to this Offering (2): | 120,965,260 shares |
| Common Stock Issued and Outstanding after this Offering (3):    | 154,893,831 shares |

Use of Proceeds: We will not receive cash proceeds from the exercise of all or any portion of the put right exercisable for shares of common stock being registered in this offering; however, in the event of any such exercise, we will receive up to a 50% equity interest in H Pharmaceuticals K/S (formerly Hedrin Pharmaceuticals K/S), a Danish limited partnership, of which we and the selling securityholder are partners, of the 52.38% equity interest which is currently held by the selling securityholder. We also will receive the proceeds of any cash exercise of the warrant.

Over the Counter Bulletin Board Symbol: MHAN

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(1) Includes (i) 26,785,714 shares of common stock, which we refer to as the Original Put Shares, are issuable upon exercise of the selling securityholder's right to put up to a 50% equity interest in H Pharmaceuticals K/S of the 52.38% equity interest currently held by the selling securityholder and (ii) 7,142,857 shares of common stock, which we refer to as the Original Warrant Shares are issuable upon exercise of an outstanding warrant held by the selling securityholder.

(2) Based on the number of shares outstanding on June 18, 2010. Excludes (i) the Original Put Shares; (ii) an additional 44,642,857 shares issuable, or which may become issuable, upon exercise of the selling securityholder's right to put up to a 50% equity interest in H Pharmaceuticals K/S of the 52.38% equity interest currently held by the selling securityholder, and our right to call up to a 50% equity interest in H Pharmaceuticals K/S of the 52.38% equity interest currently held by the selling securityholder, as adjusted pursuant to the anti-dilution provisions of the selling securityholder's put right, which we refer to as the Additional Put Shares; (iii) up to 14,285,714 shares of our common stock issuable upon the exercise of the warrant held by the selling securityholder; (iv) up to 157,620,003 shares of our common stock issuable upon exercise of outstanding warrants (excluding the warrant held by the securityholder) and options to purchase shares of our common stock; (v) up to 24,718,481 shares of our common stock which may be issuable upon the achievement of certain milestones set forth in the Ariston Merger Agreement and (vi) up to 43,630,723 shares of our common stock which may be issuable upon conversion of the outstanding Ariston convertible promissory notes and trade payable.

(3) Consists (A) 120,965,260 shares outstanding on June 18, 2010, (B) (i) the 26,785,714 Original Put Shares and (ii) the 7,142,857 Original Warrant Shares, in each case, assuming the selling stockholder's election of its right exercise its put right with respect to the Original Put Shares and its exercise of the warrant to purchase the Original Warrant Shares.





## 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<br>March, 31 |              | Years Ended<br>December 31, |                      | Cumulative<br>period from<br>August 6, 2001<br>(inception) to<br>March 31, 2010 |
|---|---------------------------------|--------------|-----------------------------|----------------------|---|
|   | 2010                            | 2009         | 2009                        | 2010                 | (unaudited)   |
|   | (unaudited)                     | (unaudited)  |                             |                      |   |
| <b>Statements of Operations Data:</b>     |                                 |              |                             |                      |   |
| 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   |
| <b>Statements of Cash Flows Data:</b>     |                                 |              |                             |                      |   |
| 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<br>31, 2010 | At December<br>31, 2009   |
|   |                                 |              |                             | (unaudited)          |   |
| <b>Balance Sheets Data:</b>               |                                 |              |                             |                      |   |
| 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.





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.

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.

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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;
    - economic or other crises and other external factors;
    - period-to-period fluctuations in our revenues and other results of operations;
    - changes in financial estimates by securities analysts; and
    - sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.



Our common stock is not listed on a national exchange and there is a limited market for our common stock which may make it more difficult for you to sell your stock.

Our common stock is quoted on the OTC Bulletin Board under the symbol "MHAN.OB." There is a limited trading market for our common stock which negatively impacts the liquidity of our common stock not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. Accordingly, there can be no assurance as to the liquidity of any markets that may develop for our common stock, the ability of holders of our common stock to sell our common stock, or the prices at which holders may be able to sell our common stock.

The fact that our common stock is not listed on a national exchange may negatively impact our ability to attract investors and to use our common stock to raise capital to fund our operations.

In order to maintain liquidity in our common stock, we depend upon the continuing availability of a market on which our securities may be traded. We need to raise substantial additional funds in the future to continue our operations and the fact that our common stock is not listed on a national exchange may impact our ability to attract investors and to use our common stock to raise sufficient capital to continue to fund our operations. See the Risk Factor "We have no product revenues and will need to raise substantial additional funds in the future. If we are unable to obtain funds necessary to continue our operations, we will be required to delay, scale back or eliminate one or more of our drug development programs" above.

If we fail to file periodic reports with the SEC our common stock may be removed from the OTCBB.

Pursuant to the Over-The-Counter Bulletin Board ("OTCBB") rules relating to the timely filing of periodic reports with the SEC, any OTCBB issuer which fails to file a periodic report (Form 10-Q's or 10-K's) by the due date of such report (as extended by the filing of a Form 12b-25), three (3) times during any twenty-four (24) month period is automatically de-listed from the OTCBB. In the event an issuer is de-listed, such issuer would not be eligible to be re-listed on the OTCBB for a period of one-year, during which time any subsequent late filing would reset the one-year period of de-listing. If we are late in our filings three times in any twenty-four (24) month period and are de-listed from the OTCBB, our common stock would likely be listed for trading only on the "Pink Sheets," which generally provide an even less liquid market than the OTCBB. In such event, investors may find it more difficult to trade our common stock or to obtain accurate, current information concerning market prices for our common stock.

We are at greater risk for market fraud since our common stock is not traded on a national securities exchange.

OTCBB securities are frequent targets of fraud or market manipulation. Not only because of their generally low price, but also because the OTCBB reporting requirements for these securities are less stringent than for listed on a national securities exchange and no exchange requirements are imposed. Dealers may dominate the market and set prices that are not based on competitive forces. Individuals or groups may create fraudulent markets and control the sudden, sharp increase of price and trading volume and the equally sudden collapse of market prices.

Penny stock regulations may impose certain restrictions on marketability of our securities.

The Securities and Exchange Commission has adopted Rule 15g-9 which establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person's account for transactions in penny stocks; and

- the broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Commission relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and
- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also must be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

If we are unable to obtain future capital on acceptable terms, this will negatively affect our business operations and current investors.

We expect that in the future we will seek additional capital through public or private financings. Additional financing may not be available on acceptable terms, or at all. If additional capital is raised through the sale of equity, or securities convertible into equity, further dilution to then existing stockholders will result. In addition, certain warrants held by certain of our investors and the Nordic put contain full-ratchet anti-dilution protection provisions which would result in significant dilution to existing stockholders in the event we are required to raise capital at an effective price per share below \$0.07 per common share. If additional capital is raised through the incurrence of debt, our business could be affected by the amount of leverage incurred. For instance, such borrowings could subject us to covenants restricting our business activities, paying interest would divert funds that would otherwise be available to support commercialization and other important activities, and holders of debt instruments would have rights and privileges senior to those of equity investors. If we are unable to obtain adequate financing on a timely basis, we may be required to delay, reduce the scope of or eliminate some of our planned activities, any of which could have a material adverse effect on the business.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of your stock.

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our stock if you require dividend income. Further, you will only realize income on an investment in our stock in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.



If you are not an institutional investor, you may purchase our securities in this offering only if you reside within certain states and may engage in resale transactions only in those states and a limited number of other jurisdictions.

If you are not an “institutional investor,” you will need to be a resident of certain jurisdictions to purchase our securities in this offering. The definition of an “institutional investor” varies from state to state but generally includes financial institutions, broker-dealers, banks, insurance companies and other qualified entities. In order to prevent resale transactions in violation of states’ securities laws, you may engage in resale transactions only in the states and in other jurisdictions in which an applicable exemption is available or a registration application has been filed and accepted. This restriction on resale may limit your ability to resell the securities purchased in this offering and may impact the price of our shares.

If you are not an institutional investor, you generally will not be permitted to purchase shares in this offering unless there is an available exemption or we register the shares covered by this prospectus in such states.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business,” and elsewhere in this prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1993 (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934 that are based on management’s assumptions, expectations and projections about us, and the industry within which we operate, that have been made pursuant to the Private Securities Litigation Reform Act of 1995 and which reflect our expectations regarding our future growth, results of operations, performance and business prospects and opportunities. These statements also involve known and unknown risks, uncertainties and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, those listed under “Risk Factors” and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terminology such as “indicates,” “may,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “continue” or the negative of such terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We caution you not to place undue reliance on these statements, which speak only as of the date of this prospectus. We are under no duty to update any of the forward-looking statements after the date of this prospectus to conform such statements to actual results.

### USE OF PROCEEDS

We are registering shares of our common stock pursuant to registration rights granted to the selling securityholder. We will not receive any of the proceeds from the sale of the common stock by the selling securityholder named in this prospectus. All proceeds from the sale of the common stock will be paid directly to the selling securityholder.

We will not receive cash proceeds from the exercise of all or any portion of the put right exercisable for shares of common stock being registered in this offering; however, in the event of any such exercise, we would receive up to a 50% equity interest in H Pharmaceuticals K/S of the 52.38% equity interest currently held by the selling securityholder. If all of the warrant exercisable for shares of common stock being registered in this offering is exercised for cash, we could receive net proceeds of up to approximately \$1,000,000. We intend to use the estimated net proceeds received upon exercise of the warrant, if any, for working capital and general corporate purposes. The warrant may not be exercised and we cannot assure you that the warrant will be exercised.

We have agreed to pay all costs, expenses and fees relating to registering the shares of our common stock referenced in this prospectus. The selling securityholder will pay any brokerage commissions and/or similar charges incurred for the sale of such shares of our common stock.

## PRICE RANGE FOR OUR COMMON STOCK

Prior to March 26, 2008 our common stock traded on the American Stock Exchange “AMEX” under the symbol “MHA”. On March 26, 2008, our common stock was voluntarily delisted from the AMEX and began trading on the Over the Counter Bulletin Board under the symbol “MHAN”. The following table lists the high and low price for our common stock as quoted, in U.S. dollars, on the American Stock Exchange or the Over the Counter Bulletin Board for the periods indicated:

|  | High     | Low      |
|--|----------|----------|
| <b>2008</b>                            |          |          |
| First Quarter                          | \$ 0.230 | \$ 0.110 |
| Second Quarter                         | \$ 0.180 | \$ 0.100 |
| Third Quarter                          | \$ 0.200 | \$ 0.100 |
| Fourth Quarter                         | \$ 0.090 | \$ 0.007 |
| <b>2009</b>                            |          |          |
| First Quarter                          | \$ 0.060 | \$ 0.090 |
| Second Quarter                         | \$ 0.120 | \$ 0.021 |
| Third Quarter                          | \$ 0.100 | \$ 0.070 |
| Fourth Quarter                         | \$ 0.090 | \$ 0.060 |
| <b>2010</b>                            |          |          |
| First Quarter                          | \$ 0.084 | \$ 0.060 |
| Second Quarter (through June 18, 2010) | \$ 0.085 | \$ 0.050 |

The number of holders of record of our common stock as of June 18, 2010 was 559.

## DIVIDEND POLICY

To date, we have not paid any dividends on our common stock and we do not intend to pay dividends for the foreseeable future, but intend instead to retain earnings, if any, for use in our business operations. The payment of dividends in the future, if any, will be at the sole discretion of our board of directors and will depend upon our debt and equity structure, earnings and financial condition, need for capital in connection with possible future acquisitions and other factors, including economic conditions, regulatory restrictions and tax considerations. We cannot guarantee that we will pay dividends or, if we pay dividends, the amount or frequency of these dividends.

## SELECTED FINANCIAL INFORMATION

The selected 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 selected financial information at 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 selected 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<br>March, 31 |                     | Years Ended<br>December 31, |                                     | Cumulative<br>period from<br>August 6, 2001<br>(inception) to<br>March 31, 2010 |
|---|---------------------------------|---------------------|-----------------------------|-------------------------------------|---|
|   | 2010<br>(unaudited)             | 2009<br>(unaudited) | 2009                        | 2010                                | (unaudited)   |
| <b>Statements of Operations Data:</b>     |                                 |                     |                             |                                     |   |
| 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   |
| <b>Statements of Cash Flows Data:</b>     |                                 |                     |                             |                                     |   |
| 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<br>31, 2010<br>(unaudited) | At December<br>31, 2009   |
| <b>Balance Sheets Data:</b>               |                                 |                     |                             |                                     |   |
| Total assets                              |                                 |                     |                             | \$ 20,081,864                       | \$ 365,662  |
| Total liabilities                         |                                 |                     |                             | \$ 27,599,378                       | \$ 7,150,612  |
| Total stockholders’ deficiency            |                                 |                     |                             | \$ (7,517,514)                      | \$ (6,784,950)  |

MANAGEMENT'S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion contains forward-looking statements and involves numerous risks and uncertainties, including, but not limited to, those described in the "Risk Factors" section of this prospectus. Actual results may differ materially from those contained in any forward-looking statements. The following discussion should be read in conjunction with "Selected Financial Information" and our financial statements and notes thereto included elsewhere in this prospectus.

Overview

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. ("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 the Company.

On March 8, 2010, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") by and among the Company, Ariston Pharmaceuticals, Inc., a Delaware corporation ("Ariston") and Ariston Merger Corp., a Delaware corporation and wholly-owned subsidiary of the Company (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 (the "Merger"), with Ariston being the surviving corporation of the Merger. As a result of the Merger, Ariston became a wholly-owned subsidiary of the Company.

We are a specialty healthcare product company focused on developing and commercializing pharmaceutical 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.

You should read the following discussion of our results of operations and financial condition in conjunction with the financial statements and notes thereto appearing elsewhere in this prospectus. This discussion includes "forward-looking" statements that reflect our current views with respect to future events and financial performance. We use words such as we "expect," "anticipate," "believe," and "intend" and similar expressions to identify forward-looking statements. You should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties inherent in future events, particularly those risks identified under the heading "Risk Factors", and should not unduly rely on these forward looking statements. All share and per share information in this discussion has been adjusted for the 1-for-5 combination of our common stock effected on September 25, 2003.

## Results of Operations

Three-month Period ended March 31, 2010 versus 2009

|  | Quarters ended March 31, |                   | Increase          | % Increase     |
|--|--------------------------|-------------------|-------------------|----------------|
|  | 2010                     | 2009              | (decrease)        | (decrease)     |
| <b>Costs and expenses:</b>                       |                          |                   |                   |                |
| <b>Research and development:</b>                 |                          |                   |                   |                |
| Share-based compensation                         | \$ -                     | \$ -              | \$ -              | 0.00%          |
| Other research and development expenses          | 18,000                   | 45,000            | (27,000)          | -60.00%        |
| <b>Total research and development expenses</b>   | <b>18,000</b>            | <b>45,000</b>     | <b>(27,000)</b>   | <b>-60.00%</b> |
| <b>General and administrative:</b>               |                          |                   |                   |                |
| Share-based compensation                         | \$ 191,000               | 104,000           | 87,000            | 83.65%         |
| Other general and administrative expenses        | 320,000                  | 408,000           | (88,000)          | -21.57%        |
| <b>Total general and administrative expenses</b> | <b>511,000</b>           | <b>512,000</b>    | <b>(1,000)</b>    | <b>-0.20%</b>  |
| Other income/(expense)                           | (1,104,000)              | (205,000)         | (899,000)         | 438.54%        |
| <b>Net loss</b>                                  | <b>\$ 1,633,000</b>      | <b>\$ 762,000</b> | <b>\$ 871,000</b> | <b>114.30%</b> |

During each of the three month periods ended March 31, 2010 and 2009, we did not recognize any revenues. We are considered a development stage company and do not expect to have revenues relating to our products candidates prior to March 31, 2011, if at all.

For the quarter ended March 31, 2010 research and development expense was \$18,000 as compared to \$45,000 for the quarter ended March 31, 2009. This decrease of \$27,000, or 60%, is primarily due to there being no active product development projects during the 2010 period and limited product development activity during the 2009 period.

For the quarter ended March 31, 2010 general and administrative expense was \$511,000 as compared to \$512,000 for the quarter ended March 31, 2009. This decrease of \$1,000 is less than 1%.

For the quarter ended March 31, 2010 other income/(expense) was \$(1,104,000) as compared to \$(205,000) for the quarter ended March 31, 2009. This change of \$(899,000), or 439%, is primarily due to a change in fair value of a derivative of \$872,000, an increase in interest expense of \$111,000, a decrease in other income of \$52,000 offset by a decrease in equity in losses of Hedrin JV of \$136,000.

Net loss for the quarter ended March 31, 2010 was \$1,633,000 as compared to \$762,000 for the quarter ended March 31, 2009. This increase of \$871,000, or 114%, is primarily due to an increase in other expense of \$899,000 and a decrease in research and development expenses of \$27,000.

Fiscal Year Ended December 31, 2009 versus Fiscal Year Ended December 31, 2008

During each of the years ended December 31, 2009 and 2008, we had no revenues, and are considered a development stage company. We do not expect to have revenues relating to our products prior to December 31, 2010.

|  | Years ended December 31, |                     | Increase<br>(decrease) | % Increase<br>(decrease) |
|--|--------------------------|---------------------|------------------------|--------------------------|
|  | 2009                     | 2008                |                        |                          |
| <b>Costs and expenses:</b>                       |                          |                     |                        |                          |
| <b>Research and development:</b>                 |                          |                     |                        |                          |
| Share-based compensation                         | \$ 2,000                 | \$ 122,000          | \$ (120,000)           | -98.36%                  |
| Other research and development expenses          | 38,000                   | 1,681,000           | (1,643,000)            | -97.74%                  |
| <b>Total research and development expenses</b>   | <b>40,000</b>            | <b>1,803,000</b>    | <b>(1,763,000)</b>     | <b>-97.78%</b>           |
| <b>General and administrative:</b>               |                          |                     |                        |                          |
| Share-based compensation                         | 351,000                  | 342,000             | 9,000                  | 2.63%                    |
| Other general and administrative expenses        | 1,380,000                | 2,268,000           | (888,000)              | -39.15%                  |
| <b>Total general and administrative expenses</b> | <b>1,731,000</b>         | <b>2,610,000</b>    | <b>(879,000)</b>       | <b>-33.68%</b>           |
| <b>Other income/(expense):</b>                   |                          |                     |                        |                          |
| Equity in loss of Hedrin JV                      | (500,000)                | (250,000)           | (250,000)              | 100.00%                  |
| Change in fair value of derivative               | (560,000)                | -                   | (560,000)              | N/A                      |
| Swiss Pharma settlement                          | 251,000                  | -                   | 251,000                | N/A                      |
| Interest and amortization on Notes Payable       | (545,000)                | (39,000)            | (506,000)              | 1297.44%                 |
| Other interest expense                           | (3,000)                  | (26,000)            | 23,000                 | -88.46%                  |
| Interest and other income                        | 335,000                  | 459,000             | (124,000)              | -27.02%                  |
| <b>Total other income/(expense)</b>              | <b>(1,022,000)</b>       | <b>144,000</b>      | <b>(1,166,000)</b>     | <b>-809.72%</b>          |
| <b>Net loss</b>                                  | <b>\$ 2,793,000</b>      | <b>\$ 4,269,000</b> | <b>\$ (1,476,000)</b>  | <b>-34.57%</b>           |

For the year ended December 31, 2009 research and development expense was \$40,000 as compared to \$1,803,000 for the year ended December 31, 2008. This decrease of \$1,763,000, or 98%, is primarily due to there being no active product development projects during 2009, as the Hedrin product is being developed by the Hedrin JV and as we have ceased development of all other products due to the lack of funds and other factors.

For the year ended December 31, 2009 general and administrative expense was \$1,731,000 as compared to \$2,610,000 for the year ended December 31, 2008. This decrease of \$879,000, or 34%, is primarily comprised of \$493,000 of costs recognized during 2008 related to the Swiss Pharma arbitration award with no costs recognized during 2009, decreases in public company costs of \$107,000, in travel and related expenses of \$63,000, in consulting and temporary help of \$58,000, in rent and related expenses of \$51,000, in depreciation expense and loss on abandonment of fixed assets of \$38,000, in business development costs of \$28,000 and in dues and subscriptions of \$18,000, partially offset by an increase in share-based compensation of \$9,000.

For the year ended December 31, 2009 other income/(expense), net, was \$(1,022,000) as compared to \$144,000 for the year ended December 31, 2008. This change of \$(1,166,000), or 810%, is due to the recognition of \$(560,000) of change in the fair value of a derivative liability and \$251,000 relating to the settlement of the Swiss Pharma matter during 2009 with no corresponding amounts recognized during 2008, of increases in equity in losses of Hedrin JV of \$(250,000), in interest and amortization expense related to Notes Payable of \$(506,000) and a decrease of \$(124,000), in management fee revenue from the Hedrin JV.

Net loss for the year ended December 31, 2009 was \$2,793,000 as compared to \$4,269,000 for the year ended December 31, 2008. This decrease of \$1,476,000, or 35%, is primarily due to a decrease in research and development expenses of \$1,763,000, a decrease in general and administrative expense of \$879,000 offset by a change in other income/(expense) of \$(1,166,000).





## Liquidity and Capital Resources

From inception to March 31, 2010, we incurred a deficit during the development stage of \$63,566,604 primarily as a result of our net losses, and we expect to continue to incur additional losses through at least March 31, 2011 and for the foreseeable future. These losses have been incurred through a combination of research and development activities related to the various technologies under our control and expenses supporting those activities.

We have financed our operations since inception primarily through equity and debt financings and a joint venture transaction. During the quarter ended March 31, 2010, we had a net increase in cash and cash equivalents of \$2.0 million. This increase resulted largely from net cash provided by financing activities of \$2.1 million and \$0.5 million of cash acquired in the Ariston merger partially offset by net cash used in operating activities of \$0.6 million. Total liquid resources as of March 31, 2010 were \$2.0 million compared to \$18,000 at December 31, 2009.

Our current liabilities as of March 31, 2010 were \$7,203,000 compared to \$2,532,000 at December 31, 2009, an increase of \$4,671,000. As of March 31, 2010, we had working capital deficit of \$4,917,000 compared to working capital deficit of \$2,268,000 at December 31, 2009.

We received net proceeds of approximately \$2,100,000 in March 2010 from the 2010 Private Placement. We also acquired \$519,000 of cash in the merger with Ariston.

Our available working capital and capital requirements will depend upon numerous factors, including progress of our research and development programs, our progress in and the cost of ongoing and planned nonclinical and clinical testing, the timing and cost of obtaining regulatory approvals, the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, in-licensing activities, competing technological and market developments, changes in our existing collaborative and licensing relationships, the resources that we devote to developing manufacturing and commercializing capabilities, the status of our competitors, our ability to establish collaborative arrangements with other organizations and our need to purchase additional capital equipment.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing, other collaborative agreements, strategic alliances, and our ability to realize the full potential of our technology in development. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. Through March 31, 2010, a significant portion of our financing has been through equity and debt financings and a joint venture transaction. Unless our operations generate significant revenues and cash flows from operating activities, we will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. We believe that we will continue to incur net losses and negative cash flows from operating activities for the foreseeable future.

Based on the resources available to us at March 31, 2010, our management believes that we have sufficient capital to fund our operations through 2010. Our management believes that we will need additional equity or debt financing or will need to generate positive cash flow from the Hedrin JV, or generate revenues through licensing of its products or entering into strategic alliances to be able to sustain our operations into 2011. Furthermore, we will need additional financing thereafter to complete development and commercialization of our products. There can be no assurances that we can successfully complete development and commercialization of our products.

These matters raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.



We have reported net losses of \$1,633,000 and \$762,000 for the three month periods ended March 31, 2010 and 2009, respectively. The net loss attributable to common shares from date of inception, including preferred stock dividends, August 6, 2001 to March 31, 2010, amounts to \$63,567,000. Management believes that we will continue to incur net losses through at least March 31, 2011 and for the foreseeable future.

#### Joint Venture Agreement

We and Nordic Biotech Venture Fund II K/S, or Nordic, entered into a joint venture agreement on January 31, 2008, which was amended on February 18, 2008 and on June 9, 2008. Pursuant to the joint venture agreement, in February 2008, (i) Nordic contributed cash in the amount of \$2.5 million to H Pharmaceuticals K/S, a newly formed Danish limited partnership, or the Hedrin JV, in exchange for a 50% of the equity interests in the Hedrin JV, and (ii) we contributed certain assets to North American rights (under license) to our Hedrin product to the Hedrin JV in exchange for \$2.0 million in cash and 50% of the equity interests in the Hedrin JV. On or around June 30, 2008, in accordance with the terms of the joint venture agreement, Nordic contributed an additional \$1.25 million in cash to the Hedrin JV, \$1.0 million of which was distributed to us and equity in the Hedrin JV was distributed to each of us and Nordic sufficient to maintain our respective ownership interests.

Pursuant to the joint venture agreement, upon the classification by the U.S. Food and Drug Administration, or the FDA, of Hedrin as a Class II or Class III medical device, Nordic was required to contribute to the Hedrin JV an additional \$1.25 million in cash, \$0.5 million of which was to be distributed to us and equity in the Hedrin JV was to be distributed to each of us and Nordic sufficient to maintain our respective ownership interests. The FDA notified the Hedrin JV that Hedrin has been classified as a Class III medical device and in February 2009, Nordic made the \$1.25 million investment in the Hedrin JV, the Hedrin JV made the \$0.5 million milestone payment to us and equity in the Hedrin JV was distributed to us and Nordic sufficient to maintain our respective ownership interests.

The Hedrin JV is responsible for the development and commercialization of Hedrin for the North American market and all associated costs including clinical trials, if required, regulatory costs, patent costs, and future milestone payments owed to Thornton & Ross Ltd., or T&R, the licensor of Hedrin. The Hedrin JV has engaged us to provide management services to the Hedrin JV in exchange for an annualized management fee, which for the three month periods ended March 31, 2010 and 2009 was approximately \$75,000 and \$109,000, respectively.

The profits of the Hedrin JV will be shared by us and Nordic in accordance with our respective equity interests in the Hedrin JV, of which we each currently hold 47.62%, except that Nordic is entitled to receive a minimum return each year from the Hedrin JV equal to 6% on Hedrin sales, as adjusted for any change in Nordic's equity interest in the Hedrin JV, before any distribution is made to us. If the Hedrin JV realizes a profit in excess of the Nordic minimum return in any year, then such excess shall first be distributed to us until our distribution and the Nordic minimum return are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. However, in the event of a liquidation of the Hedrin JV, Nordic's distribution in liquidation must equal the amount Nordic invested in the Hedrin JV (\$5.5 million) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV before any distribution is made to us. If the Hedrin JV's assets in liquidation exceed the Nordic liquidation preference amount, then any excess shall first be distributed to us until our distribution and the Nordic liquidation preference amount are in the same ratio as our respective equity interests in the Hedrin JV and then the remainder, if any, is distributed to Nordic and us in the same ratio as our respective equity interests. Further, in no event shall Nordic's distribution in liquidation be greater than assets available for distribution in liquidation.

Pursuant to the terms of the joint venture agreement, Nordic has the right to nominate one person for election or appointment to our board of directors. The Hedrin JV's board of directors consists of four members, two members appointed by us and two members appointed by Nordic. Nordic has the right to appoint one of the directors as

chairman of the board. The chairman has certain tie breaking powers.

Pursuant to the joint venture agreement, Nordic has the right to put up to a 50% equity interest in the Hedrin JV of the 52.38% equity interest currently held by it in exchange for such number of shares of our common stock in an amount not to exceed \$5,000,000 of Nordic's investment in the Hedrin JV divided by \$0.07, as adjusted for the 2010 Private Placement, and as further adjusted from time to time for stock splits and other specified events, multiplied by a conversion factor, which is (i) 1.00 for so long as Nordic's distributions from the Hedrin JV are less than the amount of its investment, (ii) 1.25 for so long as Nordic's distributions from the Hedrin JV are less than two times the amount of its investment but greater than or equal to the amount of its investment amount, (iii) 1.50 for so long as Nordic's distributions from the Hedrin JV are less than three times the amount of its investment but greater than or equal to two times the amount of its investment amount, (iv) 2.00 for so long as Nordic's distributions from the Hedrin JV are less than four times the amount of its investment but greater than or equal to three times the amount of its investment amount and (v) 3.00 for so long as Nordic's distributions from Hedrin JV are greater than or equal to four times the amount of its investment. The put right expires upon the earlier to occur of (i) February 25, 2018 and (ii) 30 days after the date when Nordic's distributions from the Hedrin JV exceed five times the amount Nordic has invested in the Hedrin JV (or 10 days after such date if we have provided Nordic notice thereof).

Pursuant to the joint venture agreement, we have the right to call up to a 50% equity interest in the Hedrin JV of the 52.38% equity interest currently held by Nordic in exchange for such number of shares of our common stock equal to the portion of Nordic's investment in the Hedrin JV (not to exceed \$5 million) that we call by the dollar amount of Nordic's investment in the Hedrin JV up to \$5 million, divided by \$0.07, as adjusted for the 2010 Private Placement, and as further adjusted from time to time for stock splits and other specified events. The call right is only exercisable by us if the price of our common stock has closed at or above \$1.40 per share for 30 consecutive trading days. During the first 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 25% of the call right. During the second 30 consecutive trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 50% of the call right on a cumulative basis. During the third consecutive 30 trading days in which our common stock closes at or above \$1.40 per share, we may exercise up to 75% of the call right on a cumulative basis. During the fourth consecutive 30 days in which our common stock closes at or above \$1.40 per share, we may exercise up to 100% of the call right on a cumulative basis. Nordic may refuse the call, either by paying \$1.5 million multiplied by the percentage of Nordic's investment being called or forfeiting an equivalent portion of the put right, calculated on a pro rata basis for the percentage of the Nordic equity interest called by us. The call right expires on February 25, 2013. For purposes of Nordic's right to put, and our right to call, up to a 50% equity interest in the Hedrin JV of the 52.38% equity interest currently held by Nordic, the amount of Nordic's investment is \$5,000,000.

In connection with our joint venture agreement, on February 25, 2008, Nordic paid us a non-refundable fee of \$150,000 in exchange for the right to receive a warrant to purchase up to 14,285,714 shares of our common stock at \$0.07 per share, as adjusted for the 2010 Private Placement, and as further adjusted from time to time for stock splits and other specified events.

In connection with the joint venture agreement, we entered into a registration rights agreement with Nordic on February 25, 2008, as modified pursuant to a letter agreement, dated September 17, 2008, pursuant to which we agreed to file with the Securities and Exchange Commission, or the SEC, an initial registration statement registering the resale by Nordic of any shares of our common stock issuable to Nordic through the exercise of the warrant or the put right, within 10 calendar days following the date on which our annual report on Form 10-K for the year ended December 31, 2007 was required to be filed with the SEC, which was subsequently extended until May 1, 2008. We filed an initial registration statement on May 1, 2008, which was declared effective on October 15, 2008. On June 2, 2009, we filed an additional Registration Statement registering the additional 28,769,841 shares of our common stock that may be issued to Nordic upon exercise of a put right, which we refer to as the Put Shares, held by Nordic as a result of Nordic's additional investment of \$1,250,000 in the Hedrin JV, as adjusted pursuant to the anti-dilution provisions of the put right and the additional 3,968,254 shares issuable upon exercise of an outstanding warrant held

by Nordic. The SEC has informed us that we may not register the Put Shares for resale until Nordic exercises its put right and such shares of common stock are outstanding. Further, although we diligently pursued registration with the SEC, such registration statement was not declared effective within 105 days of the required filing date. We have withdrawn such registration statement in light of the SEC staff's position that the shares of common stock underlying Nordic's put right cannot be registered because such shares are not outstanding and do not underlie a currently outstanding convertible security.

We also have agreed to file with the SEC any additional registration statements which may be required no later than 45 days after the date we first know such additional registration statement is required; provided, however, that (i) in the case of the classification by the FDA of Hedrin as a Class II or Class III medical device described above and the payment in full by Nordic of the related final milestone payment of \$1.25 million, the registration statement with respect to the additional shares of our common stock relating to such additional investment must be filed within 45 days after achievement of such classification; and (ii) in the event we provide Nordic with notice of exercise of our right to call up to a 50% equity interest in the Hedrin JV of the 52.38% equity interest currently held by Nordic, a registration statement with respect to the shares of our common stock payable to Nordic in connection with such call right (after giving effect to any reduction in the number of such shares resulting from Nordic's refusal of all or a portion of such call in accordance with the terms of our joint venture agreement) must be filed within 16 days after delivery of such notice to Nordic. If we fail to file a registration statement on time or if a registration statement is not declared effective by the SEC within 105 days of the required filing date, or otherwise fail to diligently pursue registration with the SEC in accordance with the terms of the registration rights agreement, we will be required to pay as partial liquidated damages and not as a penalty, to Nordic or its assigns, an amount equal to 0.5% of the amount invested in the Hedrin JV by Nordic pursuant to the joint venture agreement per month until the registration statement is declared effective by the SEC; provided, however, that in no event shall the aggregate amount payable by us exceed 9% of the amount invested in the Hedrin JV by Nordic under the joint venture agreement.

As per the limited partnership agreement between us and Nordic, in the event that a limited partner in the Hedrin JV determines, in its reasonable good faith discretion, that the Hedrin JV requires additional capital for the proper conduct of its business that limited partner shall provide each limited partner with a written request for contribution of such limited partner's proportionate share, in accordance to the then respective equity ownership in the Hedrin JV, of such requested additional capital amount.

As per the terms of the limited partnership agreement, if a limited partner declines to so contribute, elects to contribute but thereafter fails to do so timely, or elects to contribute and timely does contribute some, but not all of, its proportionate share of the requested additional capital amount, the other limited partner shall have the option to contribute the remaining balance of such requested additional capital amount.

As per the terms of the limited partnership agreement, the general partner shall determine the fair market value of the shares for purposes of determining how to allocate the number of shares of the Hedrin JV to be issued in consideration for the contribution of capital. If the general partner is unable to determine the fair market value of the shares, the fair market value for the shares shall be determined in good faith by the contributing limited partner if such amount is equal to or greater than the most recent valuation of such Hedrin JV shares.

On December 31, 2009, Nordic delivered a written notice to us for a \$1,000,000 capital increase to the Hedrin JV. In January 2010, Nordic made its capital contribution to the Hedrin JV of \$500,000. We did not have sufficient funds to make such a capital contribution within the required time prescribed in the limited partnership agreement.

The general partner was unable to determine the fair market value of the shares. The contributing limited partner, Nordic, determined in good faith that the fair market value of the shares is equal to the most recent valuation. The most recent valuation was the February 2009 investment of \$1,500,000 into the Hedrin JV by Nordic at \$5,000 per share. As a result of Nordic's investing an additional \$500,000 in the Hedrin JV, the ownership percentages of the Hedrin JV have changed from 50% to Nordic and 50% for us to 52.38% to Nordic and 47.62% for us. In the event that Nordic exercises its option to invest the remaining \$500,000 of the \$1,000,000 capital increase then the ownership percentage shall change to 54.55% for Nordic and 45.45% for us.

Disagreement with Nordic



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.

## 2010 Private Placement

On March and April 2010, we raised aggregate gross proceeds of approximately \$2.6 million in connection with our 2010 Private Placement. We sold an aggregate of 104.3 units for a purchase price of \$25,000 per unit. We issued to each investor units consisting of 357,143 shares of our common stock and 535,714 warrants, each of which 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. In addition in April 2010, a 12% original discount senior secured subordinated convertible debenture, which we refer to as the Convertible 12% Debenture, with a stated value of \$400,000 and \$21,886 of accrued interest, was converted by its holder into 16.88 units (including all accrued interest thereon). The conversion price was equal to the per unit purchase price paid by the investors in the 2010 Private Placement.

## Convertible 12% Note Payable

On October 27, 2009, we entered into a Settlement Agreement and Mutual Release with Swiss Pharma Contract LTD (“Swiss Pharma”) pursuant to which we agreed to pay Swiss Pharma \$200,000 and issue Swiss Pharma an interest free promissory note in the principal amount of \$250,000 in full satisfaction of the September 5, 2008 arbitration award. The amount of the Arbitration award was \$683,027 at September 30, 2009 and is included as a component of accrued expenses in the balance sheet as of September 30, 2009.

In conjunction with the Settlement Agreement and Mutual Release with Swiss Pharma described above, on October 28, 2009, we entered into a subscription agreement pursuant to which we sold the 12% Convertible Debenture and a warrant to purchase 2,222,222 shares of our common stock, par value \$.001 per share for a purchase price of \$200,000. The warrant is exercisable at an exercise price of \$0.11 per share, subject to adjustment, prior to October 28, 2014. The Convertible 12% Debenture is convertible into shares of our common stock at an initial conversion price of \$0.09 per share, subject to adjustment or, in the event that we issues new securities in connection with a financing, the Convertible 12% Debenture may be converted into such new securities at a conversion price equal to the purchase price paid by the purchasers of such new securities. The Convertible 12% Debenture was subordinated to our outstanding Secured 12% Notes in the aggregate principal amount of \$1,725,000. On April 8, 2010, the holder of the Convertible 12% Debenture converted the 12% Convertible Debenture (including all interest accrued thereon) into approximately 17 units, with each unit consisting of (i) 357,143 shares of our common stock and (ii) warrants to purchase 535,714 shares of our common stock at a per share purchase price of \$0.08. In connection with the issuance of the Convertible 12% Debenture and the warrants, we issued warrants to purchase an aggregate of 222,222 shares of common stock at an exercise price of \$0.11 per share to the placement agent and certain of its designees.

## Secured 10% Notes Payable

On September 11, 2008, we issued secured 10% promissory notes to certain of our directors and officers and an employee for aggregate principal amount of \$70,000. Principal and interest on the notes was payable in cash on March 10, 2009 unless paid earlier by us. The secured 10% notes were repaid in February 2009 along with interest thereon. In connection with the issuance of the notes, we issued to the noteholders 5-year warrants to purchase an aggregate of 140,000 shares of our common stock at an exercise price of \$0.20 per share.

### Secured 12% Notes Payable

On February 3, 2009, we completed a private placement of 345 units, with each unit consisting of secured 12% notes in the principal amount of \$5,000 and a warrant to purchase up to 166,667 shares of our common stock at an exercise price of \$.09 per share which expires on December 31, 2013, for aggregate gross proceeds of \$1,725,000. The private placement was completed in three closings which occurred on November 19, 2008 with respect to 207 units, December 23, 2008 with respect to 56 units and February 3, 2009 with respect to 82 units.

To secure our obligations under the notes, we entered into a security agreement and a default agreement with the investors. The security agreement provides that the notes will be secured by a pledge of our assets other than (i) our interest in the Hedrin joint venture, including, without limitation, our interest in H Pharmaceuticals K/S and H Pharmaceuticals General Partner ApS, (ii) our rent deposit for our former office space, (iii) our refund of a prepayment and (iv) our tax refund for the 2007 fiscal year from the State of New York and City of New York. In addition, to provide additional security for our obligations under the notes, we entered into a default agreement, which provides that upon an event of default under the notes, we shall, at the request of the holders of the notes, use our reasonable commercial efforts to either (i) sell a part or all of our interests in the Hedrin JV or (ii) transfer all or part of our interest in the Hedrin JV to the holders of the notes, as necessary, in order to fulfill our obligations under the notes, to the extent required and to the extent permitted by the applicable Hedrin JV agreements.

In connection with the private placement, we, the placement agent and the investors entered into a registration rights agreement. Pursuant to the registration rights agreement, we agreed to file a registration statement to register the resale of the shares of our common stock issuable upon exercise of the warrants issued to the investors in the private placement, within 20 days of the final closing date and to cause the registration statement to be declared effective within 90 days (or 120 days upon full review by the SEC). During the three month period ended March 31, 2009, we filed the registration statement, received a comment letter from the SEC, responded to the SEC comment letter and re-filed the registration statement. The registration statement was declared effective by the SEC on April 17, 2009.

### Acquisition of Ariston Pharmaceuticals, Inc.

On March 8, 2010, we entered into the Merger Agreement by and among Ariston, the Merger Sub and us. Pursuant to the terms and conditions set forth in the Merger Agreement, on March 8, 2010, the Merger Sub merged with and into Ariston (the "Merger"), with Ariston being the surviving corporation of the Merger. As a result of the Merger, Ariston became our wholly-owned subsidiary.

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), 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 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), 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 served 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.

We merged with Ariston principally to add new products to our portfolio. Ariston, prior to the Merger, 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.

#### AST-726

Ariston is developing a nasally-delivered Vitamin B12 remediation treatment which it calls AST-726. AST-726 has demonstrated pharmacokinetic equivalence to a marketed intramuscular injection product for Vitamin B12 remediation. Ariston believes that AST-726 may enable both a single, once-monthly treatment for maintenance of normal Vitamin B12 levels in deficient patients, and more frequent administration to restore normal levels in newly diagnosed B12 deficiency. Further, Ariston believes that AST-726 could offer a convenient, painless, safe and cost-effective treatment for Vitamin B12 deficiency, without the need for intramuscular injections.

Ariston has positioned AST-726 to currently require only a single, relatively small Phase III clinical trial prior to submission of a 505(b)(2) new drug application ("NDA") to the FDA.

Ariston has developed a CMC/manufacturing process for AST-726 that Ariston believes provides a commercially viable stability profile. Ariston has two issued patents in the United States with respect to AST-726, one of which relates to its application in Vitamin B12 remediation.

More than 9 million people in the US are deficient in Vitamin B12, indicating substantial market potential for a facile, convenient, safe and effective treatment that can replace the need for painful and frequent intramuscular injections or other less than fully effective delivery forms. Ariston believes that substantial market opportunity also exists internationally.

#### Vitamin B12 Deficiency-Background of the Disease

Untreated Vitamin B12 deficiency can result in serious clinical problems including hematological disorders, such as life-threatening anemias, and a range of central and peripheral neurological abnormalities such as fatigue, confusion, cognition impairment, dementia, depression, peripheral neuropathies and gait disturbances. Neuronal damage may involve peripheral nerves, the spinal cord and the brain and if the condition is left untreated may become permanent. Furthermore, clinically asymptomatic patients with low normal or below normal Vitamin B12 levels may have changes in blood chemistries, including elevated levels of methylmalonic acid or homocysteine, known risk factors for

other medical conditions associated with an increased risk of circulatory problems, blood clots and cardiovascular disease.

The primary diagnosis of Vitamin B12 deficiency is made when measurement of its blood concentration falls below the expected normal range of 200 to 900 picograms/ml. Vitamin B12 deficiency is most often caused by pathological conditions that limit the body's ability to absorb the vitamin. Such disorders include pernicious anemia, atrophic gastritis, problems caused by gastric surgical procedures to treat stomach cancer and obesity, Crohn's disease and simple age-related changes. Some studies show the inability to properly absorb Vitamin B12 as a side effect from chronic use of certain widely prescribed antacid medications such as Prilosec® and diabetes treatments such as Glucophage®.

Approximately 15% of the elderly and up to 40% of nursing home residents in the U.S. have Vitamin B12 deficiency. A study of over 11,000 U.S. civilians ages four and older found a 3% prevalence of Vitamin B12 deficiency in the general population using the 200 picograms/ml deficiency standard, indicating that approximately 9 million people in the U.S. are in need of B12 replacement therapy. Some experts advocate a higher deficiency standard of 300-350 picograms/ml on the basis that levels below this coincide with elevated methylmalonic acid and homocysteine, risk factors for cardiovascular disease as found in the Framingham Heart Study. On this basis the prevalence of Vitamin B12 deficiency increases substantially.

#### Current Treatments for Vitamin B12 Deficiency

Once Vitamin B12 deficiency is diagnosed by a simple blood test, the goal of treatment is generally to:

- o restore circulating blood levels to normal as rapidly as possible;
- o replenish and normalize the substantial stores of the vitamin in the body; and
- o institute a lifelong therapeutic regimen that will maintain normal levels of the vitamin.

Ariston believes that parenteral (intramuscular injection) treatment is often considered the treatment of choice for Vitamin B12 deficiency. Cyanocobalamin is predominantly used for this purpose in the United States, but hydroxocobalamin, the active ingredient in AST-726, is also available for pediatrics and for adults for whom injection of cyanocobalamin is poorly tolerated. Hydroxocobalamin injection is the predominant treatment for Vitamin B12 deficiency in Europe.

In the United States, intramuscular injections are generally given by a physician or nurse, necessitating an office/medical center visit by the patient or a visiting nurse home call for each treatment. Following a diagnosis of B12 deficiency, injections are required quite frequently in order to restore normal vitamin levels. Once normalization is achieved, the frequency can be reduced to once or twice per month. While the treatment is usually highly effective, the inconvenience and cost of frequent office visits and the pain and side-effects associated with intramuscular injections are problematic for many patients.

Intranasal treatment with Vitamin B12 deficiency seeks to alleviate these problems, but the two intranasal products currently available in the United States have to be administered on a daily or weekly basis and are not usually recommended for the treatment of newly diagnosed patients. Both products are based on cyanocobalamin.

Oral or sublingual administration of high doses of Vitamin B12 can restore deficient patients to normal in certain cases. Such high dose supplements are generally available in pharmacies and nutrition/health food stores. Adequate results can almost certainly be obtained when nutritional insufficiency (e.g., strict vegan diet) is the primary cause of the problem. However, the normal gastrointestinal tract has a very limited capability to absorb Vitamin B12 and if this is compromised, as is the case in many deficient patients, oral or sublingual supplementation may not be ideal for rapidly restoring circulating levels and storage depots of the vitamin to normal. In such cases of pathological Vitamin B12 deficiency, intramuscular injection still often remains the current treatment of choice.

An unapproved Vitamin B12 patch is available in the United States, but Ariston believes that its effectiveness in moderate to severe Vitamin B12 deficient patients is substantially untested.



### Potential Advantages of Ariston's AST-726 Treatment

Ariston believes that Ariston's AST-726 treatment has the potential to directly substitute for and replace the need for injection treatment by applying the current injection frequency paradigms for both newly diagnosed and normalized Vitamin B12 deficient patients. AST-726 is proposed to be self-administered at home by the patient, without costly, time-consuming and inconvenient visits to a doctor's office or medical facility needed for each of the many intramuscular injections required for life. Because it is delivered through a nasal spray, additional advantages include freedom from injection pain and reduced anxiety in individuals, including children and the elderly, who may have fear of injections. Ariston believes that the delivery profile of AST-726 is comparable to that of the marketed intramuscular injection, and that therefore newly diagnosed patients will be able to self-administer the nasal spray on a daily basis or several times a week to restore their Vitamin B12 status to normal and will then be self-maintained on a single monthly nasal spray treatment.

### Additional Clinical Trial Is Needed

AST-726, a commercial nasal spray formulation of hydroxocobalamin, has satisfactorily completed preclinical toxicology, and an Investigational New Drug ("IND") Application has been filed with the FDA. This product candidate is being developed utilizing the 505(b)(2) regulatory pathway. AST-726 has also successfully completed a safety and pharmacokinetic study in healthy volunteers and an end of Phase II meeting with FDA has been completed. We are planning a Phase III Vitamin B12 replacement study in the United States. The study is designed to enroll approximately 40 Vitamin B12 deficient patients currently treated with injection therapy. Patients will first be evaluated on injection therapy and then will receive AST-726 by nasal spray on a monthly basis for 12 weeks. The primary purpose of this study is to determine that levels of Vitamin B12 in the patients' bloodstream remain within the normal range following monthly administration of AST-726. We anticipate that the data from this study and additional manufacturing information will support the planned 505(b)(2) new drug application ("NDA") filing for AST-726.

### AST-915

AST-915 is an orally delivered treatment for essential tremor. We acquired global rights to AST-915 as part of the Ariston acquisition. This product candidate is being studied under a Cooperative Research and Development Agreement (CRADA) with the National Institutes of Health (NIH) and a Phase 1 clinical study is currently underway in essential tremor patients. AST-915 was formerly referred to as "AST-914 metabolite".

### Essential Tremor

Essential tremor is a neurological disorder that is characterized by involuntary shaking of the hands, arms, head, voice, and upper body. The most disabling tremors occur during voluntary movement, affecting common skills such as writing, eating and drinking. Essential tremor is often misdiagnosed as Parkinson's disease, yet according to the National Institutes of Neurological Disorders and Stroke, approximately 8 times as many people have essential tremor as have Parkinson's. Essential tremor is not confined to the elderly. Children, newborns, and middle-aged people can also have the condition.

### Market opportunity

Essential tremor is the most common involuntary movement disorder, with increasing incidence as people age. According to the National Institute of Health (NIH), essential tremor affects 14% of people 65 years and older, which equates to approximately 5.4 million Americans. There is no cure for essential tremor and the currently available drug therapies do not work in certain patients, produce at best a 50% response in others and have significant side effects.

We believe AST-915 may provide a new treatment option for this serious and prevalent disorder. We believe that substantial market opportunity also exists internationally.

## Commitments

### General

We often contract with third parties to facilitate, coordinate and perform agreed upon research and development of our product candidates. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and nonclinical testing costs based on the work performed under the contracts.

These contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain milestones. This method of payment often does not match the related expense recognition resulting in either a prepayment, when the amounts paid are greater than the related research and development costs recognized, or an accrued liability, when the amounts paid are less than the related research and development costs recognized.

### Development Commitments

At present we have no development commitments.

### Hedrin

In collaboration with Nordic and through the Hedrin JV we are developing Hedrin for the treatment of pediculosis (head lice). To date, Hedrin has been clinically studied in 326 subjects and is currently marketed as a device in Western Europe and as a pharmaceutical in the United Kingdom (U.K.).

In a randomized, controlled, equivalence clinical study conducted in Europe by T&R, Hedrin was administered to 253 adult and child subjects with head louse infestation. The study results, published in the British Medical Journal in June 2005, demonstrated Hedrin's equivalence when compared to the insecticide treatment, phenothrin, the most widely used pediculicide in the U.K. In addition, according to the same study, the Hedrin-treated subjects experienced significantly less irritation (2%) than those treated with phenothrin (9%).

An additional clinical study published in the November 2007 issue of PLoS One, an international, peer-reviewed journal published by the Public Library of Science (PLoS), demonstrated Hedrin's superior efficacy compared to a U.K. formulation of malathion, a widely used insecticide treatment in both Europe and North America. In this randomized, controlled, assessor blinded, parallel group clinical trial, 73 adult and child subjects with head lice infestations were treated with Hedrin or malathion liquid. Using intent-to-treat analysis, Hedrin achieved a statistically significant cure rate of 70% compared to 33% with malathion liquid. Using the per-protocol analysis Hedrin achieved a highly statistically significant cure rate of 77% compared to 35% with malathion. In Europe it has been widely documented that head lice had become resistant to European formulations of malathion, and we believe this resistance had influenced these study results. To date, there have been no reports of resistance to U.S. formulations of malathion. Additionally, Hedrin treated subjects experienced no irritant reactions, and Hedrin showed clinical equivalence to malathion in its ability to inhibit egg hatching. Overall, investigators and study subjects rated Hedrin as less odorous, easier to apply, and easier to wash out, and 97% of Hedrin treated subjects stated they were significantly more inclined to use the product again versus 31% of those using malathion.

Two new, unpublished Hedrin studies were completed by T&R in 2008. In the first, Hedrin achieved a 100% kill rate in vitro, including in malathion resistant head lice. In the other, a clinical field study conducted in Manisa province, a rural area of Western Turkey, Hedrin was administered to 36 adult and child subjects with confirmed head lice infestations. Using per protocol analysis, Hedrin achieved a 97% cure rate. Using intent-to-treat analysis, Hedrin achieved a 92% cure rate since 2 subjects were eliminated due to protocol violations. No subjects reported any

adverse events.

In the U.S., we, through the Hedrin JV, are pursuing the development of Hedrin as a medical device. In January 2009, the U.S. Food and Drug Administration (“FDA”) Center for Devices and Radiological Health (“CDRH”) notified H Pharmaceuticals that Hedrin had been classified as a Class III medical device. A Class III designation means that a Premarket Approval (“PMA”) Application will need to be obtained before Hedrin can be marketed in the U.S. We expect to be required to complete at least one clinical trial as part of that PMA Application. At a July 2009 meeting with the FDA, the FDA requested of the Hedrin JV that the confirmatory clinical trials consist of two parallel studies. The Hedrin JV estimates that each of the parallel studies will consist of 60 patients. In April 2010, the Hedrin JV received correspondence from the FDA in which the FDA raised certain questions about the non-clinical aspects of Hedrin. The Hedrin JV is in the process of responding to those questions and will not be able to commence the confirmatory clinical trials until such questions are responded to, to the satisfaction of the FDA.

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To date, we have incurred \$1,084,000 of project costs for the development of Hedrin. None of these costs were incurred during the three month period ended March 31, 2010. We do not expect to incur any future costs as the Hedrin JV is now responsible for all costs associated with Hedrin.

#### Topical GEL for Psoriasis

As a result of our merger with Tarpan Therapeutics in 2005, we held an exclusive, worldwide license to develop and commercialize Topical PTH (1-34) for the treatment of psoriasis. Tarpan acquired the exclusive, worldwide rights pursuant to a 2004 license agreement with IGI, Inc (“IGI”).

In April 2006, we encountered a stability issue with the original topical PTH (1-34) product which utilized IGI’s Novosome® formulation technology. In order to resolve that stability issue we created a new topical gel version of PTH (1-34).

In September 2007, the U.S. FDA accepted our Investigational New Drug (“IND”) application for this new gel formulation of Topical PTH (1-34), and in October 2007, we initiated and began dosing subjects in a Phase 2a clinical study of Topical PTH (1-34) for the treatment of psoriasis. This U.S., multi-center, randomized, double-blind, vehicle-controlled, parallel group study was designed to evaluate safety and preliminary efficacy of Topical PTH (1-34) in patients with mild to moderate psoriasis. Approximately 54 subjects were enrolled and randomized to receive one of two dose levels of Topical PTH (1-34), or the gel vehicle (placebo), for an 8 week treatment period. In this study the vehicle was the topical gel (“GEL”) without the active ingredient, PTH (1-34).

In July 2008, we announced the results of a Phase 2a clinical study where PTH (1-34) failed to show statistically or clinically meaningful improvements in psoriasis as compared to the vehicle (placebo). We have conducted no further clinical activities with PTH (1-34), terminated the agreement with IGI in May 2009 and have no further financial liability or commitment to IGI under the license agreement.

The gel vehicle (placebo) used in the above-mentioned study is our proprietary topical GEL which unexpectedly showed evidence of psoriasis improving properties. At the end of week 2, 15% of study subjects treated with the GEL achieved a clear or almost clear state. At the end of week 4, 20% of subjects treated with the GEL had achieved a clear or almost clear state, and at the end of week 8, 25% of subjects had achieved a clear or almost clear state. We own worldwide rights to this topical GEL and is exploring the possibility of developing it as an OTC product for mild psoriasis.

To date, we have incurred \$6,504,000 of project costs related to our development of Topical PTH (1-34). These project costs have been incurred since April 1, 2005, the date of the Tarpan Therapeutics acquisition. None of these costs were incurred during the three month period ended March 31, 2010.

#### Summary of Contractual Commitments

##### Leases

Rent expense for the years ended December 31, 2009 and 2008 was \$88,363 and \$139,636, respectively. Future minimum rental payments subsequent to December 31, 2009 under an operating lease for our office facility, which expires on September 30, 2010, are \$36,000.

##### Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.



### Critical Accounting Policies

In December 2001, the SEC requested that all registrants discuss their most “critical accounting policies” in management’s discussion and analysis of financial condition and results of operations. The SEC indicated that a “critical accounting policy” is one which is both important to the portrayal of the company’s financial condition and results and requires management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect certain reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

### Research and Development Expenses

All research and development costs are expensed as incurred and include costs of consultants who conduct research and development on behalf of our company and our subsidiaries. Costs related to the acquisition of technology rights and patents for which development work is still in process are expensed as incurred and considered a component of research and development costs.

We often contract with third parties to facilitate, coordinate and perform agreed upon research and development of a new drug. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contracts.

These contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain milestones. This method of payment often does not match the related expense recognition resulting in either a prepayment, when the amounts paid are greater than the related research and development costs expensed, or an accrued liability, when the amounts paid are less than the related research and development costs expensed.

### Share-Based Compensation

We have stockholder-approved stock incentive plans for employees, directors, officers and consultants. Prior to January 1, 2006, we accounted for the employee, director and officer plans using the intrinsic value method. Effective January 1, 2006, we adopted the share-based payment method for employee options using the modified prospective transition method. This new method of accounting for stock options eliminated the option to use the intrinsic value method and required us to expense the fair value of all employee options over the vesting period. Under the modified prospective transition method, we recognized compensation cost which includes a) period compensation cost related to share-based payments granted prior to, but not yet vested, as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions; and b) period compensation cost related to share-based payments granted on or after January 1, 2006, based on the grant date fair value estimated in accordance with the new accounting methodology. In accordance with the modified prospective method, we have not restated prior period results.

### New Accounting Pronouncements

In May 2009, the Financial Accounting Standards Board (“FASB”) issued a statement which sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. This statement was effective for interim or annual periods ending after June 15, 2009, and we adopted the provisions of this statement for the quarter ended June 30, 2009. The adoption of this statement did not have a material impact on our financial statements. We have evaluated all events or transactions that occurred after March 31, 2010 up through the date we issued these financial statements, and we have disclosed all events or transactions that have a material impact on our financial statements.



In August 2009, the FASB issued a new pronouncement to provide clarification on measuring liabilities at fair value when a quoted price in an active market is not available. In particular, this pronouncement specifies that a valuation technique should be applied that uses either the quote of the liability when traded as an asset, the quoted prices for similar liabilities when traded as assets, or another valuation technique consistent with existing fair value measurement guidance. This statement is prospectively effective for financial statements issued for interim or annual periods ending after October 1, 2009. The adoption of this statement at December 31, 2009 did not impact our results of operations or financial condition.

In January 2010, the FASB issued a new pronouncement, Improving Disclosures about Fair Value Measurements (ASU 2010-06). This provision amends previous provisions that require reporting entities to make new disclosures about recurring and nonrecurring fair value measurements including the amounts of and reasons for significant transfers into and out of Level 1 and Level 2 fair value measurements and separate disclosure of purchases, sales, issuances, and settlements in the reconciliation of Level 3 fair value measurements. This pronouncement was effective for interim and annual reporting periods beginning after December 15, 2009, except for Level 3 reconciliation disclosures which are effective for interim and annual periods beginning after December 15, 2010. The adoption of this pronouncement did not have a material impact on our results of operations or financial condition.

In February 2010, the FASB issued new accounting guidance that amends the previous guidance to (1) eliminate the requirement for an SEC filer to disclose the date through which it has evaluated subsequent events, (2) clarify the period through which conduit bond obligors must evaluate subsequent events and (3) refine the scope of the disclosure requirements for reissued financial statements. We adopted this new accounting guidance for the quarterly period ended March 31, 2010. The adoption of this guidance did not have a material impact on our financial statements.

## BUSINESS

### 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. Our current portfolio of product candidates includes:

- Hedrin™, a novel, non-insecticide treatment for pediculosis (head lice)
- AST-726, a nasally delivered form of hydroxocobalamin for the treatment of vitamin B12 deficiency
- AST-915, an oral treatment for essential tremor
- A topical GEL for the treatment of mild psoriasis

In the short term, we are focusing our efforts on the commercialization of Hedrin and AST-726. We have not received regulatory approval for, or generated commercial revenue from, marketing or selling any products.

Our executive offices are located at 48 Wall Street, 11th floor, New York, NY 10005 USA. Our telephone number is (212) 582-3950 and our internet website address is [www.manhattanpharma.com](http://www.manhattanpharma.com).

### Recent Developments

On April 8, 2010, we completed a private placement of approximately 121 units, which we refer to as 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 placement 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.

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.



## Business Strategy

Our goal is to locate, develop, and commercialize specialty healthcare products. In order to achieve this, we look for innovative, or next generation, products with one or more of the following characteristics:

- Low clinical, regulatory, and/or marketing risk
- Quick to market (such as medical devices, 505(b)(2), or over-the-counter)
- Low cost to develop
- Low cost and/or simple to manufacture
- Serves a niche or underserved patient population

All of our current products meet some or all of these criteria.

## Products

### Hedrin

Hedrin is a novel, non-insecticide, one hour treatment for pediculosis (head lice) and is currently being developed in the United States as a prescription medical device. Hedrin is the top selling head lice product in Europe. It is currently marketed in over 27 countries and, according to Thornton & Ross Ltd. (“T&R”), achieved 2008 annual sales through its licensees of approximately \$48 million (USD) at in-market public prices, garnering approximately 23% market share across Europe.

In June 2007, we entered into an exclusive license agreement with T&R and Kerris, S.A. (“Kerris”) for Hedrin (the “Hedrin License Agreement”). We acquired an exclusive North American license to certain patent rights and other intellectual property relating to the product. In addition, and at the same time, we also entered into a Supply Agreement with T&R pursuant to which T&R will be our exclusive supplier of Hedrin product (the “Hedrin Supply Agreement”).

In February 2008, we entered into a joint venture agreement with Nordic Biotech Advisors ApS (“Nordic”) to develop and commercialize Hedrin for the North American market. The joint venture entity, H Pharmaceuticals (“H Pharmaceuticals” or the “Hedrin JV”), now owns, is developing, and is working to secure commercialization partners for Hedrin in both the U.S. and Canada. We manage the day-to-day operations of the Hedrin JV under a management contract with the Hedrin JV. H Pharmaceuticals is independently funded and is responsible for all costs associated with the Hedrin project, including any necessary U.S. clinical trials, patent costs, and future milestones owed to the original licensor, T&R.

We, through the Hedrin JV, are currently working to secure commercialization and marketing partners for the U.S. and Canada.

### Pediculosis (Head lice)

Head lice (*Pediculus humanus capitis*) are small parasitic insects that live mainly on the human scalp and neck hair. Head lice are not known to transmit disease, but they are highly contagious and are acquired by direct head-to-head contact with an infested person’s hair, and may also be transferred with shared combs, hats, and other hair accessories. They can also live on bedding or upholstered furniture for a brief period. Head lice are seen across the socioeconomic spectrum and are unrelated to personal cleanliness or hygiene. Children are more frequently infested than are adults, and Caucasians more frequently than other ethnic groups. Lice are most commonly found on the scalp, behind the ears, and near the neckline at the back of the neck. Common symptoms include a tickling feeling of something

moving in the hair, itching, irritability caused by poor sleep, and sores on the head caused by scratching.

## Mechanism of Action

Hedrin is a novel, non-insecticide combination of silicones (dimethicone and cyclomethicone) that acts as a pediculicidal (lice killing) agent by disrupting the insect's mechanism for managing fluid and breathing. In contrast with most currently available lice treatments, Hedrin contains no chemical insecticides. Because Hedrin kills lice by preventing the louse from excreting waste fluid, rather than by acting on the central nervous system, the insects cannot build up resistance to the treatment. Recent studies have indicated that resistance to chemical insecticides may be increasing and therefore contributing to insecticide treatment failure. We believe there is significant market potential for a convenient, non-insecticide treatment alternative. Both silicones in this proprietary formulation of Hedrin are used extensively in cosmetics and toiletries.

## Product Development

To date, Hedrin has been clinically studied in over 400 subjects. In a randomized, controlled, equivalence, clinical study (conducted in Europe by T&R), Hedrin was administered to 253 adult and child subjects with head lice infestation. The study results, published in the British Medical Journal in June 2005, demonstrated Hedrin's equivalence when compared to the insecticide treatment, phenothrin, the most widely used pediculicide in the U.K. In addition, according to the same study, the Hedrin treated subjects experienced significantly less irritation (2%) than those treated with phenothrin (9%).

A clinical study published in the November 2007 issue of PLoS One, an international, peer-reviewed journal published by the Public Library of Science (PLoS), demonstrated Hedrin's superior efficacy compared to a U.K. formulation of malathion, a widely used insecticide treatment in both Europe and North America. In this randomized, controlled, assessor blinded, parallel group clinical trial, 73 adult and child subjects with head lice infestations were treated with Hedrin or malathion liquid. Using intent-to-treat analysis, Hedrin achieved a statistically significant cure rate of 70% compared to 33% with malathion liquid. Using the per-protocol analysis Hedrin achieved a highly statistically significant cure rate of 77% compared to 35% with malathion. In Europe, it has been widely documented that head lice has become resistant to malathion, and we believe this resistance may have influenced the study results. To date, there have been no reports of malathion resistance in the U.S. Additionally, Hedrin treated subjects experienced no irritant reactions, and Hedrin showed clinical equivalence to malathion in its ability to inhibit egg hatching. Overall, investigators and study subjects rated Hedrin as less odorous, easier to apply, and easier to wash out. In addition, 97% of Hedrin treated subjects stated they were significantly more inclined to use the product again versus 31% of those using malathion.

Two unpublished Hedrin studies were completed by T&R in 2008. In the first, Hedrin achieved a 100% kill rate in vitro, including malathion resistant head lice. In the other, a clinical field study conducted in Manisa province, a rural area of Western Turkey, Hedrin was administered to 36 adult and child subjects with confirmed head lice infestations. Using per protocol analysis, Hedrin achieved a 97% cure rate. Using intent-to-treat analysis, Hedrin achieved a 92% cure rate since 2 subjects were eliminated due to protocol violations. No subjects reported any adverse events.

In April 2009, T&R published a new clinical field study where 40 adult and child subjects with head lice infestations were treated with Hedrin using a 1 hour application time. Treatment was given twice with 7 days between applications. In this study, Hedrin achieved a cure rate of 90%.

In the U.S., we, through the Hedrin JV, are pursuing the development of Hedrin as a prescription medical device. In January 2009, the U.S. Food and Drug Administration ("FDA") Center for Devices and Radiological Health ("CDRH") notified H Pharmaceuticals that Hedrin had been classified as a Class III medical device. A Class III designation means that a Premarket Approval ("PMA") Application will need to be obtained before Hedrin can be marketed in the U.S. In July 2009, the CDRH division of the FDA confirmed that two pivotal studies, which can occur



simultaneously, using the same protocol consisting of approximately 60 subjects each, or 120 patients in total, are required for the completion of the PMA Application. In April, 2010, the Hedrin JV received correspondence from the FDA in which the FDA raised certain questions about the non-clinical aspects of Hedrin (including certain deficiencies in safety documentation that will require further study). The Hedrin JV is in the process of responding to those questions and will not be able to commence the confirmatory clinical trials, and the Hedrin JV's application to conduct those trials will not be accepted by the FDA, unless and until such questions are responded to, to the satisfaction of the FDA.

## Market and Competition

According to the American Academy of Pediatrics an estimated 6-12 million Americans are infested with head lice each year, with pre-school and elementary children and their families affected most often. The total U.S. head lice market is estimated to be over \$200 million with prescription and over-the-counter (OTC) therapies comprising approximately 50% of that market. The remaining 50% of the market is comprised of alternative therapies such as tea tree oils, mineral oils, and “nit picking”, or physical combing to remove lice. In addition, the head lice market is experiencing an increasing trend toward healthier, more environmentally friendly consumer products and a growing activism against pesticide products. We believe there is significant market potential for a convenient, non-insecticide treatment for head lice.

The prescription and OTC segment of the market is dominated by 4-5 name brand products and numerous, low cost generics and store brand equivalents. The active ingredients in these pharmacological therapies are chemical insecticides. The most frequently prescribed insecticide treatments are Ovide (malathion) and Kwell (lindane), and the most frequently purchased OTC brands are Rid (piperonyl butoxide), Nix (permethrin), and Pronto (piperonyl butoxide). Lindane has been banned in 52 countries worldwide and has now been banned in the state of California due to its toxicity. In addition, New York, Michigan, and Minnesota have initiated legislation to ban the use of lindane. European formulations of malathion have experienced widespread resistance. Resistance to U.S. formulations of malathion has not been widely reported to date, but experts believe it is likely to develop with continued use. Head lice resistance to piperonyl butoxide and permethrin has been reported in the U.S. and treatment failures are common.

See also “Management’s Discussion and Analysis of Financial Condition and Results of Operations- Liquidity and Capital Resources- Research and Development Projects- Hedrin.”

## AST-726

AST-726 is a nasally delivered form of hydroxocobalamin for the treatment of Vitamin B12 deficiency. We acquired global rights to AST-726 as part of the Ariston merger. AST-726 has demonstrated pharmacokinetic equivalence to a marketed intramuscular injection product for Vitamin B12 remediation. We believe that AST-726 may enable both a single, once-monthly treatment for maintenance of normal Vitamin B12 levels in deficient patients, and more frequent administration to restore normal levels in newly diagnosed B12 deficiency. Further, we believe that AST-726 could offer a convenient, painless, safe and cost-effective treatment for Vitamin B12 deficiency, without the need for intramuscular injections.

## Vitamin B12 Deficiency - Background of the Disease

Untreated Vitamin B12 deficiency can result in serious clinical problems including hematological disorders, such as life-threatening anemias, and a range of central and peripheral neurological abnormalities such as fatigue, confusion, cognition impairment, dementia, depression, peripheral neuropathies and gait disturbances. Neuronal damage may involve peripheral nerves, the spinal cord and the brain and if the condition is left untreated may become permanent. Furthermore, clinically asymptomatic patients with low normal or below normal Vitamin B12 levels may have changes in blood chemistries, including elevated levels of methylmalonic acid or homocysteine, known risk factors for other medical conditions associated with an increased risk of circulatory problems, blood clots and cardiovascular disease.

The primary diagnosis of Vitamin B12 deficiency is made when measurement of its blood concentration falls below the expected normal range of 200 to 900 picograms/ml. Vitamin B12 deficiency is most often caused by pathological conditions that limit the body’s ability to absorb the vitamin. Such disorders include pernicious anemia, atrophic

gastritis, problems caused by gastric surgical procedures to treat stomach cancer and obesity, Crohn's disease and simple age-related changes. Some studies show the inability to properly absorb Vitamin B12 as a side effect from chronic use of certain widely prescribed antacid medications such as Prilosec® and diabetes treatments such as Glucophage®.

## Product Development

AST-726, a commercial nasal spray formulation of hydroxocobalamin, has satisfactorily completed preclinical toxicology, and an Investigational New Drug (“IND”) Application has been filed with the FDA. This product candidate is being developed utilizing the 505(b)(2) regulatory pathway. AST-726 has also successfully completed a safety and pharmacokinetic study in healthy volunteers and an end of Phase II meeting with FDA has been completed. We are planning a Phase III Vitamin B12 replacement study in the United States. The study is designed to enroll approximately 40 Vitamin B12 deficient patients currently treated with injection therapy. Patients will first be evaluated on injection therapy and then will receive AST-726 by nasal spray on a monthly basis for 12 weeks. The primary purpose of this study is to determine that levels of Vitamin B12 in the patients’ bloodstream remain within the normal range following monthly administration of AST-726. We anticipate that the data from this study and additional manufacturing information will support the planned 505(b)(2) new drug application (“NDA”) filing for AST-726.

A CMC/manufacturing process has been developed for AST-726 that we believe provides a commercially viable stability profile. We have two issued patents in the United States with respect to AST-726, one of which relates to its application in Vitamin B12 remediation.

## Market and Competition

More than 9 million people in the U.S. are deficient in Vitamin B12, indicating substantial market potential for a facile, convenient, safe and effective treatment that can replace the need for painful and frequent intramuscular injections or other less than fully effective delivery forms.

Approximately 15% of the elderly and up to 40% of nursing home residents in the U.S. have Vitamin B12 deficiency. A study of over 11,000 U.S. civilians ages four and older found a 3% prevalence of Vitamin B12 deficiency in the general population using the 200 picograms/ml deficiency standard, indicating that approximately 9 million people in the U.S. are in need of B12 replacement therapy. Some experts advocate a higher deficiency standard of 300-350 picograms/ml on the basis that levels below this coincide with elevated methylmalonic acid and homocysteine, risk factors for cardiovascular disease as found in the Framingham Heart Study. On this basis the prevalence of Vitamin B12 deficiency increases substantially.

We believe that substantial market opportunity also exists internationally.

## Current Treatments for Vitamin B12 Deficiency

Once Vitamin B12 deficiency is diagnosed by a simple blood test, the goal of treatment is generally to:

- Restore circulating blood levels to normal as rapidly as possible;
- Replenish and normalize the substantial stores of the vitamin in the body; and
- Institute a lifelong therapeutic regimen that will maintain normal levels of the vitamin.

We believe that parenteral (intramuscular injection) treatment is often considered the treatment of choice for Vitamin B12 deficiency. Cyanocobalamin is predominantly used for this purpose in the United States, but hydroxocobalamin, the active ingredient in AST-726, is also available for pediatrics and for adults for whom injection of cyanocobalamin is poorly tolerated. Hydroxocobalamin injection is the predominant treatment for Vitamin B12 deficiency in Europe.

In the United States, intramuscular injections are generally given by a physician or nurse, necessitating an office/medical center visit by the patient or a visiting nurse home call for each treatment. Following a diagnosis of

B12 deficiency, injections are required quite frequently in order to restore normal vitamin levels. Once normalization is achieved, the frequency can be reduced to once or twice per month. While the treatment is usually highly effective, the inconvenience and cost of frequent office visits and the pain and side effects associated with intramuscular injections are problematic for many patients.

Intranasal treatment for Vitamin B12 deficiency seeks to alleviate these problems, but the two intranasal products currently available in the United States, Nascobal® and Calomist®, have to be administered on a daily or weekly basis and are not usually recommended for the treatment of newly diagnosed patients. Both products are based on cyanocobalamin.

Oral or sublingual administration of high doses of Vitamin B12 can restore deficient patients to normal in certain cases. Such high dose supplements are generally available in pharmacies and nutrition/health food stores. Adequate results can almost certainly be obtained when nutritional insufficiency (e.g., strict vegan diet) is the primary cause of the problem. However, the normal gastrointestinal tract has a very limited capability to absorb Vitamin B12 and if this is compromised, as is the case in many deficient patients, oral or sublingual supplementation may not be ideal for rapidly restoring circulating levels and storage depots of the vitamin to normal. In such cases of pathological Vitamin B12 deficiency, intramuscular injection still often remains the current treatment of choice.

An unapproved Vitamin B12 patch is available in the United States, but we believe that its effectiveness in moderate to severe Vitamin B12 deficient patients is substantially untested.

#### Potential Advantages of AST-726 Treatment

We believe that AST-726 treatment has the potential to directly substitute for and replace the need for injection treatment by applying the current injection frequency paradigms for both newly diagnosed and normalized Vitamin B12 deficient patients. AST-726 is proposed to be self-administered at home by the patient, without costly, time consuming, and inconvenient visits to a doctor's office or medical facility needed for each of the many intramuscular injections required for life. Because it is delivered through a nasal spray, additional advantages include freedom from injection pain and reduced anxiety in individuals, including children and the elderly, who may have fear of injections. We believe that the delivery profile of AST-726 is comparable to that of the marketed intramuscular injection, and that therefore newly diagnosed patients will be able to self-administer the nasal spray on a daily basis or several times a week to restore their Vitamin B12 status to normal and will then be self-maintained on a single monthly nasal spray treatment.

#### AST-915

AST-915 is an orally delivered treatment for essential tremor. We acquired global rights to AST-915 as part of the Ariston merger. This product candidate is being studied under a Cooperative Research and Development Agreement (CRADA) with the National Institutes of Health (NIH) and a Phase 1 clinical study is currently underway in essential tremor patients. AST-915 was formerly referred to as "AST-914 metabolite".

#### Essential Tremor

Essential tremor is a neurological disorder that is characterized by involuntary shaking of the hands, arms, head, voice, and upper body. The most disabling tremors occur during voluntary movement, affecting common skills such as writing, eating and drinking. Essential tremor is often misdiagnosed as Parkinson's disease, yet according to the National Institutes of Neurological Disorders and Stroke, approximately 8 times as many people have essential tremor as have Parkinson's. Essential tremor is not confined to the elderly. Children, newborns, and middle-aged people can also have the condition.

#### Market opportunity

Essential tremor is the most common involuntary movement disorder, with increasing incidence as people age. According to the National Institute of Health (NIH), essential tremor affects 14% of people 65 years and older, which equates to approximately 5.4 million Americans. There is no cure for essential tremor and the currently available drug therapies do not work in certain patients, produce at best a 50% response in others and have significant side effects. We believe AST-915 may provide a new treatment option for this serious and prevalent disorder. We believe that substantial market opportunity also exists internationally.



## Topical GEL for Psoriasis

This topical GEL was used as the vehicle (placebo) in a prior clinical study versus a discontinued product candidate, topical PTH (1-34), and showed evidence of psoriasis improving properties. In that Phase 2a study 15% of study subjects achieved a clear or almost clear state at the end of week 2. At the end of week 4, 20% of subjects treated with the GEL had achieved a clear or almost clear state, and at the end of week 8, 25% of subjects treated with the GEL had achieved a clear or almost clear state. We own global rights to this topical GEL and is exploring the possibility of developing it as an OTC product for mild psoriasis.

## Psoriasis

Psoriasis is a common, chronic, immune-mediated disease that results in the over-production of skin cells. In healthy skin, immature skin cells migrate from the lowest layer of the epidermis to the skin's surface over a period of 28-30 days. In psoriasis, these cells reproduce at an extremely accelerated rate and advance to the surface in only 7 days. This results in a build up of excess, poorly differentiated skin cells that accumulate in dry, thick patches known as plaques. These plaques can appear anywhere on the body resulting in itching, skin irritation, and disability.

## Market and Competition

According to the National Psoriasis Foundation approximately 125 million people worldwide, including approximately 6 million Americans, suffers from psoriasis. Of these, approximately 65% (4.4 million) have mild psoriasis and are the most likely of psoriasis sufferers to be treated with an OTC product. According to Datamonitor, only an estimated 55% of psoriasis sufferers have been formally diagnosed by a physician, so the OTC market could potentially be much larger.

There are a number of treatments available today for psoriasis, including numerous OTC creams and ointments that help to reduce inflammation, stop itching, and soothe skin. Products such as Psoriasin, CortAid, Dermarest, and Cortizone 10 are the most common, but none are viewed as particularly effective for psoriasis.

See also "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - Research and Development Projects – Topical Psoriasis Product."

## Discontinued Research and Development Programs

### Altoderm™

In April 2007 we entered into a license agreement with T&R, pursuant to which we acquired exclusive rights to develop and commercialize Altoderm in North America. Altoderm is a novel, proprietary formulation of topical cromolyn sodium and is designed to enhance the absorption of cromolyn sodium into the skin in order to treat pruritus (itch) associated with dermatologic conditions including atopic dermatitis (eczema).

In a Phase 3, randomized, double-blind, vehicle-controlled clinical study (conducted in Europe by T&R) Altoderm was safe and well tolerated, and showed a trend toward improvement in pruritus, but the efficacy results were inconclusive. Altoderm treated subjects and vehicle only treated subjects experienced a similar improvement (each greater than 30%), and therefore, the study did not achieve statistical significance.

As a result of the inconclusive European study data and a lack of sufficient funds to develop Altoderm, in March 2009 we discontinued development and returned the project to T&R under the terms of the license agreement.



Altolyn™

In April 2007 we entered into a license agreement with T&R, pursuant to which we acquired exclusive rights to develop and commercialize Altolyn in North America. Altolyn is a novel, proprietary oral tablet formulation of cromolyn sodium designed to treat mastocytosis and possibly other gastrointestinal disorders such as food allergy and symptoms of irritable bowel syndrome.

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Due to small market opportunity and lack of sufficient funds to develop Altolyn, in March 2009 we discontinued development and returned the project to T&R under the terms of the license agreement.

#### Commercialization, Marketing, and Sales

In order to maximize the commercial value of our product candidates, it is likely that we will partner with, and/or out-license the marketing rights to, a marketing organization with expertise in the therapeutic areas we operate in. We are currently working to secure a marketing partner for Hedrin in both the United States and Canada. Longer term, we may explore the possibility of securing commercialization partners for AST-726, AST-915, and the topical GEL in the United States and global territories.

#### Intellectual Property and License Agreements

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. This knowledge and experience we call “know-how”. To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality 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.

#### Hedrin

On June 26, 2007, we entered into an exclusive license agreement for Hedrin (“the Hedrin Agreement”) with T&R and Kerris. Pursuant to the Hedrin Agreement, we have acquired an exclusive North American license to certain patent rights and other intellectual property relating to Hedrin™, a non-insecticide product candidate for the treatment of pediculosis (“head lice”):

U.S. Patent Application No. 2007/0142330, entitled, “Method and composition for the control of arthropods.” Jayne Ansell, Inventor. Application filed February 12, 2007. This application is a divisional of U.S. application Ser. No. 10/097,615, filed Mar. 15, 2002, which is a continuation of International Application No. PCT/GB00/03540, which designated the United States and was filed on September 14, 2000. This application has not yet issued as a patent. Any patent that issues will expire on September 14, 2020.

This patent application has numerous, detailed and specific claims related to the use of Hedrin (novel formulation of silicon derivatives) in controlling and repelling arthropods such as insects and arachnids, and in particular control and eradication of head lice and their ova.

On February 25, 2008, we assigned and transferred our rights in Hedrin to the Hedrin JV. The Hedrin JV is now responsible for all of our obligations under the Hedrin License Agreement and the Hedrin Supply Agreement.



#### AST-726

Pursuant to the Merger Agreement with Ariston, we acquired patent rights and other intellectual property relating to AST-726:

- 1.U.S. Patent No. 5,801,161 entitled, "Pharmaceutical composition for the intranasal administration of hydroxocobalamin." Franciscus W.H.M. Merkus, Inventor. Application filed June 17, 1996. Patent issued September 1, 1998. This patent is scheduled to expire on May, 13, 2014.
- 2.U.S. Patent No. 5,925,625 entitled, "Pharmaceutical composition for the intranasal administration of hydroxocobalamin." Franciscus W.H.M. Merkus, Inventor. Application filed December 30, 1997. Patent issued July 20, 1999. This patent is scheduled to expire on May, 13, 2014.
- 3.European Patent No. EP0735859B1 (granted July 30, 1997, national phase of PCT Publication No. WO9517164) entitled, "Pharmaceutical composition for the intranasal administration of hydroxocobalamin." Franciscus W.H.M. Merkus, Inventor. Application filed May 13, 1994. Patents validated in Great Britain, Austria, Belgium, Denmark, France, Ireland, Italy, the Netherlands, Switzerland, Germany, Spain, and Sweden are scheduled to expire on May, 13, 2014.

#### AST-915

Pursuant to the Merger Agreement with Ariston, we have acquired patent rights and other intellectual property relating to AST-915:

U.S. Patent Application No. PCT/US2009/000876 entitled "Octanoic acid formulations and methods of treatment using the same." McLane, Nahab, and Hallet, Inventors. Application filed February 12, 2009. This application has not yet issued as a patent.

#### Manufacturing

We do not have any manufacturing capabilities. T&R will supply any Hedrin product required to conduct human clinical studies, and we are in contact with several contract cGMP manufacturers for the supply of AST-726, AST-915, and the topical GEL for psoriasis.

#### Government Regulations

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

Drug Approval Process. None of our drugs may be marketed in the U.S. until the drug has received FDA approval. The steps required before a drug may be marketed in the U.S. include:

- nonclinical laboratory tests, animal studies, and formulation studies,
- submission to the FDA of an Investigational New Drug application (IND) or, in the case of medical devices, an Investigational Device Exemption (IDE), for human clinical testing, which must become effective before human

clinical trials may begin,

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication,
- submission to the FDA of a New Drug Application (NDA) or, in the case of medical devices a Premarket Approval (PMA),

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMPs, and
- FDA review and approval of the NDA or PMA.

Nonclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the nonclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the nonclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND or IDE, which must become effective before human clinical trials may begin. An IND/IDE will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND/IDE. In such a case, the IND/IDE sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND/IDE will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational drug or medical device to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND/IDE.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) preliminarily evaluate the efficacy of the drug for specific indications. Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that Phase 1, Phase 2, or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDCA permits FDA and the IND/IDE sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA or PMA application. This process is known as Special Protocol Assessment, or SPA. These agreements may not be changed after the clinical studies begin, except in limited circumstances.

Assuming successful completion of the required clinical testing, the results of the nonclinical and clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of a NDA or PMA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort, and financial resources. The agencies review the application and may deem it to be inadequate to support the registration and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review, and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening

conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, that the review time will be reduced.

Section 505(b)(2) of the FDCA allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or data used by FDA in the approval of other drugs. This procedure potentially makes it easier for generic drug manufacturers to obtain rapid approval of new forms of drugs based on proprietary data of the original drug manufacturer. We intend to rely on Section 505(b)(2) to obtain approval for AST-726.

Before approving an NDA or a PMA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless cGMP compliance is satisfactory. If the FDA evaluates the NDA/PMA and the manufacturing facilities as acceptable, the FDA may issue an approval letter, or in some cases, an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA/PMA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA/PMA approval, the FDA may require post marketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before we can market our product candidates for additional indications, we must obtain additional approvals from FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. We cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

**Post-Approval Requirements.** Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA or PMA are required to: (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. We intend to use third party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA/PMA, including withdrawal of the product from the market.

**Non-United States Regulation.** Before our products can be marketed outside of the United States, they are subject to regulatory approval similar to that required in the United States, although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union ("EU") member states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the



centralized procedure. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.

## History

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".

## Employees

We currently have two full time and two part time employees, including: our Chief Operating and Financial Officer, the Chief Executive Officer of Ariston and two persons in business development, clinical management, administration and finance. None of our employees is covered by a collective bargaining unit. We believe our relations with our employees are satisfactory.

## Properties

Our executive offices are located at 48 Wall Street, New York, New York 10005. We currently occupy this space pursuant to a written lease that expires on September 30, 2010 under which we pay rent of approximately \$4,000 per month.

We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

## Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We are not aware of any pending or threatened legal proceeding that, if determined in a manner adverse to us, could have a material adverse effect on our business and operations.

## MANAGEMENT

## Directors

The name and age of each of our directors as of June 18, 2010, his position with us, his principal occupation, and the period during which such person has served as a director of our company are set forth below. All directors hold office until the next annual meeting of shareholders or until their respective successors are elected and qualified. We believe that each of our directors has professional experience in areas relevant to our strategy and operations. Each of our directors holds or has held senior-level positions in complex business, government, or academic settings. We also believe each of our directors has other attributes necessary to create an effective board: high personal and professional ethics, integrity and values; practical wisdom and judgment; an inquisitive and objective perspective; the willingness to engage management and each other in a constructive and collaborative fashion; the ability to devote significant time to serve on our board and its committees; and a commitment to representing the long-term interests of all our shareholders.

| Name                 | Age | Position(s) Held                                       | Director Since |
|----------------------|-----|--|----------------|
| Douglas Abel         | 48  | Director, Chairman of the Board                        | 2005           |
| Neil Herskowitz      | 53  | Director   | 2004           |
| Michael McGuinness   | 56  | Principal Operating and Financial Officer and Director | 2010           |
| Timothy McInerney    | 49  | Director   | 2004           |
| Malcolm Morville     | 64  | Director   | 2010           |
| David Shimko         | 50  | Director   | 2010           |
| Richard I. Steinhart | 53  | Director   | 2004           |

Douglas Abel served as our President and Chief Executive Officer from April 2005 until June 2009. Mr. Abel continues to serve as our Chairman of the Board. Mr. Abel has been a director of our company since 2005. Mr. Abel currently serves as General Manager for Onset Therapeutics LLC. Mr. Abel was President and CEO of Tarpan Therapeutics, Inc., a privately-held biopharmaceutical company, from November 2004 until April 2005, when Tarpan was acquired by us. Prior to becoming President and CEO of Tarpan, Mr. Abel served as Vice President of the Dermatology Business Unit at Biogen Idec where he worked from August 2000 to November 2004. While at Biogen, he led more than 100 employees to support the launch of AMEVIVE®. Before that, Mr. Abel was at Allergan Pharmaceuticals from December 1987 to August of 2000, with his most recent position being Director of BOTOX® Marketing. Mr. Abel received his A.B. in chemistry from Lafayette College and an M.B.A. from Temple University. Mr. Abel's qualifications to serve as a director include his 4 years of experience as our Chief Executive Officer, his experience as the CEO of Tarpan, his experience as a vice president at Biogen Idec, his A.B. degree in chemistry and his MBA degree. Serving as the CEO of Manhattan and Tarpan provided him with relevant perspective on the dynamics and challenges of small, specialty pharmaceutical companies. In addition, while at Biogen Idec he oversaw the successful growth and evolution of a business unit.

Neil Herskowitz has been a director of our company since July 2004. He has served as the Managing Member of ReGen Partners LLC, an investment fund located in New York, and as the President of its affiliate, Riverside Contracting LLC since June 1998. Mr. Herskowitz currently serves as a director of Innovive Pharmaceuticals (OTCBB: IVPH) a publicly traded pharmaceutical development company. He also serves on the board of directors of Starting Point Services for Children, a not-for-profit corporation, and of Vacation Village, a 220-unit development in Sullivan County, New York. Mr. Herskowitz received a B.B.A. in Finance from Bernard M. Baruch College in 1978. Mr. Herskowitz's qualifications to serve as a director include his executive positions with ReGen Partners and Riverside Contracting and his service as a director of another publicly traded company, Innovive Pharmaceuticals. Serving as an executive of two small companies, ReGen Partners and Riverside Contracting has provided him with

relevant perspective on the dynamics and challenges of small companies. His service as a director for Innovative Pharmaceuticals has provided him with relevant perspective on the dynamics and challenges of small, publicly traded life science companies.

Michael G. McGuinness has been our Chief Financial Officer and Secretary since July 2006. Mr. McGuinness was appointed Chief Operating Officer on April 1, 2008. Mr. McGuinness has been a director of our company since March 2010. Prior to joining our company, Mr. McGuinness served as chief financial officer of Vyteris Holdings (Nevada), Inc. (OTCBB: VYHN), a product-based drug delivery company, from September 2001 to April 2006, and from 1998 to 2001 he was chief financial officer of EpiGenesis Pharmaceuticals, a privately-held biotechnology company. Mr. McGuinness received a BBA in public accounting from Hofstra University. Mr. McGuinness' qualifications to serve as a director include his three plus years of service as our Chief Financial Officer and his service as the chief financial officer of Vyteris and his BBA degree in public accounting. Serving as a chief financial officer of publicly traded companies for over eight years has provided him with relevant perspective on the dynamics and challenges of small, publicly traded life science companies.

Timothy McInerney has been a director of our company since July 2004. Mr. McInerney serves as a partner at Riverbank Capital Securities, Inc., a position he has held since June 2007. Mr. McInerney currently serves on the board of directors of ZIOPHARM Oncology Inc. (NASDAQ: ZIOP). From 1992 to March 2007, Mr. McInerney was a Managing Director of Paramount BioCapital, Inc. where he oversaw the overall distribution of Paramount's private equity product. Prior to 1992, Mr. McInerney was a research analyst focusing on the biotechnology industry at Ladenburg, Thalman & Co. Prior to that, Mr. McInerney held equity sales positions at Bear, Stearns & Co. and Shearson Lehman Brothers, Inc. Mr. McInerney also worked in sales and marketing for Bristol-Myers Squibb. He received his B.S. in pharmacy from St. John's University at New York. He also completed a post-graduate residency at the New York University Medical Center in drug information systems. Mr. McInerney's qualifications to serve as a director include his executive positions with Riverbank Capital and Paramount, his service as a director of another publicly traded company, ZIOPHARM, his service as a research analyst at Ladenburg Thalman and his B.S. degree in pharmacy. Serving as an executive of two financial firms that specialize in small cap companies, Riverbank Capital and Paramount, and serving on the board of directors for ZIOPHARM has provided him with relevant perspective on the dynamics and challenges of small, publicly traded companies.

Malcolm Morville, Ph.D., has been a director of our company since March 2010. Dr. Morville serves as President and CEO of Ariston, which as a result of the merger is a wholly-owned subsidiary of our company. Dr. Morville was appointed President and CEO of Ariston in December 2003 and served as a director of Ariston until the consummation of our merger with Ariston. From 1970 to 1988, Dr. Morville was employed by Pfizer, both in the U.K. and U.S., in the discovery, development and marketing of many drugs and potential drugs for the treatment of neurology and central nervous system disorders, infectious, immunological, respiratory, cardiovascular and gastrointestinal diseases as well as diabetes and obesity. From 1988 to 1993, he held senior executive management positions at Immulogic Pharmaceuticals Corporation, a public biotechnology company. From 1993 to 2003, Dr. Morville was President and CEO and a director of Phytera, Inc., a private biotechnology corporation. He remains a director of Phytera. From 1993 to 2009, Dr. Morville was a director of Indevus Pharmaceuticals, Inc. (formerly Interneuron Pharmaceuticals, Inc.) a public biopharmaceutical company which was acquired by Endo Pharmaceuticals Holdings, Inc. in March, 2009. Dr. Morville received his B.Sc. and Ph.D. in biochemistry from the University of Manchester Institute of Science and Technology in the U.K. Dr. Morville's qualifications to serve as a director include his service as the CEO of Ariston, his service as the CEO of Phytera, his service as an executive with Immulogic Pharmaceuticals, his service in the discovery, development and marketing functions for Pfizer and his Ph. D. in biochemistry. Serving as an executive for Ariston, Phytera and Immulogic Pharmaceuticals has provided Dr. Morville with relevant perspective on the dynamics and challenges of life science companies. His service at Pfizer has provided Dr. Morville with relevant perspective on the dynamics and challenges of the development and marketing of pharmaceutical products

David Shimko, Ph.D., was appointed a director of our company in March 2010. Mr. Shimko served as a director of Ariston until the consummation of our merger with Ariston. Mr. Shimko co-founded Risk Capital Management Partners LLC, an independent risk management consulting firm with a specialization in financial risk, and served as

its President until it was acquired by Towers Perrin in June 2006. Mr. Shimko provided transition services to Towers Perrin in connection with its acquisition of Risk Capital Management through December 2007. Since the acquisition, Mr. Shimko has continued to act as an independent risk management consultant and has served as President of Winhall LLC. Mr. Shimko received his Ph.D. in finance from Northwestern University. Mr. Shimko's qualifications to serve as a director include his service on the board of directors of Ariston, his service as an executive at Risk Capital and Winhall and his Ph.D. in economics. Serving as on the board of directors of Ariston and serving as an executive for Risk Capital and Winhall has provided Mr. Shimko with relevant perspective on the dynamics and challenges of small companies. His Ph.D. in economics and his service as an executive with two companies provided Mr. Shimko with the relevant perspective on the dynamics and challenges of the audit committee of small, publicly traded companies.

Richard I. Steinhart has been a director of our company since July 2004. Since April 2006, Mr. Steinhart has served as Chief Financial Officer of Electro-Optical Sciences, Inc., a publicly-held medical device company. From May 1992 to April 2006, Mr. Steinhart was principal of Forest Street Capital, a boutique investment banking, venture capital, and management consulting firm. Prior to Forest Street Capital, from May 1991 to May 1992, he was the Vice President and Chief Financial Officer of Emisphere Technologies, Inc., a publicly held biopharmaceutical company that is working to develop and commercialize a proprietary oral drug delivery system. Prior to joining Emisphere Technologies, Mr. Steinhart spent seven years at CW Group, Inc., a venture capital firm focused on medical and healthcare investments, where he was a General Partner and Chief Financial Officer. Mr. Steinhart has previously served as a director of a number of privately-held companies, including ARRIS Pharmaceuticals, Inc., a biotechnology company involved with rational drug design; Membrex, Inc., a laboratory equipment manufacturing company; and Photest, Inc., a diagnostics company. He began his career working as a certified public accountant and continues to be a New York State Certified Public Accountant. Mr. Steinhart holds a Bachelors of Business Administration and Masters of Business Administration from Pace University. Mr. Steinhart's qualifications to serve as a director include his service as Chief Financial Officer of Electro-Optical Sciences, as a director include his service principal of Forest Street Capital, as Chief Financial Officer of Emisphere Technologies, Inc., and his Certified Public Accounting license. Serving as a chief financial officer of two life science publicly traded companies, Electro-Optical and Emisphere, and serving as executive of a financial firm that specialize in small cap companies has provided Mr. Steinhart with relevant perspective on the dynamics and challenges of small, life science, publicly traded companies. His service as a chief financial officer of two public companies and his Certified Public Accounting license provided Mr. Steinhart with the relevant perspective on the dynamics and challenges of the audit committee of small, publicly traded companies.

There are no family relationships among any of our executive officers, directors and key employees.

#### Independence of the Board of Directors

Our common stock has not been listed on a national securities exchange since we voluntarily de-listed our shares from the American Stock Exchange, or AMEX, effective March 26, 2008 and therefore, we are not subject to any corporate governance requirements regarding independence of board or committee members. However, we have chosen the definition of independence contained in the AMEX rules as a benchmark to evaluate the independence of its directors. Under the AMEX listing standards, an "independent director" of a company means a person who is not an officer or employee of the company or its subsidiaries and who the board of directors has affirmatively determined does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. After review of all relevant transactions or relationships between each director, or any of his family members, and our company, our senior management and our independent registered public accounting firm, the Board has determined that all of our directors are independent directors within the meaning of the applicable AMEX listing standard, except for Mr. Abel, our former President and Chief Executive Officer, Mr. McGuinness, our Chief Operating and Financial Officer and Dr. Morville, President and CEO of our wholly owned subsidiary Ariston.

#### Board Committees

The Board of Directors has three standing committees: an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The following table provides membership for each of the Board committees:

|                   |  |
|-------------------|--|
| Name of Committee | Membership                                       |
| Audit             | Messrs. Herskowitz, Shimko and Steinhart (Chair) |
| Compensation      | Messrs. Shimko, Steinhart and McInerney (Chair)  |

Nominating and Governance

Messrs. Herskowitz, McInerney and Abel (Chair)

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#### Audit Committee

The Audit Committee oversees our accounting and financial reporting process. For these purposes, the Audit Committee performs several functions. For example, the Committee evaluates and assesses the qualifications of the independent registered public accounting firm; determines the engagement of the independent registered public accounting firm; determines whether to retain or terminate the existing independent registered public accounting firm; reviews and approves the retention of the independent registered public accounting firm to perform any non-audit services; reviews the financial statements to be included in our Annual Report on Form 10-K; and discusses with management and the independent registered public accounting firm the results of the annual audit and the results of our quarterly financial statements. The Board of Directors adopted a written Audit Committee Charter, a copy of which can be found on our company website at [www.manhattanpharma.com](http://www.manhattanpharma.com).

Our Board of Directors has reviewed the definition of independence for Audit Committee members and has determined that each member of our Audit Committee is independent (as independence for audit committee members is currently defined under applicable SEC rules and the relevant AMEX listing standards). The Board has further determined that Mr. Steinhart qualifies as an “audit committee financial expert,” as defined by applicable rules of the SEC.

#### Compensation Committee

The Compensation Committee of the Board of Directors oversees our compensation policies, plans and programs. The Compensation Committee reviews and approves corporate performance goals and objectives relevant to the compensation of our executive officers and other senior management; reviews and recommends to the Board the compensation and other terms of employment of our Chief Executive Officer and our other executive officers; administers our equity incentive and stock option plans; and makes recommendations to the Board concerning the issuance of awards pursuant to those plans. All current members of the Compensation Committee are independent (as independence is currently defined under applicable AMEX listing standards). The Board of Directors has adopted a written charter of the Compensation Committee, a copy of which can be found on our company website at [www.manhattanpharma.com](http://www.manhattanpharma.com).

#### Nominating and Governance Committee

The Nominating and Governance Committee considers and recommends to the Board persons to be nominated for election by the stockholders as directors. In addition to nominees recommended by directors, the Nominating and Governance Committee will consider nominees recommended by stockholders if submitted in writing to our Secretary at the address of Company’s principal offices. The Board believes that any candidate for director, whether recommended by stockholders or by the Board, should be considered on the basis of all factors relevant to the needs of our company and the credentials of the candidate at the time the candidate is proposed. Such factors include relevant business and industry experience and demonstrated character and judgment. All current members of the Nominating and Governance Committee, except for Mr. Abel who serves as Chair of the Nominating and Corporate Governance Committee are independent (as independence is currently defined under applicable AMEX listing standards). The Board of Directors adopted a written charter of the Nominating and Governance Committee, a copy of which can be found on our company website at [www.manhattanpharma.com](http://www.manhattanpharma.com).

#### Communication with the Board of Directors

Although we have not adopted a formal process for stockholder communications with our Board of Directors, we believe stockholders should have the ability to communicate directly with the Board so that their views can be heard by the Board or individual directors, as applicable, and that appropriate and timely responses are provided to

stockholders. All communications regarding general matters should be directed to our Secretary at the address below and should prominently indicate on the outside of the envelope that it is intended for the complete Board of Directors or for any particular director(s). If no designation is made, the communication will be forwarded to the entire board. Stockholder communications to the Board should be sent to: Corporate Secretary, Attention: Board of Directors (or name(s) of particular directors), Manhattan Pharmaceuticals, Inc., 48 Wall Street, New York, NY 10005.

## Code of Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees of our company. A copy of our Code of Business Conduct and Ethics is available on our company's website at [www.manhattanpharma.com](http://www.manhattanpharma.com). If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the code to an executive officer or director, we will promptly disclose the nature of the amendment or waiver by filing with the SEC a current report on Form 8-K.

## Executive Officers

Set forth below are the names, ages and titles of all of our executive officers as of March 23, 2010. All directors hold office until the next annual meeting of stockholders or until their respective successors are elected and qualified.

| Name                  | Age | Position  |
|-----------------------|-----|---|
| Michael G. McGuinness | 56  | Chief Operating and Financial Officer & Secretary |

The biographies of our executive officers are set forth below.

Michael G. McGuinness has been our Chief Financial Officer and Secretary since July 2006. His complete biography is set forth above under the caption "Management - Directors."

None of our executive officers is related to any other executive officer or to any of our directors.

## Summary Compensation of Executive Officers

The following table sets forth all of the compensation awarded to, earned by or paid to (i) each individual serving as our principal executive officer during our last completed fiscal year and (ii) the two most highly compensated executive officers, other than the principal executive officer, that served as an executive officer at the conclusion of the fiscal year ended December 31, 2009 and who received total compensation in excess of \$100,000 during such fiscal year (collectively, the "named executives").