

MANHATTAN PHARMACEUTICALS INC  
Form 10-K  
March 31, 2011

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

x Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2010.

.. Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from \_\_\_ to \_\_\_

Commission File Number 1-32639

MANHATTAN PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

36-3898269  
(I.R.S. Employer Identification No.)

48 Wall Street, 11th Floor, New York, New York  
(Address of Principal Executive Offices)

10005  
(Zip Code)

(212) 582-3950  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, \$0.001 par value	OTC Bulletin Board

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. .. Yes x No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. .. Yes x No

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes .. No

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding twelve months (or for such shorter period of time that the registrant was required to submit and post such files) .. Yes .. No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form

10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).  Yes  No

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates of the registrant on June 30, 2010 based on the closing price of the common stock as reported on the OTC Bulletin Board on such date was \$5,035,015.

As of March 14, 2011 there were 129,793,289 outstanding shares of common stock, par value \$.001 per share.

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References to the “Company,” the “Registrant,” “we,” “us,” or “our” in this Annual Report on Form 10-K refer to Manhattan Pharmaceuticals, Inc., a Delaware corporation, and our consolidated subsidiaries, together taken as a whole, unless the context indicates otherwise.

### Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “expect,” “may,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. These statements are therefore subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Such risks and uncertainties relate to, among other factors:

- our ability to obtain adequate financing to continue our operations;
  - the development of our pharmaceutical product candidates;
  - the regulatory approval of our pharmaceutical product candidates;
    - our use of clinical research centers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
  - acceptance of our products by doctors, patients or payors;
    - our ability to market any of our products;
    - our history of operating losses;
- our ability to compete against other companies and research institutions;
  - our ability to secure adequate protection for our intellectual property;
    - our ability to attract and retain key personnel;
    - availability of reimbursement for our products;
  - the effect of potential strategic transactions on our business; and
    - the volatility of our stock price.

Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

## PART I

### ITEM 1. 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:

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

In the short term, we are focusing our efforts on the development of AST-726, AST-915, and, through the Hedrin JV, Hedrin. 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

##### QTDP Grant

On November 8, 2010, the Company was awarded a grant of \$244,479 under the U.S. Government's Qualifying Therapeutic Discovery Project ("QTDP") credit program. The Company was awarded this grant for its lead product candidate AST-726 for the treatment of vitamin B12 deficiency.

The QTDP was created by Congress in March 2010, as enacted under the Patient Protection and Affordable Care Act, and provides a tax credit or grant equal to 50% of eligible costs and expenses for the tax years 2009 and 2010. The QTDP was designed to promote medical research and innovation that could improve health and save lives. The program targeted projects in new innovative therapies to prevent, diagnose, and treat acute and chronic diseases. Companies that received QTDP grants were selected jointly by the Treasury Department and the Department of Health and Human Services. The grants were limited to companies with 250 or fewer employees.

##### Nordic Settlement

On January 4, 2011 the Company entered into settlement and release agreement (the "Settlement and Release Agreement") with Nordic Biotech Venture Fund II K/S ("Nordic") and H Pharmaceuticals K/S (the "Joint Venture"). The Company and Nordic are partners in the Joint Venture for the development and commercialization in North America of Hedrin™, a non-pesticide, one-hour, treatment for pediculosis (head lice). As previously reported, the Company and Nordic have had various disputes relating to the Joint Venture and to Nordic's option to purchase Company common stock in exchange for a portion of Nordic's interest in the Joint Venture (the "Put Right"), and Nordic's warrant to purchase Company common stock (the "Warrant"). The Settlement and Release Agreement resolves all disputes between the Company, on the one hand, and Nordic and the Joint Venture, on the other.

The principal terms of the Settlement and Release Agreement are:

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The Put Right has been terminated. The Company believed the Put Right permitted Nordic to become the owner, upon exercise of the Put Right, of 71,428,571 shares of the Company's common stock. Nordic asserted that the Put Right would have permitted Nordic to become the owner of 183,333,333 shares of the Company's common stock.

- The Warrant has been terminated. The Company believed the Warrant covered 14,285,714 shares of the Company's common stock. Nordic asserted that the Warrant covered 33,333,333 shares of the Company's common stock.
- Nordic was required to make an additional, non-dilutive capital contribution to the Joint Venture of \$1,500,000, which includes \$300,000 contributed to the Joint Venture by Nordic on December 15, 2010.
- The Joint Venture paid the Company a settlement amount of \$500,000, less any "Excess Payment" (defined below), in two installments. An "Excess Payment" is the amount by which Nordic's and the Joint Venture's reasonable out-of-pocket legal and other costs incurred with respect to the Settlement and Release Agreement exceed \$70,000. To date there have been no Excess Payments.
- Our equity interest in the Joint Venture was reduced to 15%, and further reductions in our equity interest are possible if and when Nordic makes additional contributions to the Joint Venture. In no event shall capital contributions by Nordic reduce our ownership in the Joint Venture below 5%.
- The Joint Venture paid \$75,000 to the Company under the Services Agreement, dated February 21, 2008, and that Services Agreement is terminated.
- The Joint Venture Agreement, dated January 31, 2008, as amended on February 18, 2008, and as further amended by an Omnibus Amendment on June 9, 2008, between Manhattan and Nordic; the Shareholders' Agreement, dated February 21, 2008, as amended by an Omnibus Amendment on June 9, 2008, with respect to the Joint Venture, and the Registration Rights Agreement, dated February 25, 2009, are terminated.
- Messrs. Michael G. McGuinness and Douglas Abel resigned from the Board of Directors of the Joint Venture.

Ariston Milestone Shares On January 31, 2011 the Company announced that its Board of Directors has decided to continue development of AST-915, an orally delivered treatment for essential tremor. Under the terms of the merger agreement between the Company and Ariston Pharmaceuticals, Inc., the achievement of this milestone requires the company to issue 8,828,029 shares of its common stock to debt holders and former shareholders of Ariston. These shares were issued in March 2011.

#### Extension of Maturity Date of Secured 12% Notes

On February 9, 2011, the Company entered into a waiver and forbearance agreement (the "Extension Agreement") with the requisite holders of the 12% senior secured notes whereby the holders of the Notes (the "Noteholders") agreed to forbear the exercise of their rights under the Notes and waive the default thereof until December 31, 2011. The Company issued a total of \$1,725,000 principal amount of the Notes in 2008 and 2009. \$1,035,000 of the Notes matured on November 19, 2010, \$280,000 of the Notes matured on December 22, 2010 and \$410,000 of the Notes matured on February 3, 2011.

As part of the Extension Agreement, the Company has agreed to take prompt steps to seek to reduce its outstanding indebtedness by permitting the Noteholders to convert the Notes into shares of the Company's common stock at a conversion price of \$0.01 per share, which will require the Company to obtain stockholder approval to, among other things, increase the number of its authorized common stock.

#### Amendment of ICON Note Payable

On March 1, 2011 Ariston entered into an amended and restated convertible promissory note (the "Amended Note") with ICON Clinical Research Limited. The principal terms of the Amended Note are that monthly payments of principal and interest will be waived for the thirteen month period ended December 31, 2011 (the "Waiver Period") in exchange for a single payment of \$100,000 on March 31, 2011, an increase in the interest on the Amended Note from 5% to 8% per annum during the Waiver Period and a balloon payment on January 31, 2012. The Amended Note will decrease the debt service requirements of the Company and Ariston by approximately \$300,000 during the thirteen month period ended December 31, 2011.

#### 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

##### AST-726

AST-726 is a nasally delivered form of hydroxocobalamin for the treatment of Vitamin B12 deficiency. Manhattan Pharmaceuticals acquired global rights to AST-726 as part of the Ariston acquisition. AST-726 has demonstrated pharmacokinetic equivalence to a marketed intramuscular injection product for Vitamin B12 remediation. Manhattan Pharmaceuticals 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, Manhattan Pharmaceuticals believes that AST-726 could offer a convenient, painless, safe and cost-effective treatment for Vitamin B12 deficiency, eliminating 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.

In February 2011, Manhattan Pharmaceuticals filed a Special Protocol Assessment ("SPA") with the FDA for a pivotal Phase III Vitamin B12 replacement study in the United States. The SPA is a regulatory process that allows for official FDA evaluation of the clinical protocols of a Phase III clinical trial intended to form the primary basis for an efficacy claim and provides trial sponsors with written agreement that the design and analysis of the trial are adequate to support a New Drug Application ("NDA") if the trial is performed according to the SPA. Final marketing approval depends on efficacy results, the safety profile and evaluation of the therapeutic benefit/risk demonstrated in the Phase III trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or

if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on Special Protocol Assessments please visit the FDA website at [www.fda.gov](http://www.fda.gov).

The final study design is subject to FDA feedback and approval, but Manhattan Pharmaceuticals expects the pivotal study 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 objective of this study is to demonstrate 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) NDA filing for AST-726.

A CMC/manufacturing process has been developed for AST-726 that we believe provides a commercially viable stability profile. Manhattan Pharmaceuticals has issued patents in the United States and Europe with respect to AST-726.

#### Market and Competition

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.

Prevalence estimates for Vitamin B12 deficiency in the U.S. range between 20-40% of people over 65 years of age (8-16 million people). A study of over 11,000 U.S. civilians ages four and older found a 3% prevalence of Vitamin B 12 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 B 12 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 B 12 deficiency increases substantially.

Manhattan Pharmaceuticals believes that substantial market opportunity also exists internationally.

#### Current Treatments for Vitamin B12 Deficiency

Once Vitamin B 12 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.

Intramuscular injection of Vitamin B12 is currently considered the gold standard treatment for Vitamin B12 deficiency. Cyanocobalamin injection is predominantly used for this purpose in the United States because it is the most easily produced for the lowest cost, however cyanocobalamin is poorly tolerated in certain patients such as in children or in heavy smokers who may have elevated cyanide levels in the blood. In these patients hydroxocobalamin, the active ingredient in AST-726, is used. Both cyanocobalamin and hydroxocobalamin must be converted in the body to an active form of Vitamin B12. Hydroxocobalamin is thought to be converted more easily than cyanocobalamin and it has longer retention time in the body. Hydroxocobalamin injection is the preferred treatment for Vitamin B12 deficiency in Europe comprising the vast majority of all Vitamin B12 injections.

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 typically administered daily for 5-10 days 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. There are two intranasal products currently available in the United States, Nascobal ® which is administered once weekly, and Calomist ®, which is administered once daily. Both can only be used once a deficient patient has been normalized with injections. Both products use cyanocobalamin as the active ingredient.

Oral administration of very high doses of Vitamin B12 can restore deficient patients to normal in certain cases, but conventional oral supplementation is plagued by limited bioavailability. 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, if the gastrointestinal tract is compromised, as is the case in many B12 deficient patients, oral supplementation may not be successful at restoring circulating levels and storage depots of the vitamin to normal. For example, older people create less stomach acid which results in a reduced ability to absorb Vitamin B12 from food. These patients would also be unable to absorb the vitamin from oral supplements. In such cases, intramuscular injection would be the treatment of choice, since it is administered directly into the bloodstream and does not rely on absorption in the gastrointestinal tract.

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 for Vitamin B12 Deficiency

We believe that treatment with AST-726 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 has been designed 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 monthly 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. Manhattan Pharmaceuticals 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 our AST-726 nasal spray product candidate on a daily basis for approximately 5-10 days to restore their Vitamin B12 status to normal and will then be self-maintained on a single monthly nasal spray treatment of AST-726.

#### More About Vitamin B12

Vitamin B12 is involved in the metabolism of every cell of the body, especially in energy production, fatty acid synthesis, and synthesis and regulation of DNA. It also plays a crucial role in many major body systems. In the brain and nervous system Vitamin B12 plays an important role in cognitive function and memory, the function and maintenance of nerve cells and surrounding myelin sheath, and the synthesis of serotonin, dopamine, and norepinephrine. Vitamin B12 is also known to reduce homocysteine, an amino acid produced by the body. Elevated homocysteine levels have been linked to brain and nerve cell damage, cardiovascular disease, and bone weakness and fractures. Vitamin B12 also plays a key role in the immune system, creation of melatonin for sleep, and the synthesis of red blood cells.

Two recent published studies have highlighted the beneficial effects that homocysteine lowering B vitamins have on cognitive impairment and cognitive decline. The first of these two studies (Smith, AD, PLoS One 2010) published in September 2010 shows that high doses of B vitamins slow the rate of brain atrophy by approximately 30%. Brain atrophy (or brain shrinkage) is one of the main symptoms of mild cognitive impairment, a known precursor to dementia, and sometimes Alzheimer's Disease. The second study (Hooshmand, B, Neurology 2010), a population based, 7-year cohort study published in October 2010, shows that higher baseline serum homocysteine levels correlated positively with an increased risk of Alzheimer's Disease.

#### AST-915

AST-915 is an orally delivered treatment for essential tremor. Manhattan Pharmaceuticals acquired global rights to AST-915 as part of the Ariston acquisition. This product candidate was studied under a Cooperative Research and Development Agreement (CRADA) with the National Institute of Neurological Disorders and Stroke (NINDS), a division of the National Institutes of Health (NIH).

In December 2010, Manhattan Pharmaceuticals announced the achievement of human proof-of concept with AST-915 with the release of preliminary results from a Phase 1/2 study conducted by the NIH of AST-915 for the treatment of essential tremor. Data from this single dose study showed that AST-915 was well tolerated and demonstrated a clear effect on tremor power.

In this randomized, double-blind, placebo-controlled, crossover design study, 18 subjects with essential tremor received single oral doses of AST-915. Primary and secondary outcome measures included the effect on tremor power using accelerometry to test the central tremor component at various time points after treatment. Safety, pharmacokinetic data, and other efficacy measures were also evaluated. AST-915 was well tolerated with non-serious adverse events being evenly distributed between active and placebo treatments, and two observed serious events being unrelated to study drug.

Statistically significant reductions in tremor power were evident at several time points between 80 and 300 minutes. 300 minutes was the latest timepoint measured following administration of AST-915. Further analysis, conducted using each subject as its own control, demonstrated statistically significant lower tremor amplitudes in favor of AST-915 compared to placebo. Additional analysis continues to examine other secondary endpoints. Statistically significant effect on tremor power was not evident 80 minutes after administration of AST-915 (defined as the primary endpoint timeframe),

The NINDS/NIH intends to submit an abstract to the 15th International Congress of Parkinson's Disease and Movement Disorders taking place in Toronto in June 2011. Complete study findings are expected to be disclosed at this and other scientific meetings, and by submission to scientific journals. Manhattan Pharmaceuticals intends to continue to work with the NINDS/NIH and to proceed toward Phase 2 with the AST-915 development program.

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

According to the International Essential Tremor Foundation, an estimated 10 million Americans have essential tremor. The condition is most common among people over 60, but it also occurs in children, adolescents and the middle-aged. There is no curative treatment for essential tremor and current therapy is inadequately effective in a large portion of patients and/or limited by side effects. Manhattan Pharmaceuticals believes AST-915 may provide a new treatment option for this serious and prevalent disorder. Manhattan Pharmaceuticals believes that substantial market opportunity also exists internationally.

#### 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. According to Thornton & Ross Ltd. ("T&R"), it is currently marketed in over 27 countries and 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, Manhattan Pharmaceuticals entered into an exclusive license agreement with Thornton & Ross Ltd ("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 the Company's exclusive supplier of Hedrin product (the "Hedrin Supply Agreement").

In February 2008, Manhattan Pharmaceuticals 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 United States and Canada. H Pharmaceuticals is independently funded and is responsible for all costs associated with the Hedrin project, including any necessary United States ("U.S.") clinical trials, patent costs, and future milestones owed to the original licensor, T&R. We currently own 15% of the

Hedrin JV.

The Hedrin JV is currently working to complete development and secure commercialization and marketing partners for Hedrin in the U.S. and Canada.

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#### 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. Manhattan Pharmaceuticals believes 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

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., the Hedrin JV, is 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, CDRH 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 questions about certain manufacturing and 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 trials, and the Hedrin JV’s application to conduct those clinical 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 have not been widely reported to date, but experts believe it is likely 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.”

#### 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. The Company owns 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 <sup>TM</sup>

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 the Company discontinued development and returned the project to T&R under the terms of the license agreement.

##### Altolyn <sup>TM</sup>

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.

Due to small market opportunity and lack of sufficient funds to develop Altolyn, in March 2009 the Company 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.

#### AST-726

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

- 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 September 1, 2015.

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, the Company has 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.

#### Hedrin

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

- U.S. Patent No. 7,829,551 entitled, “Method and composition for the control of arthropods.” Jayne Ansell, Inventor. Application filed February 12, 2007. Patent issued November 9, 2010. This patent is scheduled to expire on March 9, 2023. This patent 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 the Company assigned and transferred its rights in Hedrin to the Hedrin JV. The Hedrin JV is now responsible for all of the Company’s obligations under the Hedrin License Agreement and the Hedrin Supply Agreement.

#### 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. (“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, Manhattan Pharmaceuticals, Inc. entered into an Agreement and Plan of Merger by and among the Company, Ariston Pharmaceuticals, Inc., a Delaware corporation and Ariston Merger Corp., a Delaware corporation and wholly-owned subsidiary of the Company. 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.

Under the terms of the Merger Agreement, the consideration payable by the Company to the stockholders and note holders of Ariston consists of the issuance of 7,062,423 shares of the Company's common stock, par value \$0.001 per share, (“Common Stock”) at Closing (as defined in the Merger Agreement) plus the right to receive up to an additional 24,718,481 shares of Common Stock (the “Milestone Shares”) upon the achievement of certain product-related milestones described below. In addition, the Company has reserved 38,630,723 shares of its 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 the Company 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 the Company's Common Stock at the rate of \$0.40 per share. Further, the Company has reserved 5,000,000 shares of its 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 the Company 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 the Company's Common Stock at the rate of \$0.20 per share.

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

- Upon the affirmative decision of the Company’ Board of Directors, provided that such decision is made prior to March 8, 2011, to further develop the AST-915 product candidate, either internally or through a corporate partnership, the Company would issue 8,828,029 of the Milestone Shares. This milestone was reached in January 2011 and the shares have been issued.
- Upon the acceptance by the FDA of the Company's filing of the first New Drug Application for the AST-726 product candidate, the Company would issue 7,062,423 of the Milestone Shares.
- Upon the Company receiving FDA approval to market the AST-726 product candidate in the United States of America, the Company would issue 8,828,029 of the Milestone Shares.

## Employees

We currently have two full time and one part time employees, including: our Chief Operating and Financial Officer 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.



#### Additional Public Information

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and in accordance with such laws we file annual, quarterly and current reports and other information with the Securities and Exchange Commission (the “SEC”). The SEC maintains a website that contains annual, quarterly and current reports, proxy and information statements and other information filed with the SEC. The SEC’s website address is [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at the SEC’s public reference room, 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of its public reference room. The information we file with the SEC and other information about us is also available on our website at [www.manhattanpharma.com](http://www.manhattanpharma.com). However, the information on our website is not a part of, nor is such information to be deemed incorporated by reference into, this report.

## ITEM 1A. 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 Annual Report before making an investment in our securities.

### Risks Related to Our Business

We currently have no product revenues, we are unlikely to have product revenues in the foreseeable future, and will need to raise substantial additional funds to continue operations. 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 FDA and other regulatory authorities for any of our 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, 2010, we had \$478,668 of cash and cash equivalents. During the first quarter of 2011 we received \$500,000 from the Nordic Settlement. We expect funding of approximately \$244,000 from the US Government's Qualifying Therapeutic Discovery Project ("QTDP") in the second quarter of 2011. We expect these shall be sufficient to fund our operations through the end of 2011. 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, lack of product revenues, and the conversion and anti-dilution features of our outstanding securities 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, 2010, 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.

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 operating losses in every period since our inception on August 6, 2001, except for the year ended December 31, 2010. For the year ended December 31, 2010 we realized net income of \$623,645 and for the period from August 6, 2001 (inception) through December 31, 2010, we incurred net losses applicable to common shares of \$61,309,790. 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.

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 with only two full-time employees and one part-time employee 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 that was paid (and that may be paid in the future) to the former stockholders and noteholders of Ariston in connection with the Ariston Merger. We can provide no assurance that the fair value of the consideration paid (and that may be paid in the future) to the former stockholders and noteholders of Ariston in the Ariston Merger will not exceed the fair value of the assets acquired.

In connection with the Ariston 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 Ariston Merger that became liabilities of the Company's upon consummation of the Ariston Merger.

There may be liabilities of Ariston and/or its affiliates that were unknown at the time of the consummation of the Ariston Merger. As a result of the Ariston Merger, any such unknown liabilities may become liabilities of the combined company. In the event any such liabilities become known following the Ariston Merger, they may lead to claims against a subsidiary of the combined company, including but not limited to lawsuits, administrative proceedings, and other claims. Any such liabilities may subject the combined company 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 Ariston Merger, any such liability-related expenses may materially impact the combined company's financial condition and results of operations.

We depend greatly on the intellectual capabilities and experience of our key executive, and the loss of him could affect our ability to develop our remaining products.

We had only two full-time and one part-time employees as of March 15, 2011. The loss of Michael G. McGuinness, our Chief Operating and Financial Officer, could harm us. Mr. McGuinness' employment agreement with the Company expired in July 2009. Mr. McGuinness has been working for the Company on the same terms and conditions that were set forth in the employment agreement that expired. We cannot predict our success in hiring or retaining the personnel we require for continued operations or whether we will have the financial ability to do so.

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 these product candidates will be completed.

When the clinical testing for our product candidates is complete, we will submit to the FDA an NDA or PMA 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 drug candidates, 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 considered 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:

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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.

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

Achieving the benefits of the Ariston Merger will depend in part on the successful integration of Ariston's drug development programs 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 Ariston 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 generally carry clinical trial insurance in an amount up to \$5,000,000 when we are conducting clinical trials, 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.

Our directors, executive officers and principal stockholders beneficially own approximately 19% percent of our outstanding voting stock and, including shares underlying outstanding options and warrants. Upon the anticipated conversion of the Secured 12% Notes and the resultant anti-dilution adjustments to our outstanding warrants, that percentage will drop to 8%. Prior to the anticipated conversion of the Secured 12% Notes and even without the exercise of its rights to acquire additional shares of our common stock, our directors, officers and principal stockholders, 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.

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 \$0.016 in the fourth quarter of 2010 to a high of \$0.085 in the second quarter of 2009. 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 the 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 the Common Stock, the ability of holders of our Common Stock to sell the Common Stock, or the prices at which holders may be able to sell the 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 currently have no product revenues, we are unlikely to have product revenues in the foreseeable future, and will need to raise substantial additional funds to continue operations. 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" 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 the Company is late in its filings three times in any twenty-four (24) month period and is de-listed from the OTCBB, the 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 the Common Stock or to obtain accurate, current information concerning market prices for the Common Stock.



There is a risk of market fraud.

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 or Nasdaq traded securities, 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.

As a result of anticipated conversions of our outstanding Secured 12% Notes and the effect of anti-dilution provisions in, and which we expect will be added to, our outstanding warrants, the holders of our common stock will experience substantial dilution.

In connection with the extension of the maturity of the Secured 12% Notes, we have agreed to take prompt steps to seek to reduce our outstanding indebtedness to the Noteholders by permitting the Noteholders to convert the Secured 12% Notes into shares of our common stock at a conversion price of \$0.01 per share. In addition, we agreed to change the terms of the warrants issued with the Secured 12% Notes by adding full ratchet anti-dilution rights. If the Secured 12% Notes convert into common stock at a conversion price of \$0.01 the anti-dilution rights of the warrants issued with Secured 12% Notes, the warrants issued with the Convertible 12% Note and the warrants issued in the 2010 Equity Pipe transaction will be triggered causing significant potential dilution to our current stockholders.



We anticipate implementing a reverse split of our outstanding shares of common stock, which may not result in a higher stock price per share.

We have asked our stockholders to authorize our board to implement a reverse split of our outstanding shares of common stock, the exact split ratio within a range of 25:1 to 50:1 to be determined by our Board of Directors, in its sole discretion. If we receive that approval, and if our board determines to implement that reverse stock split, there can be no assurances that the price per share of our common stock will increase proportionately with the reverse stock split, or at all.

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 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 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 or if the Secured 12% Notes convert, as anticipated, into common stock at \$0.01 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.

ITEM 2. 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, 2011 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.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. REMOVED AND RESERVED

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

## Market for Common Stock

Our common stock is traded on the Over the Counter Bulletin Board ("OCTBB") 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 Over the Counter Bulletin Board for the periods indicated:

Quarter Ended	Price Range			
	2010		2009	
	High	Low	High	Low
March 31	\$ 0.084	\$ 0.060	\$ 0.060	\$ 0.009
June 30	0.085	0.045	0.120	0.021
September 30	0.050	0.020	0.100	0.070
December 31	0.040	0.016	0.090	0.060

## Stock Chart

Comparison to NASDAQ Biotechnology Index

## Record Holders

The number of holders of record of our common stock as of March 23, 2011 was 589.

## Dividends

We have not paid or declared any dividends on our common stock and we do not anticipate paying dividends on our common stock in 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.

## Stock Repurchases

We did not make any repurchases of our common stock during 2010.

## Securities authorized for issuance under equity compensation plans

### Equity Compensation Plan Information

Plan Category	Number of securities	Weighted average	Number of securities
	to be issued upon exercise of outstanding options, warrants and rights	exercise price of outstanding options, warrants and rights	remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	11,574,936	\$ 0.487	4,524,528
Equity compensation plans not approved by security holders	-		-
<b>Total</b>	<b>11,574,936</b>	<b>\$ 0.487</b>	<b>4,524,528</b>

## Recent Sales of Unregistered Securities

On September 11, 2008, the Registrant entered into a series of 10% secured promissory notes with certain of its directors and officers and an employee of the Registrant (the "Note Holders") for aggregate of \$70,000. Principal and interest on the notes was paid in cash in 2009. In connection with the issuance of the notes, the Registrant also issued to the Note Holders 5-year warrants to purchase an aggregate of 140,000 shares of the Registrant's common stock at an exercise price of \$0.20 per share. The issuance of such securities was considered to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act, or Regulation D promulgated thereunder, as a transaction by an issuer not involving a public offering. The recipient of such securities represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the warrant certificates issued in this transaction. All recipients either received adequate information about us or had access to such information.

On February 3, 2009, the Registrant completed a private placement (the "2009 Private Placement") of 345 units, with each unit consisting of a 12% senior secured promissory note in the principal amount of \$5,000 and a warrant to purchase up to 166,667 shares of 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.

All of the investors represented in the 2009 Private Placement 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.

On March 2, 2010, the Company raised aggregate gross proceeds of approximately \$2,547,500 pursuant to a private placement of its securities (the "2010 Equity Financing"). The Company entered into subscription agreements (the "Subscription Agreements") with seventy-seven accredited investors (the "Investors") pursuant to which the Company sold an aggregate of 101.9 Units (as defined herein) for a purchase price of \$25,000 per Unit. Pursuant to the Subscription Agreements, the Company issued to each Investor units (the "Units") consisting of (i) 357,143 shares of common stock, \$0.001 par value per share (the "Common Stock" or "Shares") of the Company and (ii) 535,714 warrants (each a "Warrant" and collectively the "Warrants"), each of which will entitle the holder to purchase one additional share of Common Stock for a period of five years (each a "Warrant Share" and collectively the "Warrant Shares") at an exercise price of \$0.08 per share.

On April 8, 2010, the Company completed the final closing of the 2010 Equity Financing. In connection with the final closing, the Company sold an aggregate of 2.4 additional Units and received net proceeds of approximately \$51,700 after payment of an aggregate of \$8,300 of commissions and expense allowance to placement agent. In connection with the final closing, the Company also issued a warrant to purchase 12,857 shares of Common Stock at an exercise price of \$0.08 per share to the placement agent as additional compensation for its services.

Also in connection with the final closing on April 8, 2010, the holder of the Convertible 12% Note, exercised its option to convert its Convertible 12% Note (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 2010 Equity Financing.

All of the Investors 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.

The Company received net proceeds of approximately \$2.2 million after payment of an aggregate of \$300,000 of commissions and expense allowance to the Placement Agent, and approximately \$100,000 of other offering and related costs in connection with the private placement. In addition, the Company issued a warrant to purchase 3,652,146 shares of Common Stock at an exercise price of \$0.08 per share to the Placement Agent as additional compensation for its services.

The Company did not use any form of advertising or general solicitation in connection with the sale of the Units. The Shares, the Warrants and the Warrant Shares are non-transferable in the absence of an effective registration statement under the Act, or an available exemption therefrom, and all certificates are imprinted with a restrictive legend to that effect.



ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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. The operating results of Ariston from March 8, 2010 to December 31, 2010 are included in the accompanying Consolidated Statements of Operations. The Consolidated Balance Sheet as of December 31, 2010 reflects the acquisition of Ariston, effective March 8, 2010, the date of the Merger.

We are a specialty healthcare product company focused on developing and commercializing pharmaceutical treatments for underserved patients 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 Form 10-K. 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. Investors 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" following Item 1 in this Annual Report, and should not unduly rely on these forward looking statements.

## Results Of Operations

## 2010 versus 2009

During each of the years ended December 31, 2010 and 2009, 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, 2011.

	Years ended December 31,		Increase	% Increase
	2010	2009	(decrease)	(decrease)
<b>Costs and expenses:</b>				
<b>Research and development:</b>				
Share-based compensation	\$-	\$ 2,000	\$(2,000 )	-100.00 %
Other research and development expenses	496,000	38,000	458,000	1205.26 %
Total research and development expenses	496,000	40,000	456,000	1140.00 %
<b>General and administrative:</b>				
Share-based compensation	217,000	351,000	(134,000 )	-38.18 %
Other general and administrative expenses	1,304,000	1,380,000	(76,000 )	-5.51 %
Total general and administrative expenses	1,521,000	1,731,000	(210,000 )	-12.13 %
<b>Other income/(expense):</b>				
Equity in loss of Hedrin JV	-	(500,000 )	500,000	-100.00 %
Change in fair value of derivative	3,523,000	(560,000 )	4,083,000	N/A
Swiss Pharma settlement	-	251,000	(251,000 )	N/A
Interest and amortization on notes payable	(1,271,000)	(548,000 )	(723,000 )	131.93 %
Loss on early extinguishment of debt	(159,000 )	-	(159,000 )	N/A
Interest and other income	548,000	335,000	213,000	63.58 %
Total other income/(expense)	2,641,000	(1,022,000)	3,663,000	-358.41 %
<b>Net income/(loss)</b>	<b>\$ 624,000</b>	<b>\$(2,793,000)</b>	<b>\$3,417,000</b>	<b>-122.34 %</b>

For the year ended December 31, 2010 research and development expense was \$496,000 as compared to \$40,000 for the year ended December 31, 2009. This increase of \$456,000, or 1,140%, is primarily due to the development activities of AST-726, a product added to our pipeline from the Ariston Merger. There were minimal research and development activities during 2009.

For the year ended December 31, 2010 general and administrative expense was \$1,521,000 as compared to \$1,731,000 for the year ended December 31, 2009. This decrease of \$210,000, or 12%, is primarily comprised of a decrease of \$134,000 in share-based compensation and \$44,000 in rent expense.

For the year ended December 31, 2010 other income/(expense), net, was \$2,641,000 as compared to \$(1,022,000) for the year ended December 31, 2009. This change of \$3,663,000 is due to the recognition of \$4,083,000 of change in the fair value of a derivative liability, an increase in interest expense of \$723,000, an increase in other income of \$213,000, the recognition of a loss of \$159,000 on the early extinguishment of debt, and the recognition during 2009 of \$500,000 of equity in loss of Hedrin JV and a 2009 charge of \$251,000 relating to the Swiss Pharma settlement with no corresponding amounts recognized during 2010.

Net income for the year ended December 31, 2010 was \$624,000 as compared to a loss of \$2,793,000 for the year ended December 31, 2009. This change of \$3,417,000 is primarily due to a change in other income of \$3,663,000 and a decrease in general and administrative expenses of \$210,000 offset by an increase in research and development expenses of \$456,000.



### Liquidity and Capital Resources

From inception to December 31, 2010, we incurred a deficit during the development stage of \$61,310,000 primarily as a result of our net losses, and we expect to continue to incur additional losses through at least December 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 year ended December 31, 2010, we had a net increase in cash and cash equivalents of \$461,000. This increase resulted from net cash provided by investing activities of \$517,000 and net cash provided by financing activities of \$1,914,000 offset by cash used in operating activities of \$1,970,000. Total liquid resources as of December 31, 2010 were \$479,000 compared to \$18,000 at December 31, 2009.

Our current liabilities as of December 31, 2010 were \$3,293,000 compared to \$2,532,000 at December 31, 2009, an increase of \$761,000. As of December 31, 2010, we had working capital deficit of \$2,424,000 compared to working capital deficit of \$2,268,000 at December 31, 2009. These matters raise substantial doubt about the Company's 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.

During 2010, we received approximately \$2,163,000 from the sale of common stock and warrants, \$519,000 from the Ariston Merger and repaid debt of \$249,000. In addition, we assumed \$16.5 million in debt from the Ariston Merger. 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 planned 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 December 31, 2010, a significant portion of our financing has been through private placements of debt, common stock and warrants and the Hedrin JV. 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 of the Company available at December 31, 2010, the net proceeds received in January and March 2011 from the Nordic Settlement totaling \$575,000, the \$244,000 grant under the U.S. Government's Qualifying Therapeutic Discovery Project credit program and the extension of the maturity date of the Secured 12% Notes to December 31, 2011, management believes that we have sufficient capital to fund our operations through 2011 on a limited basis, including the operations of Ariston Pharmaceuticals, Inc. which we acquired in March 2010. Management believes that we will need additional equity or debt financing or will need to generate positive cash flow from the Hedrin joint venture, or generate revenues through licensing of our products or entering into strategic alliances to be able to sustain our operations into 2012, and to conduct clinical trials for AST-726. Furthermore, we will need additional financing thereafter to complete development and commercialization of its products. There can be no assurances that we can successfully complete development and commercialization of

our products.

We have reported net income of \$624,000 for the year ended December 31, 2010 and a net loss of \$2,793,000 for the year ended December 31, 2009. The net loss attributable to common shares, including preferred stock dividends, from date of inception August 6, 2001, to December 31, 2010, amounts to \$61,310,000. Management believes that we will continue to incur net losses through at least December 31, 2011.

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#### 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, on June 9, 2008 and on January 4, 2011 (the "Nordic Settlement"). Pursuant to the joint venture agreement (i) Nordic contributed cash in the amount of \$7.5 million to H Pharmaceuticals K/S (formerly Hedrin Pharmaceuticals K/S), a newly formed Danish limited partnership, or the Hedrin JV, in exchange for 85% 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 \$3.7 million in cash and 15% of the equity interests in the Hedrin JV.

The Hedrin JV is responsible for the development and commercialization of Hedrin for the North American market and all associated costs including clinical trials, regulatory costs, patent costs, and future milestone payments owed to Thornton & Ross Ltd., or T&R, the licensor of Hedrin. The Hedrin JV engaged us to provide management services to the Hedrin JV through December 31, 2010 in exchange for a management fee, which for years ended December 31, 2010 and 2009 and for the period from February 18, 2008 through December 31, 2010 was approximately \$300,000, \$334,000 and \$1,081,000, 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 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 (\$7.5 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.

The Hedrin JV's Board of Directors consisted of four members, two appointed by us and two appointed by Nordic. Nordic appointed one of the directors as chairman of the Board. The chairman has certain tie breaking powers. In the Nordic Settlement we gave up our right to representation on the Hedrin JV's Board of Directors. Nordic had the right to nominate a person to serve on the Company's Board of Directors. No Nordic nominee was appointed to the Company's Board of Directors. In the Nordic Settlement Nordic gave up its right to representation on the Company's Board of Directors.

Pursuant to the joint venture agreement, Nordic had the right to put all or a portion of its interest in the Hedrin JV in exchange for shares of our common stock. This put right terminated upon the execution of the Nordic Settlement.

Pursuant to the joint venture agreement, we had the right to call all or a portion of Nordic's equity interest in the Hedrin JV in exchange for shares of our common stock. This call right terminated upon the execution of the Nordic Settlement.

In connection with the joint venture agreement Nordic paid us \$150,000 in exchange for a warrant to purchase shares of our common stock. This warrant terminated upon the execution of the Nordic Settlement.

We granted Nordic registration rights for the shares to be issued upon exercise of the warrant, the put or the call. We filed an initial registration statement on May 1, 2008. The registration statement was declared effective on October 15, 2008. On June 2, 2009, we filed an additional Registration Statement registering the additional shares of Common Stock that may be issued to Nordic upon exercise of a put right (the "Put Shares") held by Nordic. The Securities and Exchange Commission ("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. We believe that we have used commercially reasonable efforts to cause the registration statement to be declared effective and have satisfied our obligations under the registration rights agreement with respect to the registration of the Put Shares. We were required to file additional registration statements, if required, within 45 days of the date we first knew that such additional registration statement was required. Nordic's registration rights terminated upon the execution of the Nordic Settlement, as did Nordic's put rights and warrant.

#### Nordic Settlement

On January 4, 2011 the Company entered into settlement and release agreement (the "Settlement and Release Agreement") with Nordic Biotech Venture Fund II K/S ("Nordic") and H Pharmaceuticals K/S (the "Joint Venture"). The Company and Nordic are partners in the Joint Venture for the development and commercialization in North America of Hedrin™, a non-pesticide, one-hour, treatment for pediculosis (head lice). As previously reported, the Company and Nordic have had various disputes relating to the Joint Venture and to Nordic's option to purchase Company's common stock in exchange for a portion of Nordic's interest in the Joint Venture (the "Put Right"), and Nordic's warrant to purchase Company common stock (the "Warrant"). The Settlement and Release Agreement resolves all disputes between the Company, on the one hand, and Nordic and the Joint Venture, on the other.

The principal terms of the Settlement and Release Agreement are:

- The Put Right has been terminated. The Company believed the Put Right permitted Nordic to become the owner, upon exercise of the Put Right, of 71,428,571 shares of the Company's common stock. Nordic asserted that the Put Right would have permitted Nordic to become the owner of 183,333,333 shares of the Company's common stock.
- The Warrant has been terminated. The Company believed the Warrant covered 14,285,714 shares of the Company's common stock. Nordic asserted that the Warrant covered 33,333,333 shares of the Company's common stock.
- Nordic was required to make an additional, non-dilutive capital contribution to the Joint Venture of \$1,500,000, which includes \$300,000 contributed to the Joint Venture by Nordic on December 15, 2010.
- The Joint Venture paid the Company a settlement amount of \$500,000, less any "Excess Payment" (defined below), in two installments. An "Excess Payment" is the amount by which Nordic's and the Joint Venture's reasonable out-of-pocket legal and other costs incurred with respect to the Settlement and Release Agreement exceed \$70,000. To date there have been no Excess Payments.
- Our equity interest in the Joint Venture was reduced to 15%, and further reductions in our equity interest are possible if and when Nordic makes additional contributions to the Joint Venture. In no event shall capital contributions by Nordic reduce our ownership in the Joint Venture below 5%.
- The Joint Venture paid \$75,000 to the Company under the Services Agreement, dated February 21, 2008, and that Services Agreement is terminated as of December 31, 2010.
- The Joint Venture Agreement, dated January 31, 2008, as amended on February 18, 2008, and as further amended by an Omnibus Amendment on June 9, 2008, between Manhattan and Nordic; the Shareholders' Agreement, dated February 21, 2008, as amended by an Omnibus Amendment on June 9, 2008, with respect to the Joint Venture, and the Registration Rights Agreement, dated February 25, 2009, are terminated.
- Messrs. Michael G. McGuinness and Douglas Abel resigned from the Board of Directors of the Joint Venture.

#### 2010 Equity Financing

In March and April 2010, we raised aggregate gross proceeds of approximately \$2.6 million pursuant to a private placement of our securities (the "2010 Equity Financing"). We sold an aggregate of 104.3 Units for a purchase price of \$25,000 per Unit. We issued to each investor units (the "Units") consisting of 357,143 shares of common stock, \$0.001 par value per share of the Company and 535,714 warrants, each of which will entitle the holder to purchase one additional share of Common Stock for a period of five years at an exercise price of \$0.08 per share. In addition in April 2010, the holder of the Convertible 12% Note exercised its option to convert its 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.



#### Secured 10% Notes Payable

In 2008, we issued secured 10% promissory notes to certain of our directors and officers and an employee for aggregate principal amount of \$70,000. 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. The secured 10% notes were repaid in February 2009 along with interest thereon.

#### 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, among other things, the notes will be secured by a pledge of our assets other than our interest in the Hedrin joint venture, including, without limitation, our interest in H Pharmaceuticals K/S and H Pharmaceuticals General Partner ApS. 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.

The first tranche of the Secured 12% Notes matured on November 19, 2010. We could not repay the debt and defaulted on the Secured 12% Notes. National Securities Corporation (“National”), the placement agent for the Secured 12% Notes, had the right to either act as or appoint a security agent on behalf of the holders of the 12% Secured Notes (the “Noteholders”). In order to avoid foreclosure on the collateral we negotiated a waiver and forbearance agreement (the “Extension Agreement”) for the extension of the maturity of the Secured 12% Notes to December 31, 2011 with National. On February 9, 2011 we received the agreement of the requisite Noteholders to enter into the Extension Agreement and the maturity date of the entire issue of \$1,725,000 principal amount of the Secured 12% Notes was extended until December 31, 2011. As part of the Extension Agreement, we have agreed to take prompt steps to seek to reduce our outstanding indebtedness to the Noteholders by permitting the Noteholders to convert the 12% Secured Notes into shares of our common stock at a conversion price of \$0.01 per share, which will require us to obtain stockholder approval to, among other things, effect a reverse stock split of our common shares.

In addition, we agreed to change the terms of the warrants issued with the Secured 12% Notes by adding full ratchet, antidilution rights once we have obtained stockholder approval to increase the number of our authorized common shares. If the Secured 12% Notes convert into common stock at a conversion price of \$0.01 the antidilution rights of the warrants issued with Secured 12% Notes, the warrants issued with the Convertible 12% Note and the warrants issued in the 2010 Equity Pipe transaction will be triggered causing significant potential dilution to our current stockholders. The following table illustrates the potential dilution:

	As of March 15, 2011		Conversion of Secured 12% Notes		After Conversion	
	Shares	%	Shares (1)	Shares	%	
<b>Shares outstanding:</b>						
Before conversion	129,793,289	45.66	%		129,793,289	8.78 %
Conversion of Secured 12% Notes				231,826,600	231,826,600	15.67 %
Total outstanding	129,793,289			231,826,600	361,619,889	
<b>Shares issuable:</b>						
Options	11,574,936	4.07	%		11,574,936	0.78 %
<b>Warrants:</b>						
<b>With antidilution rights:</b>						
Issued with Secured 12% Notes	57,500,115	20.23	%	460,000,920	517,501,035	34.99 %
Other	72,411,248	25.47	%	503,037,467	575,448,715	38.90 %
Without antidilution rights	12,989,189	4.57	%		12,989,189	0.88 %
Total issuable	154,475,488			963,038,387	1,117,513,875	
Total outstanding and issuable	284,268,777	100.00	%	1,194,864,987	1,479,133,764	100.00 %

(1) Share conversion assumes conversion of principal and interest on May 31, 2011, the date on which we project the conversion will occur.

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). The registration statement was declared effective by the SEC on April 17, 2009.

#### SwissPharma Contract LLC Settlement

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.

In conjunction with the Settlement Agreement and Mutual Release with Swiss Pharma described above, on October 28, 2009, we entered into a Subscription Agreement (the “Subscription Agreement”) pursuant to which we sold a 12% Original Issue Discount Senior Subordinated Convertible Debenture with a stated value of \$400,000 (the “Convertible 12% Note”) and a warrant (the “Warrant”) and, together with the Convertible 12% Note, (the “Securities”) to purchase 2,222,222 shares of our common stock, par value \$.001 per share (“Common Stock”) for a purchase price of \$200,000. The Convertible 12% Note is convertible into shares of Common Stock. The Warrant is exercisable at an exercise price of \$0.11 per share, subject to adjustment, prior to October 28, 2014. In April 2010 the Convertible 12% Note was converted into the 2010 Equity Financing, as discussed above.

In connection with the issuance of the Securities, 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.

#### Acquisition of Ariston Pharmaceuticals, Inc.

On March 8, 2010, we 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 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 "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 the 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 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-915 product candidate, either internally or through a corporate partnership, we would issue 8,828,029 of the Milestone Shares. This milestone was reached in January 2011 and the shares have been issued.
- Upon the acceptance by the FDA of the Company's filing of the first New Drug Application for the AST-726 product candidate, we would issue 7,062,423 of the Milestone Shares.
- Upon the Company receiving FDA approval to market the AST-726 product candidate in the United States of America, we would issue 8,828,029 of the Milestone Shares.

Certain members of our Board of Directors and principal stockholders of the Company at the time of the Merger owned Ariston securities. Timothy McInerney, a director of Manhattan, 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, a director of Manhattan, indirectly owned convertible promissory notes of Ariston with interest and principal in the amount of \$192,739. Michael Weiser, a former director of Manhattan, 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 Manhattan 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.

The Company merged with Ariston principally to add new products to our portfolio, AST-726 and AST-915. 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.

8% Note

In December 2009, we entered into a Future Advance Promissory Note (the “8% Note”) with Ariston under which the Company may withdraw up to \$67,000. Principal and interest accrued at 8% shall be due and payable to Ariston on February 10, 2010. As of December 31, 2009, the Company has withdrawn \$27,000 from Ariston subject to the terms of the 8% Note. On January 13, 2010, the Company withdrew \$20,000 subject to the 8% Note with Ariston Pharmaceuticals, Inc. On January 28, 2010, the Company withdrew an additional \$20,000 subject to the 8% Note. On March 4, 2010, the Company repaid Ariston the \$67,000 withdrawn subject to the 8% Note and accrued interest of \$816.

## 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.

## Research and Development Projects

### AST-726

AST-726 is a nasally delivered form of hydroxocobalamin for the treatment of Vitamin B12 deficiency. Manhattan Pharmaceuticals acquired global rights to AST-726 as part of the Ariston acquisition. AST-726 has demonstrated pharmacokinetic equivalence to a marketed intramuscular injection product for Vitamin B12 remediation. Manhattan Pharmaceuticals 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, Manhattan Pharmaceuticals believes that AST-726 could offer a convenient, painless, safe and cost-effective treatment for Vitamin B12 deficiency, eliminating 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.

In February 2011, Manhattan Pharmaceuticals filed a Special Protocol Assessment (“SPA”) with the FDA for a pivotal Phase III Vitamin B12 replacement study in the United States. The SPA is a regulatory process that allows for official FDA evaluation of the clinical protocols of a Phase III clinical trial intended to form the primary basis for an efficacy claim and provides trial sponsors with written agreement that the design and analysis of the trial are adequate to support a New Drug Application (“NDA”) if the trial is performed according to the SPA. Final marketing approval depends on efficacy results, the safety profile and evaluation of the therapeutic benefit/risk demonstrated in the Phase III trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on Special Protocol Assessments please visit the FDA website at [www.fda.gov](http://www.fda.gov).

The final study design is subject to FDA feedback and approval, but Manhattan Pharmaceuticals expects the pivotal study 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 objective of this study is to demonstrate 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) NDA filing for AST-726.

A CMC/manufacturing process has been developed for AST-726 that we believe provides a commercially viable stability profile. Manhattan Pharmaceuticals has issued patents in the United States and Europe with respect to AST-726.

#### Market and Competition

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.

Prevalence estimates for Vitamin B12 deficiency in the U.S. range between 20-40% of people over 65 years of age (8-16 million people). A study of over 11,000 U.S. civilians ages four and older found a 3% prevalence of Vitamin B 12 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 B 12 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 B 12 deficiency increases substantially.

Manhattan Pharmaceuticals believes that substantial market opportunity also exists internationally.

#### Current Treatments for Vitamin B12 Deficiency

Once Vitamin B 12 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.

Intramuscular injection of Vitamin B12 is currently considered the gold standard treatment for Vitamin B12 deficiency. Cyanocobalamin injection is predominantly used for this purpose in the United States because it is the most easily produced for the lowest cost, however cyanocobalamin is poorly tolerated in certain patients such as in children or in heavy smokers who may have elevated cyanide levels in the blood. In these patients hydroxocobalamin, the active ingredient in AST-726, is used. Both cyanocobalamin and hydroxocobalamin must be converted in the body to an active form of Vitamin B12. Hydroxocobalamin is thought to be converted more easily than cyanocobalamin and it has longer retention time in the body. Hydroxocobalamin injection is the preferred treatment



for Vitamin B12 deficiency in Europe comprising the vast majority of all Vitamin B12 injections.

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 typically administered daily for 5-10 days 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. There are two intranasal products currently available in the United States, Nascobal ® which is administered once weekly, and Calomist ®, which is administered once daily. Both can only be used once a deficient patient has been normalized with injections. Both products use cyanocobalamin as the active ingredient.

Oral administration of very high doses of Vitamin B12 can restore deficient patients to normal in certain cases, but conventional oral supplementation is plagued by limited bioavailability. 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, if the gastrointestinal tract is compromised, as is the case in many B12 deficient patients, oral supplementation may not be successful at restoring circulating levels and storage depots of the vitamin to normal. For example, older people create less stomach acid which results in a reduced ability to absorb Vitamin B12 from food. These patients would also be unable to absorb the vitamin from oral supplements. In such cases, intramuscular injection would be the treatment of choice, since it is administered directly into the bloodstream and does not rely on absorption in the gastrointestinal tract.

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 for Vitamin B12 Deficiency

We believe that treatment with AST-726 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 has been designed 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 monthly 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. Manhattan Pharmaceuticals 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 our AST-726 nasal spray product candidate on a daily basis for approximately 5-10 days to restore their Vitamin B12 status to normal and will then be self-maintained on a single monthly nasal spray treatment of AST-726.

#### More About Vitamin B12

Vitamin B12 is involved in the metabolism of every cell of the body, especially in energy production, fatty acid synthesis, and synthesis and regulation of DNA. It also plays a crucial role in many major body systems. In the brain and nervous system Vitamin B12 plays an important role in cognitive function and memory, the function and maintenance of nerve cells and surrounding myelin sheath, and the synthesis of serotonin, dopamine, and norepinephrine. Vitamin B12 is also known to reduce homocysteine, an amino acid produced by the body. Elevated homocysteine levels have been linked to brain and nerve cell damage, cardiovascular disease, and bone weakness and fractures. Vitamin B12 also plays a key role in the immune system, creation of melatonin for sleep, and the synthesis of red blood cells.

Two recent published studies have highlighted the beneficial effects that homocysteine lowering B vitamins have on cognitive impairment and cognitive decline. The first of these two studies (Smith, AD, PLoS One 2010) published in September 2010 shows that high doses of B vitamins slow the rate of brain atrophy by approximately 30%. Brain atrophy (or brain shrinkage) is one of the main symptoms of mild cognitive impairment, a known precursor to dementia, and sometimes Alzheimer's Disease. The second study (Hooshmand, B, Neurology 2010), a population based, 7-year cohort study published in October 2010, shows that higher baseline serum homocysteine levels correlated positively with an increased risk of Alzheimer's Disease.

AST-915

AST-915 is an orally delivered treatment for essential tremor. Manhattan Pharmaceuticals acquired global rights to AST-915 as part of the Ariston acquisition. This product candidate was studied under a Cooperative Research and Development Agreement (CRADA) with the National Institute of Neurological Disorders and Stroke (NINDS), a division of the National Institutes of Health (NIH).

In December 2010, Manhattan Pharmaceuticals announced the achievement of human proof-of concept with AST-915 with the release of preliminary results from a Phase 1/2 study conducted by the NIH of AST-915 for the treatment of essential tremor. Data from this single dose study showed that AST-915 was well tolerated and demonstrated a clear effect on tremor power.

In this randomized, double-blind, placebo-controlled, crossover design study, 18 subjects with essential tremor received single oral doses of AST-915. Primary and secondary outcome measures included the effect on tremor power using accelerometry to test the central tremor component at various time points after treatment. Safety, pharmacokinetic data, and other efficacy measures were also evaluated. AST-915 was well tolerated with non-serious adverse events being evenly distributed between active and placebo treatments, and two observed serious events being unrelated to study drug.

Statistically significant reductions in tremor power were evident at several time points between 80 and 300 minutes. 300 minutes was the latest timepoint measured following administration of AST-915. Further analysis, conducted using each subject as its own control, demonstrated statistically significant lower tremor amplitudes in favor of AST-915 compared to placebo. Additional analysis continues to examine other secondary endpoints. Statistically significant effect on tremor power was not evident 80 minutes after administration of AST-915 (defined as the primary endpoint timeframe),

The NINDS/NIH intends to submit an abstract to the 15th International Congress of Parkinson's Disease and Movement Disorders taking place in Toronto in June 2011. Complete study findings are expected to be disclosed at this and other scientific meetings, and by submission to scientific journals. Manhattan Pharmaceuticals intends to continue to work with the NINDS/NIH and to proceed toward Phase 2 with the AST-915 development program.

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

According to the International Essential Tremor Foundation, an estimated 10 million Americans have essential tremor. The condition is most common among people over 60, but it also occurs in children, adolescents and the middle-aged. There is no curative treatment for essential tremor and current therapy is inadequately effective in a large portion of patients and/or limited by side effects. Manhattan Pharmaceuticals believes AST-915 may provide a new treatment option for this serious and prevalent disorder. Manhattan Pharmaceuticals believes that substantial market opportunity also exists internationally.

#### 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, Manhattan Pharmaceuticals entered into an exclusive license agreement with Thornton & Ross Ltd (“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 the Company’s exclusive supplier of Hedrin product (the “Hedrin Supply Agreement”).

In February 2008, Manhattan Pharmaceuticals 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 United States and Canada. H Pharmaceuticals is independently funded and is responsible for all costs associated with the Hedrin project, including any necessary United States (“U.S.”) clinical trials, patent costs, and future milestones owed to the original licensor, T&R.

The Hedrin JV is currently working to complete development and secure commercialization and marketing partners for Hedrin in 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. Manhattan Pharmaceuticals believes 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

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., the Hedrin JV, is 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, CDRH 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 questions about certain manufacturing and 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 trials, and the Hedrin JV’s application to conduct those clinical 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 have not been widely reported to date, but experts believe it is likely develop with continued use. Head lice resistance to piperonyl butoxide and permethrin has been reported in the U.S. and treatment failures are common.

#### 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. The Company owns global rights to this topical GEL and is exploring the



possibility of developing it as an OTC product for mild psoriasis.

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### 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.

### 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 the Company 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.

Due to small market opportunity and lack of sufficient funds to develop Altolyn, in March 2009 the Company 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.

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#### 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.

#### AST-726

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

- 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 September 1, 2015.
- 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, the Company has 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.

#### Hedrin

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

- U.S. Patent No. 7,829,551 entitled, “Method and composition for the control of arthropods.” Jayne Ansell, Inventor. Application filed February 12, 2007. Patent issued November 9, 2010. This patent is scheduled to expire on March 9, 2023. This patent 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 the Company assigned and transferred its rights in Hedrin to the Hedrin JV. The Hedrin JV is now responsible for all of the Company’s obligations under the Hedrin License Agreement and the Hedrin Supply Agreement.



#### 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.

#### Summary of Contractual Commitments

##### Leases

Rent expense for the years ended December 31, 2010 and 2009 was \$44,316 and \$88,363, respectively. Future minimum rental payments subsequent to December 31, 2010 under an operating lease for the Company's office facility, which expires on September 30, 2011, are as follows:

Years Ending December 31, Commitment	
2011	\$ 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 the Company and its 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.

The Company often contracts 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, the Company records 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.



#### In-process Research and Development

All acquired research and development projects are recorded at their fair value as of the date acquisition. The fair values are assessed as of the balance sheet date to ascertain if there has been any impairment of the recorded value. If there is an impairment the asset is written down to its current fair value by the recording of an expense.

#### 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. We use a Black-Scholes model to estimate the value.

#### Derivative Liability

We evaluate whether warrants or convertible instruments to acquire stock of the Company contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price under the respective agreements. Down-round provisions reduce the exercise price of a warrant or convertible instrument if a company either issues equity shares for a price that is lower than the exercise price, and such instruments are recorded as derivative liabilities. We use a Black-Scholes model to estimate the fair value of our convertible notes and warrants.

#### New Accounting Pronouncements

In June 2008, the FASB ratified a pronouncement which provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. This statement was effective for fiscal years beginning after December 15, 2008. The adoption of this statement had a significant impact on our financial statements (see Note 12 to our financial statements for the period ended December 31, 2009).

In January 2010, the Financial Accounting Standards Board ("FASB") issued a new pronouncement, "Improving Disclosures about Fair Value Measurements". 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 the Company's results of operations or financial condition.

In April 2010, the FASB issued a new pronouncement "Revenue Recognition – Milestone Method". This pronouncement provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. A vendor can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The following criteria must be met for a milestone to be considered substantive. The consideration earned by achieving the milestone should 1. Be commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the vendor's performance to achieve the milestone. 2, Related solely to past performance. 3. Be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement. Accordingly, an arrangement may contain both substantive and nonsubstantive milestones. This pronouncement is effective on a prospective basis for milestones



achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this guidance does not have a material impact on our financial statements.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

For a list of the financial statements filed as part of this report, see the Index to Financial Statements beginning at Page F-1 of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2010, we carried out an evaluation, under the supervision and with the participation of our Chief Operating and Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based upon that evaluation, our Chief Operating and Financial Officer concluded that our disclosure controls and procedures were effective as of that date to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and to ensure that information required to be disclosed by us in such reports is accumulated and communicated to our management, including our Chief Operating and Financial Officer, as appropriate to allow timely decisions regarding required disclosure. There were no changes in our internal controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2010 that have materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Our disclosure controls or internal controls over financial reporting were designed to provide only reasonable assurance that such disclosure controls or internal control over financial reporting will prevent all errors or all instances of fraud, even as the same are improved to address any deficiencies. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be only reasonable, not absolute assurance that any design will succeed in achieving its stated goals under all potential future conditions. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs.

Because of the inherent limitation of a cost-effective control system, misstatements due to error or fraud may occur and not be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls.

Management's Report on Internal Control

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the SEC, internal control over financial reporting is a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with U.S. generally accepted accounting principles.

Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of our annual financial statements, management has undertaken an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control – Integrated framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO Framework. Management’s assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting is effective as of December 31, 2010.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management’s report on internal control in this report.

ITEM 15. EXHIBITS LIST

The following documents are included or incorporated by reference in this report.

Exhibit No. Description

- 2.1 Agreement and Plan of Merger among the Company, Manhattan Pharmaceuticals Acquisition Corp. and Manhattan Research Development, Inc. (formerly Manhattan Pharmaceuticals, Inc.) dated December 17, 2002 (incorporated by reference to Exhibit 2.1 from Form 8-K filed March 5, 2003).
- 2.2 Agreement and Plan of Merger among the Registrant, Tarpan Therapeutics, Inc. and Tarpan Acquisition Corp., dated April 1, 2005 (incorporated by reference to Exhibit 2.1 of the Registrant's Form 8-K/A filed June 15, 2005).
- 2.3 Agreement and Plan of Merger among the Registrant, Ariston Pharmaceuticals, Inc., and Ariston Merger Corp. dated March 8, 2010 (incorporated by reference to the Registrant's Current Report on Form 8\_K filed March 12, 2010).
- 3.1 Certificate of incorporation, as amended through September 25, 2003 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-QSB for the quarter ended September 30, 2003).
- 3.2 Bylaws, as amended to date (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No.33-98478)).
- 4.1 Specimen common stock certificate (incorporated by reference from Registrant's registration statement on Form SB-2, as amended (File No.33-98478)).
- 4.2 Form of warrant issued by Manhattan Research Development, Inc., which automatically converted into warrants to purchase shares of the Registrant's common stock upon the merger transaction with such company (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-QSB for the quarter ended March 31, 2003).
- 4.3 Form of warrant issued to placement agents in connection with the Registrant's November 2003 private placement of Series A Convertible Preferred Stock and the Registrant's January 2004 private placement (incorporated by reference to Exhibit 4.18 to the Registrant's Registration Statement on Form SB-2 filed January 13, 2004 (File No. 333-111897)).
- 4.4 Form of warrant issued to investors in the Registrant's August 2005 private placement (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed September 1, 2005).
- 4.5 Form of warrant issued to placement agents in the Registrant's August 2005 private placement (incorporated by reference to Exhibit 4.2 of the Registrant's Form 8-K filed September 1, 2005).
- 4.6 Warrant, dated April 30, 2008, issued to Nordic Biotech Venture Fund II K/S (incorporated by reference to Exhibit 4.6 of the Registrant's Registration Statement on Form S-1 filed on May 1, 2008 (File No. 333-150580)).
- 4.7 Form of Warrant issued to Noteholders on September 11, 2008 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on September 15, 2008)

- 4.8 Form of Warrant issued to Noteholders on November 19, 2008 (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on November 25, 2008)
- 10.1 1995 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-QSB for the quarter ended September 30, 1996).

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- 10.2 Form of Notice of Stock Option Grant issued to employees of the Registrant from April 12, 2000 to February 21, 2003 (incorporated by reference to Exhibit 99.2 of the Registrant's Registration Statement non Form S-8 filed March 24, 1998 (File 333-48531)).
- 10.3 Schedule of Notices of Stock Option Grants, the form of which is attached hereto as Exhibit 4.2.
- 10.4 Form of Stock Option Agreement issued to employees of the Registrant from April 12, 2000 to February 21, 2003 (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 filed March 24, 1998 (File 333-48531)).
- 10.5 License Agreement dated on or about February 28, 2002 between Manhattan Research Development, Inc. (f/k/a Manhattan Pharmaceuticals, Inc.) and Oleoyl-Estrone Developments SL (incorporated by reference to Exhibit 10.6 to the Registrant's Amendment No. 2 to Form 10-QSB/A for the quarter ended March 31, 2003 filed on March 12, 2004).
- 10.6 License Agreement dated April 4, 2003 between the Registrant and NovaDel Pharma, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Amendment No. 1 to Form 10-QSB/A for the quarter ended June 30, 2003 filed on March 12, 2004).++
- 10.7 2003 Stock Option Plan (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-8 filed February 17, 2004).
- 10.8 Employment Agreement dated April 1, 2005, between the Registrant and Douglas Abel (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K/A filed June 15, 2005).
- 10.9 Sublicense Agreement dated April 14, 2004 between Tarpan Therapeutics, Inc., the Registrant's wholly-owned subsidiary, and IGI, Inc. (incorporated by reference to Exhibit 10.109 to IGI Inc.'s Form 10-Q for the quarter ended March 31, 2004 (File No. 001-08568)).
- 10.10 Form of subscription agreement between the Registrant and the investors in the Registrant's August 2005 private placement (incorporated by reference as Exhibit 10.1 to the Registrant's Form 8-K filed September 1, 2005).
- 10.11 Separation Agreement between the Registrant and Alan G. Harris December 21, 2007 (incorporated by reference to Exhibit 10.11 to the Registrant's Form 10-K filed March 31, 2008.)
- 10.12 Employment Agreement dated July 7, 2006 between the Registrant and Michael G. McGuinness (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed July 12, 2006.)
- 10.13 Summary terms of compensation plan for Registrant's non-employee directors (incorporated by reference to Exhibit 10.1 of Registrant's Form 8-K filed February 5, 2007).
- 10.14 Form of Stock Option Agreement issued under the Registrant's 2003 Stock Option Plan (Incorporated by reference to Exhibit 10.15 to the Registrant's Form 10-KSB filed April 2, 2007.)
- 10.15 Exclusive License Agreement for "Altoderm" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dates April 3, 2007. (Incorporated by reference to Exhibit 10.3 of the registrant's form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007.)

- 10.16 Exclusive License Agreement for “Altolyn” between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated April 3, 2007. (Incorporated by reference to Exhibit 10.4 of the registrant’s form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007.)



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- 10.17 Exclusive License Agreement for “Hedrin” between Thornton & Ross Ltd. , Kerris, S.A. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007. (Incorporated by reference to Exhibit 10.5 of the registrant’s form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007.)
- 10.18 Supply Agreement for “Hedrin” between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007. (Incorporated by reference to Exhibit 10.6 of the registrant’s form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007.)
- 10.19 Joint Venture Agreement between Nordic Biotech Fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize “Hedrin” dated January 31, 2008.
- 10.20 Amendment No. 1, dated February 25, 2008, to the Joint Venture Agreement between Nordic Biotech Fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize “Hedrin” dated January 31, 2008 (Incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-K filed March 31, 2008).
- 10.21 Omnibus Amendment to Joint Venture Agreement and Additional Agreements, dated June 9, 2008, among Manhattan Pharmaceuticals, Inc., Hedrin Pharmaceuticals K/S, Hedrin Pharmaceuticals General Partner ApS and Nordic Biotech Venture Fund II K/S.
- 10.22 Assignment and Contribution Agreement between Hedrin Pharmaceuticals K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008. (Incorporated by reference to Exhibit 10.21 to the Registrant's Form 10-K filed March 31, 2008.)
- 10.23 Registration Rights Agreement between Nordic Biotech Venture Fund II K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008. (Incorporated by reference to Exhibit 10.22 to the Registrant's Form 10-K filed March 31, 2008.)
- 10.24 Letter Agreement, dated September 17, 2008, between Nordic Biotech Venture Fund II K/S and Manhattan Pharmaceuticals, Inc.
- 10.25 Amendment to Employment Agreement by and between Manhattan Pharmaceuticals, Inc. and Douglas Abel (Incorporated by reference to Exhibit 10.23 to the Registrant's Form 10-K filed March 31, 2008.)
- 10.26 Form of Secured Promissory Note, dated September 11, 2008 (Incorporated by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K filed on September 15, 2008)
- 10.27 Securities Purchase Agreement, dated November 19, 2008, by and among the Registrant and the investors listed on Exhibit A-1 and A-2 thereto (incorporated by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K filed on November 25, 2008)
- 10.28 Registration Rights Agreement, dated November 19, 2008, by and among the Registrant, the Placement Agent and the investors listed on Exhibit A thereto (incorporated by reference to Exhibit 10.2 to the Registrant’s Current Report on Form 8-K filed on November 25, 2008)
- 10.29 Security Agreement, dated November 19, 2008, by and among the Registrant and each person named on Exhibit A-1 and A-2 of the Securities Purchase Agreement (incorporated by reference to Exhibit 10.3 to the Registrant’s Current Report on Form 8-K filed on November 25, 2008)

- 10.30 Default Agreement, dated November 19, 2008, by and among the Registrant and the persons and entities listed on Schedule A thereto (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on November 25, 2008)

- 10.31 Form of 12% Senior Secured Promissory Note (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on November 25, 2008)
- 10.32 Amendment No. 2 to the Employment Agreement between the Registrant and Douglas Abel, dated November 19, 2008 (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K filed on November 25, 2008)
- 10.33 Amendment No. 1 to the Employment Agreement between the Registrant and Michael McGuinness, dated November 19, 2008 (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K filed on November 25, 2008)
- 10.34 Form of Placement Agent Warrant (incorporated by reference to Exhibit 10.9 to the Registrant's Current Report on Form 8-K filed on November 25, 2008)
- 23.1 Consent of J.H. Cohn LLP
- 31.1 Certification of Principal Executive Officer
- 31.2 Certification of Principal Financial Officer
- 32.1 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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++Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act, of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2011.

Manhattan Pharmaceuticals, Inc.  
 By: /s/ Michael McGuinness  
 Michael McGuinness  
 Chief Operating and Financial Officer

13. In accordance with the Securities Exchange Act, this report has been signed below by the following persons on behalf of Manhattan Pharmaceuticals, Inc. and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael G. McGuinness Michael G. McGuinness	Secretary and Chief Operating and Financial Officer, and Director (principal executive, accounting and financial officer)	March 31, 2011
/s/ Douglas Abel Douglas Abel	Director and Chairman	March 31, 2011
/s/ Neil Herskowitz Neil Herskowitz	Director	March 31, 2011
/s/ Timothy McInerney Timothy McInerney	Director	March 31, 2011
/s/ David Shimko David Shimko	Director	March 31, 2011
/s/ Richard Steinhart Richard Steinhart	Director	March 31, 2011

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders  
Manhattan Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Manhattan Pharmaceuticals, Inc. and Subsidiary (a development stage company) as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for the years then ended, and for the period from August 6, 2001 (date of inception) to December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Manhattan Pharmaceuticals, Inc. and Subsidiary as of December 31, 2010 and 2009, and their results of operations and cash flows for the years then ended and for the period from August 6, 2001 (date of inception) to December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred net losses and negative cash flows from operating activities from its inception through December 31, 2010 and has an accumulated deficit and negative working capital as of December 31, 2010. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ J.H. Cohn LLP

Roseland, New Jersey  
March 31, 2011

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARY  
(A Development Stage Company)  
Consolidated Balance Sheets

	December 31, 2010	December 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 478,668	\$ 17,996
Grant receivable	244,479	-
Debt issue costs, current portion	4,408	158,552
Other current assets	141,622	87,177
<b>Total current assets</b>	<b>869,177</b>	<b>263,725</b>
In-process research and development	17,742,110	-
Property and equipment, net	2,984	3,541
Debt issue costs, noncurrent portion	-	77,026
Other assets	21,370	21,370
<b>Total assets</b>	<b>\$ 18,635,641</b>	<b>\$ 365,662</b>
<b>Liabilities and Stockholders' Deficiency</b>		
Current Liabilities:		
Notes payable, current portion, net	\$ 2,054,246	\$ 1,274,062
Accounts payable and accrued expenses	223,516	291,175
Interest payable, current portion	480,890	182,193
Derivative liability	534,846	784,777
<b>Total current liabilities</b>	<b>3,293,498</b>	<b>2,532,207</b>
Notes payable, noncurrent portion, net	16,130,571	614,181
Interest payable, noncurrent portion	626,697	55,048
Exchange obligation	3,949,176	3,949,176
<b>Total liabilities</b>	<b>23,999,942</b>	<b>7,150,612</b>
<b>Commitments and contingencies</b>		
Stockholders' deficiency:		
Preferred stock, \$.001 par value. Authorized 1,500,000 shares; no shares issued and outstanding at December 31, 2010 and 2009	-	-
Common stock, \$.001 par value. Authorized 500,000,000 shares; 120,965,260 shares issued and outstanding at December 31, 2010 and 70,624,232 shares issued and outstanding on December 31, 2009	120,966	70,624
Contingently issuable shares	15,890	-
Additional paid-in capital	55,808,633	55,077,861
Deficit accumulated during the development stage	(61,309,790 )	(61,933,435 )
<b>Total stockholders' deficiency</b>	<b>(5,364,301 )</b>	<b>(6,784,950 )</b>
<b>Total liabilities and stockholders' deficiency</b>	<b>\$ 18,635,641</b>	<b>\$ 365,662</b>

See accompanying notes to consolidated financial statements.

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MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARY  
(A Development Stage Company)  
Consolidated Statements of Operations

	Years ended December 31,		Cumulative period from August 6, 2001 (inception) to December 31,
	2010	2009	2010
Revenue	\$-	\$-	\$ -
Costs and expenses:			
Research and development	495,793	40,376	28,828,004
General and administrative	1,520,942	1,731,182	19,714,397
In-process research and development charge	-	-	11,887,807
Impairment of intangible assets	-	-	1,248,230
Loss on disposition of intangible assets	-	-	1,213,878
Total operating expenses	2,016,735	1,771,558	62,892,316
Operating loss	(2,016,735 )	(1,771,558 )	(62,892,316 )
Other (income) expense:			
Equity in losses of Hedrin JV	-	500,000	750,000
Interest and other income	(548,445 )	(586,697 )	(2,415,674 )
Change in fair value of derivative	(3,522,053 )	560,065	(3,091,983 )
Interest and amortization expense	1,271,048	548,359	1,912,448
Loss on early extinguishment of debt	159,070	-	159,070
Realized gain on sale of marketable equity securities	-	-	(76,032 )
Total other (income) expense	(2,640,380 )	1,021,727	(2,762,171 )
Net income (loss)	623,645	(2,793,285 )	(60,130,145 )
Preferred stock dividends (including imputed amounts)	-	-	(1,179,645 )
Net income (loss) applicable to common shares	\$623,645	\$(2,793,285 )	\$ (61,309,790 )
Net income (loss) per common share:			
Basic and diluted	\$0.006	\$(0.040 )	
Weighted average shares of common stock outstanding:			
Basic and diluted	111,875,910	70,624,232	

See accompanying notes to consolidated financial statements.

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARY  
(A Development Stage Company)  
Consolidated Statements of Stockholders' Equity (Deficiency)

	Common stock shares	Common stock amount	Additional paid-in capital	Deficit accumulated during development stage	Other	Total stockholders' equity (deficiency)
Stock issued at \$0.0004 per share for subscription receivable	10,167,741	\$ 10,168	\$ (6,168 )	\$ -	\$ (4,000 )	\$ -
Net loss	-	-	-	(56,796 )	-	(56,796 )
Balance at December 31, 2001	10,167,741	10,168	(6,168 )	(56,796 )	(4,000 )	(56,796 )
Proceeds from subscription receivable	-	-	-	-	4,000	4,000
Stock issued at \$0.0004 per share for license rights	2,541,935	2,542	(1,542 )	-	-	1,000
Stock options issued for consulting services	-	-	60,589	-	(60,589 )	-
Common stock issued at \$0.63 per share, net of expenses	3,043,332	3,043	1,701,275	-	-	1,704,318
Amortization of unearned consulting services	-	-	-	-	22,721	22,721
Net loss	-	-	-	(1,037,320 )	-	(1,037,320 )
Balance at December 31, 2002	15,753,008	15,753	1,754,154	(1,094,116 )	(37,868 )	637,923
Common stock issued at \$0.63 per share, net of expenses	1,321,806	1,322	742,369	-	-	743,691
Effect of reverse acquisition	6,287,582	6,287	2,329,954	-	-	2,336,241
Payment for fraction shares for stock combination	-	-	(300 )	-	-	(300 )
Preferred stock issued at \$10 per share, net of expenses	-	-	9,045,176	-	1,000	9,046,176
Imputed preferred stock dividend	-	-	418,182	(418,182 )	-	-
Amortization of unearned consulting services	-	-	-	-	37,868	37,868
Unrealized loss on short-term investments	-	-	-	-	(7,760 )	(7,760 )
Net loss	-	-	-	(5,960,907 )	-	(5,960,907 )
Balance at December 31, 2003	23,362,396	23,362	14,289,535	(7,473,205 )	(6,760 )	6,832,932

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Exercise of stock options	27,600	27	30,073	-	-	30,100
Common stock issued at \$1.10 per share, net of expenses	3,368,952	3,369	3,358,349	-	-	3,361,718
Preferred stock dividend accrued	-	-	-	(585,799 )	-	(585,799 )
Preferred stock dividend paid by issuance of preferred shares	-	-	281,073	-	25	281,098
Conversion of preferred stock to common stock at \$1.10 per share	1,550,239	1,551	(1,380 )	-	(171 )	-
Warrants issued for consulting services	-	-	125,558	-	(120,968)	4,590
Amortization of unearned consulting services	-	-	-	-	100,800	100,800
Unrealized gain and reversal of unrealized loss on short-term investments	-	-	-	-	20,997	20,997
Net loss	-	-	-	(5,896,031 )	-	(5,896,031 )
Balance at December 31, 2004	28,309,187	28,309	18,083,208	(13,955,035)	(6,077 )	4,150,405
Common stock issued at \$1.11 and \$1.15 per share, net of expenses	11,917,680	11,918	12,238,291	-	-	12,250,209
Common stock issued at \$1.11 in satisfaction of accounts payable	675,675	676	749,324	-	-	750,000
Exercise of stock options	32,400	33	32,367	-	-	32,400
Exercise of warrants	279,845	279	68,212	-	-	68,491
Preferred stock dividend accrued	-	-	-	(175,663 )	-	(175,663 )
Preferred stock dividend paid by issuance of preferred shares	-	-	477,736	-	42	477,778
Conversion of preferred stock to common stock at \$1.10 per share	8,146,858	8,147	(7,251 )	-	(896 )	-
Stock issued in connection with acquisition of Tarpan Therapeutics, Inc.	10,731,052	10,731	11,042,253	-	-	11,052,984
Reversal of unrealized gain on short-term investments	-	-	-	-	(12,250 )	(12,250 )
Share-based compensation	-	-	66,971	-	20,168	87,139
Net loss	-	-	-	(19,140,997)	-	(19,140,997)
Balance at December 31, 2005	60,092,697	60,093	42,751,111	(33,271,695)	987	9,540,496
	27,341	27	(27 )	-	-	-

Cashless exercise of  
warrants

Costs associated with private placement	-	-	(15,257 )	-	-	(15,257 )
Unrealized loss on short-term investments	-	-	-	-	(987 )	(987 )
Share-based compensation	-	-	1,675,499	-	-	1,675,499
Net loss	-	-	-	(9,695,123 )	-	(9,695,123 )
Balance at December 31, 2006	60,120,038	60,120	44,411,326	(42,966,818)	-	1,504,628

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MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARY  
(A Development Stage Company)  
Consolidated Statements of Stockholders' Equity (Deficiency)

	Common stock shares	Common stock amount	Additional paid-in capital	Deficit accumulated during development stage	Other	Total stockholders' equity (deficiency)
Common stock issued at \$0.84 and \$0.90 per share, net of expenses	10,185,502	\$ 10,186	\$ 7,841,999	\$ -	\$ -	\$ 7,852,185
Common stock issued to directors at \$0.72 per share in satisfaction of accounts payable	27,776	28	19,972	-	-	20,000
Common stock issued in connection with in-licensing agreement at \$0.90 per share	125,000	125	112,375	-	-	112,500
Common stock issued in connection with in-licensing agreement at \$0.80 per share	150,000	150	119,850	-	-	120,000
Warrants issued for consulting services	-	-	83,670	-	-	83,670
Exercise of warrants	10,327	15	7,219	-	-	7,234
Cashless exercise of warrants	5,589	-	(6 )	-	-	(6 )
Share-based compensation	-	-	1,440,956	-	-	1,440,956
Net loss	-	-	-	(12,032,252)	-	(12,032,252)
Balance at December 31, 2007	70,624,232	70,624	54,037,361	(54,999,070)	-	(891,085 )
Sale of warrant	-	-	150,000	-	-	150,000
Warrants issued with 12% notes	-	-	170,128	-	-	170,128
Share-based compensation	-	-	463,890	-	-	463,890
Net loss	-	-	-	(4,268,858 )	-	(4,268,858 )
Balance at December 31, 2008	70,624,232	70,624	54,821,379	(59,267,928)	-	(4,375,925 )
Cumulative effect of a change in accounting principle	-	-	(150,000 )	127,778	-	(22,222 )
Balance at January 1, 2009, as adjusted	70,624,232	70,624	54,671,379	(59,140,150)	-	(4,398,147 )
Warrants issued with secured 12% notes	-	-	46,125	-	-	46,125

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Warrants issued to placement agent - secured 12% notes	-	-	6,919	-	-	6,919
Share-based compensation	-	-	353,438	-	-	353,438
Net loss	-	-	-	(2,793,285 )	-	(2,793,285 )
Balance at December 31, 2009	70,624,232	70,624	55,077,861	(61,933,435 )	-	(6,784,950 )
Common stock issued at \$0.07 per share, net of expenses	43,278,605	43,279	2,542,207	-	-	2,585,486
Derivative liability associated with warrants issued with common stock	-	-	(3,497,898 )	-	-	(3,497,898 )
Shares issued and issuable in Merger with Ariston	7,062,423	7,063	1,468,984	-	15,890	1,491,937
Share-based compensation	-	-	217,479	-	-	217,479
Net income	-	-	-	623,645	-	623,645
Balance at December 31, 2010	120,965,260	\$ 120,966	\$ 55,808,633	\$ (61,309,790)	\$ 15,890	\$ (5,364,301 )

See accompanying notes to consolidated financial statements.

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARY  
(A Development Stage Company)  
Consolidated Statements of Cash Flows

	Years Ended Dceember 31,		Cumulative period from August 6, 2001 (inception) to December 31, 2010
	2010	2009	
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 623,645	\$ (2,793,285 )	\$ (60,130,145 )
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Equity in losses of Hedrin JV	-	500,000	750,000
Share-based compensation	217,479	353,438	4,399,790
Interest and amortization of OID and issue costs	352,658	543,182	936,631
Change in fair value of derivative	(3,522,052 )	560,065	(3,091,982 )
Loss on early extinguishment of debt	159,070	-	159,070
Depreciation	3,401	5,531	230,863
Shares issued in connection with in-licensing agreement	-	-	232,500
Warrants issued to consultant	-	-	83,670
Amortization of intangible assets	-	-	145,162
Gain on sale of marketable equity securities	-	-	(76,032 )
Non-cash portion of in-process research and development charge	-	-	11,721,623
Loss on impairment and disposition of intangible assets	-	-	2,462,108
Other	-	-	23,917
<b>Changes in operating assets and liabilities, net of acquisitions:</b>			
Decrease in restricted cash	-	730,499	-
Increase in grant receivable	(244,479 )	-	(244,479 )
Decrease (increase) in prepaid expenses and other current assets	66,425	(49,460 )	37,491
Decrease (increase) in other assets	-	13,525	(36,370 )
Decrease in accounts payable and accrued expenses	(505,273 )	(913,294 )	(122,307 )
Increase in interest payable	879,013	-	879,013
Net cash used in operating activities	(1,970,113 )	(1,049,799 )	(41,639,477 )
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(2,844 )	-	(242,452 )
Cash acquired in connection with acquisitions	519,365	-	493,334
Net cash provided from the purchase and sale of short-term investments	-	-	435,938
Proceeds from sale of license	-	-	200,001
Net cash provided by investing activities	516,521	-	886,821
<b>Cash flows from financing activities:</b>			
Proceeds related to sale of common stock, net	2,163,486	-	28,059,748
Proceeds from sale of preferred stock, net	-	-	9,046,176
Proceeds from the Hedrin JV agreement	-	500,000	3,199,176
Proceeds from sale of Secured 12% Notes	-	340,270	1,345,413
Sale of warrant	-	-	150,000
Proceeds from sale of Convertible 12% Notes	-	164,502	164,502
Proceeds from 8% Note	40,000	27,000	67,000
Repayment of 8% Note	(67,000 )	-	(67,000 )

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Proceeds from (repayments of) notes payable, net	(222,222 )	27,000	(1,107,124 )
Repayment of Secured 10% Notes	-	(70,000 )	-
Other, net	-	-	373,433
Net cash provided by financing activities	1,914,264	988,772	41,231,324
Net (decrease) increase in cash and cash equivalents	460,672	(61,027 )	478,668
Cash and cash equivalents at beginning of period	17,996	106,023	-
Cash and cash equivalents at end of period	\$ 478,668	\$ 44,996	\$ 478,668

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MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARY  
(A Development Stage Company)  
Consolidated Statements of Cash Flows

	Years Ended December 31,		Cumulative period from August 6, 2001 (inception) to December 31, 2010
	2010	2009	
<b>Supplemental disclosure of cash flow information:</b>			
Interest paid	\$ 36,075	\$ 5,397	\$ 67,505
<b>Supplemental disclosure of noncash investing and financing activities:</b>			
Investment in Hedrin JV	\$ 500,000	\$ 500,000	\$ 1,250,000
Conversion of debt to common stock and warrants	422,000	-	422,000
Issuance of common stock for acquisitions	1,491,937	-	14,881,163
Warrants issued with 12% Notes	-	27,390	27,390
Note issued to settle accrued expenses	-	211,900	211,900
Imputed and accrued preferred stock dividend	-	-	1,179,644
Common stock issued in satisfaction of accounts payable	-	-	770,000
Preferred stock dividends paid by issuance of shares	-	-	759,134
Net liabilities assumed over assets acquired in business combination	-	-	(675,416 )
Marketable equity securities received in connection with sale of license	-	-	359,907
Issuance of common stock in connection with in-licensing agreement	-	-	232,500
Warrants issued with Secured 12% Notes	-	53,044	223,172
Warrants issued to consultant	-	-	83,670
Conversion of preferred stock to common stock	-	-	1,067
Cashless exercise of warrants	-	-	33

See accompanying notes to consolidated financial statements.

Manhattan Pharmaceuticals, Inc. and Subsidiary  
(a Development Stage Company)  
Notes to Consolidated Financial Statements

(1) Merger and Nature of Operations

2003 Reverse Merger

On February 21, 2003, the Company (formerly known as “Atlantic Technology Ventures, Inc.”) completed a reverse acquisition of privately held Manhattan Research Development, Inc. (“Manhattan Research”) (formerly Manhattan Pharmaceuticals, Inc.), a Delaware corporation. At the effective time of the merger, the outstanding shares of common stock of Manhattan Research automatically converted into shares of the Company’s common stock representing 80 percent of the Company’s outstanding voting stock after giving effect to the merger. Since the stockholders of Manhattan Research received the majority of the voting shares of the Company, the merger was accounted for as a reverse acquisition whereby Manhattan Research was the accounting acquirer (legal acquiree) and the Company was the accounting acquiree (legal acquirer) under the purchase method of accounting. In connection with the merger, the Company changed its name from “Atlantic Technology Ventures, Inc.” to “Manhattan Pharmaceuticals, Inc.” The results of the combined operations have been included in the Company’s financial statements since February 2003.

As described above, the Company resulted from the February 21, 2003 reverse merger between Atlantic Technology Ventures, Inc. (“Atlantic”), which was incorporated on May 18, 1993, and privately-held Manhattan Research Development, Inc., incorporated on August 6, 2001. The Company was incorporated in the State of Delaware. In connection with the merger, the former stockholders of Manhattan Research received a number of shares of Atlantic's common stock so that following the merger they collectively owned 80 percent of the outstanding shares. Upon completion of the merger, Atlantic changed its name to Manhattan Pharmaceuticals, Inc. and thereafter adopted the business of Manhattan Research.

The Company is a biopharmaceutical company focused on developing and commercializing innovative pharmaceutical therapies for underserved patient populations. The Company acquires 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. We currently have three product candidates in development: AST-726 for the treatment of vitamin B-12 deficiency. AST-915 for the treatment of essential tremor and Hedrin™, a novel, non-insecticide treatment of pediculitis (head lice) which is being developed by the Hedrin JV (see note 6) and a topical product for the treatment of psoriasis. During 2009, the Company discontinued development of PTH (1-34), Altoderm and Altolyn.

Acquisition of Tarpan Therapeutics, Inc.

In April 2005, the Company merged with Tarpan Therapeutics, Inc., a Delaware corporation (“Tarpan”), and Tarpan Acquisition Corp., a Delaware corporation. The acquisition of Tarpan has been accounted for by the Company under the purchase method of accounting. Under the purchase method, assets acquired and liabilities assumed by the Company are recorded at their estimated fair values and the results of operations of the acquired company are consolidated with those of the Company from the date of acquisition. The excess purchase price paid by the Company to acquire the net assets of Tarpan was allocated to acquired in-process research and development totaling \$11,887,807. As required by the purchase method of accounting, the Company recorded a charge in its consolidated statement of operations for the year ended December 31, 2005 for the in-process research and development.

Acquisition of Ariston Pharmaceuticals, Inc.

On March 8, 2010, Manhattan 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

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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 Manhattan. The operating results of Ariston from March 8, 2010 to December 31, 2010 are included in the accompanying consolidated statements of operations. The consolidated balance sheet as of December 31, 2010 reflects the acquisition of Ariston, effective March 8, 2010, the date of the Merger. See Note 8.

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Manhattan Pharmaceuticals, Inc. and Subsidiary  
(a Development Stage Company)  
Notes to Consolidated Financial Statements

(2) Liquidity and Basis of Presentation

Liquidity

The Company had net income of \$623,645 and negative cash flows from operating activities of \$1,970,113 for the year ended December 31, 2010. The Company incurred a net loss of \$2,793,285 and negative cash flows from operating activities of \$1,049,799 for the year ended December 31, 2009. The net loss applicable to common shares from date of inception, August 6, 2001, to December 31, 2010 amounts to \$61,309,790.

During the year ended December 31, 2010, the Company received approximately \$2.2 million from an equity financing transaction (see Note 9). In addition approximately \$422,000 of notes payable and interest payable thereon was converted in this equity financing transaction. Subsequent to December 31, 2010 the Company received \$575,000 from the Nordic Settlement (see Note 14). The Company expects to receive \$244,000 from a federal grant program during the second quarter of 2011.

The Company received approximately \$0.3 million in February 2009 from the final closing of the sale of Secured 12% Notes, approximately \$0.5 million in February 2009 from a joint venture agreement, approximately \$0.2 million from the sale of a Convertible 12% Note and approximately \$27,000 from Ariston Pharmaceuticals, Inc. in exchange for a note in December 2009. In addition, the Company issued a \$0.2 million non-interest bearing note in connection with the Swiss Pharma Settlement. These notes are more fully described in Note 7.

Management believes that the Company will continue to incur net losses through at least December 31, 2011 and for the foreseeable future. Based on the resources of the Company available at December 31, 2010, management believes that the Company has sufficient capital to fund its operations through the end of 2011. Management believes that the Company will need additional equity or debt financing or will need to generate positive cash flow from a joint venture agreement, see Note 6, or generate revenues through licensing of its products or entering into strategic alliances to be able to sustain its operations into 2012. Furthermore, the Company will need additional financing thereafter to complete development and commercialization of its products. There can be no assurances that we can successfully complete development and commercialization of our products. In addition, \$1,725,000 principal amount of debt plus interest thereon matured in three tranches beginning in November 2010. On February 9, 2011, the Company entered into a waiver and forbearance agreement with the requisite holders of the 12% senior secured notes whereby the holders of the Notes agreed to forbear the exercise of their rights under the Notes and waive the default thereof until December 31, 2011 (see Note 14).

The Company does not have the financial resources necessary to conduct the pivotal trial of AST-726 and will have to raise funds for that purpose.

The Company's continued operation will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances and its ability to realize the full potential of its technology in development. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long-term.

These matters raise substantial doubt about the Company's 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.

(3) Summary of Significant Accounting Policies

Basis of Presentation

The Company has not generated any revenue from its operations and, accordingly, the financial statements have been prepared in accordance with the provisions of accounting and reporting for Development Stage Enterprises.

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Manhattan Pharmaceuticals, Inc. and Subsidiary  
(a Development Stage Company)  
Notes to Consolidated Financial Statements

#### 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

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

The Company often contracts 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, the Company records monthly accruals 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.

#### Fair Value Measurements

On January 1, 2008, the Company adopted a standard to establish a consistent framework in how to value the fair value of assets and liabilities. This framework is intended to increase consistency in how fair value determinations are made under various existing accounting standards that permit, or in some cases require, estimates of fair market value. This standard also expands financial statement disclosure requirements about a company's use of fair value measurements, including the effect of such measures on earnings.

This standard defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. This standard also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. That hierarchy is as follows:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Observable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the market approach to measure fair value of its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The Company's financial assets (cash equivalents) as of December 31, 2010 were held in money market funds which is a Level 1 measurable input.

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Manhattan Pharmaceuticals, Inc. and Subsidiary  
(a Development Stage Company)  
Notes to Consolidated Financial Statements

The Company utilizes the Black-Scholes Option Pricing model to estimate the fair value of its derivative liability associated with warrant obligations and a convertible note obligation (see Note 10). The Company considers them to be Level 3 instruments. The following table shows the weighted average assumptions the Company used to develop the fair value estimates for the determination of the derivative liability in 2010 and 2009:

	2010	2009
Fair value	\$0.0050 - \$0.0067	\$0.0406 - \$0.0495
Expected volatility	89% - 104%	94% - 118%
Dividend yield	-	-
Expected term (in years)	2.26 - 4.27	1.82 - 4.83
Risk-free interest rate	0.61% - 1.52%	1.14% - 2.69%

The following table summarizes the changes in Level 3 instruments for the years ended December 31, 2010 and 2009:

	2010	2009
Fair value at January 1	\$ 784,777	\$ 22,222
Purchases, sales, issuances and settlements	3,272,122	202,490
Net unrealized (gain)/loss	(3,522,053)	560,065
Fair value at December 31	\$ 534,846	\$ 784,777

#### In-process Research and Development

All acquired research and development projects are recorded at their fair value as of the date acquisition. The fair values are assessed as of the balance sheet date to ascertain if there has been any impairment of the recorded value. If there is an impairment, the asset is written down to its current fair value by the recording of an expense. Impairment is tested on an annual basis, and consists of a comparison of the fair value of the in-process research and development with its carrying amount.

#### Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between financial statement carrying amounts of existing assets and liabilities, and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in



which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized.

#### Computation of Net Income (Loss) per Common Share

Basic net income (loss) per common share is calculated by dividing net income (loss) applicable to common shares by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net income (loss) per common share, since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because the Company incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The amounts of potentially dilutive securities excluded from the calculation were 211,559,852 and 99,159,628 shares at December 31, 2010 and 2009, respectively. These amounts do not include the 71,428,571 shares issuable upon the exercise of the put or call rights issued in connection with the Hedrin JV (see Note 6). All of the dilutive securities are out of the money and are, therefore, excluded from the computation of diluted earnings per share for the year ended December 31, 2010.

Manhattan Pharmaceuticals, Inc. and Subsidiary  
(a Development Stage Company)  
Notes to Consolidated Financial Statements

### Share-Based Compensation

The Company has stockholder-approved stock incentive plans for employees, directors, officers and consultants. Prior to January 1, 2006, the Company accounted for the employee, director and officer plans using the intrinsic value method. Effective January 1, 2006, the Company adopted the share-based payment method for employee options using the modified prospective transition method. We use a Black-Scholes model to estimate the fair value.

The Company recognizes compensation expense related to stock option grants on a straight-line basis over the vesting period. For the years ended December 31, 2010 and 2009, the Company recognized share-based employee compensation cost of \$217,479 and \$353,438, respectively. The Company did not capitalize any share-based compensation cost.

Options granted to consultants and other non-employees are recorded at fair value at the date of grant and subsequently adjusted to fair value at the end of each reporting period until such options vest, and the fair value of the options, as adjusted, is amortized to consulting expense over the related vesting period. As a result of adjusting consultant and other non-employee options to fair value as of December 31, 2010 and 2009, respectively, net of amortization, the Company recognized an increase to general and administrative and research and development expenses of \$217 for the year ended December 31, 2010 and an increase to general and administrative and research and development expenses of \$1,725 for the year ended December 31, 2009. The Company has allocated share-based compensation costs to general and administrative, and research and development expenses as follows:

	2010	2009
<b>General and administrative expense:</b>		
Share-based employee compensation cost	\$ 217,262	\$ 351,713
Share-based consultant and non-employee cost	22	172
	217,284	351,885
<b>Research and development expense</b>		
Share-based employee compensation cost	-	-
Share-based consultant and non-employee cost	195	1,553
	195	1,553
<b>Total share-based compensation</b>	<b>\$ 217,479</b>	<b>\$ 353,438</b>

To compute compensation expense in 2010 and 2009 the Company estimated the fair value of each option award on the date of grant using the Black-Scholes model. The Company based the expected volatility assumption on a volatility index of peer companies as the Company did not have a sufficient number of years of historical volatility of its common stock. The expected term of options granted represents the period of time that options are expected to be outstanding. The Company estimated the expected term of stock options by the simplified method. The expected forfeiture rates are based on the historical employee forfeiture experiences. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company has not declared a dividend on its common stock since its inception and has no intentions of declaring a dividend in the foreseeable future and therefore used a dividend yield of zero.

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The following table shows the weighted average assumptions the Company used to develop the fair value estimates for the determination of the compensation charges in 2010 and 2009:

	2010		2009	
Expected volatility	87	%	94	%
Dividend yield	-		-	
Expected term (in years)	5.7		6.5	
Risk-free interest rate	2.47		2.63	

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Manhattan Pharmaceuticals, Inc. and Subsidiary  
(a Development Stage Company)  
Notes to Consolidated Financial Statements

The Company has shareholder-approved incentive stock option plans for employees under which it has granted non-qualified and incentive stock options. In December 2003, the Company established the 2003 Stock Option Plan (the "2003 Plan"), which provided for the granting of up to 5,400,000 options to officers, directors, employees and consultants for the purchase of stock. Subsequently, the Company increased the number of shares of common stock reserved for issuance under the 2003 Plan by 9,600,000 shares. At December 31, 2010, 15,000,000 shares were authorized for issuance. The options have a maximum term of 10 years and vest over a period determined by the Company's Board of Directors (generally 3 years) and are issued at an exercise price equal to or greater than the fair market value of the shares at the date of grant. The 2003 Plan expires on December 10, 2013 or when all options have been granted, whichever is sooner. At December 31, 2010, options to purchase 10,437,696 shares were outstanding, 27,776 shares of common stock were issued and there were 4,534,528 shares reserved for future grants under the 2003 Plan.

In July 1995, the Company established the 1995 Stock Option Plan (the "1995 Plan"), which provided for the granting of options to purchase up to 130,000 shares of the Company's common stock to officers, directors, employees and consultants. The 1995 Plan was amended several times to increase the number of shares reserved for stock option grants. In June 2005, the 1995 Plan expired and no further options can be granted. At December 31, 2010, options to purchase 1,137,240 shares were outstanding and no shares were reserved for future stock option grants under the 1995 Plan.

#### Financial Instruments

At December 31, 2010 and December 31, 2009, the fair values of cash and cash equivalents, accounts payable, the convertible 5% notes payable, the ICON convertible note payable and the secured 12% notes payable approximate their carrying values. At December 31, 2009 the fair value of the convertible 12% note does not approximate its carrying value as a portion of the fair value is reflected as a component of derivative liability. On April 8, 2010, the holder of the convertible 12% note exercised its option to convert (see Note 7).

#### Cash and Cash Equivalents

Cash equivalents consist of cash or short term investments with original maturities at the time of purchase of three months or less.

#### Property and Equipment

Property and equipment are stated at cost. Depreciation is provided using the straight-line method over estimated useful lives. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts, and any resulting gain or loss is recognized in operations for the period. Amortization of leasehold improvements is calculated using the straight-line method over the remaining term of the lease or the life of the asset, whichever is shorter. The cost of repairs and maintenance is charged to operations as incurred; significant renewals and improvements are capitalized.

#### Derivative Liability

The Company evaluates whether warrants or convertible instruments to acquire stock of the Company contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price under the respective agreements. Down-round provisions reduce the exercise price of a warrant or convertible instrument if a company either issues equity shares for a price that is lower than the exercise price, and such instruments are recorded as derivative liabilities. The Company uses a Black-Scholes model to estimate the fair value of its convertible notes and warrants.

Equity in Joint Venture

The Company accounts for its investment in joint venture (see Note 6) using the equity method of accounting. Under the equity method, the Company records its pro-rata share of joint venture income or losses and adjusts the basis of its investment accordingly.

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Manhattan Pharmaceuticals, Inc. and Subsidiary  
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Notes to Consolidated Financial Statements

#### New Accounting Pronouncements

In June 2008, the FASB ratified a pronouncement which provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. This statement was effective for fiscal years beginning after December 15, 2008. The adoption of this statement had a significant impact on the Company's financial statements (see Note 10).

In January 2010, the Financial Accounting Standards Board ("FASB") issued a new pronouncement, "Improving Disclosures about Fair Value Measurements". 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 the Company's results of operations or financial condition.

In April 2010, the FASB issued a new pronouncement "Revenue Recognition – Milestone Method". This pronouncement provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. A vendor can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The following criteria must be met for a milestone to be considered substantive. The consideration earned by achieving the milestone should 1. Be commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from the vendor's performance to achieve the milestone. 2. Related solely to past performance. 3. Be reasonable relative to all deliverables and payment terms in the arrangement. No bifurcation of an individual milestone is allowed and there can be more than one milestone in an arrangement. Accordingly, an arrangement may contain both substantive and nonsubstantive milestones. This pronouncement is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this guidance does not have a material impact on our financial statements.

(4) Property and Equipment

Property and equipment consist of the following at December 31:

	2010	2009
Property and equipment	\$ 38,748	\$ 35,905
Less accumulated depreciation	(35,764)	(32,364)
Net property and equipment	\$ 2,984	\$ 3,541

(5) Stockholders' Equity

As described in Note 1 the Company completed a reverse acquisition of privately held Manhattan Research Development, Inc. on February 21, 2003. In July 2003, the Board of Directors adopted a resolution authorizing an amendment to the certificate of incorporation providing for a 1-for-5 combination of the Company's common stock. The resolution approving the 1-for-5 combination was thereafter consented to in writing by holders of a majority of the Company's outstanding common stock and became effective in September 2003. Accordingly, all share and per share information in these financial statements has been restated to retroactively reflect the 1-for-5 combination and the effects of the Reverse Merger.

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Manhattan Pharmaceuticals, Inc. and Subsidiary  
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2001

During 2001, the Company issued 10,167,741 shares of its common stock to investors for subscriptions receivable of \$4,000 or \$0.0004 per share. During 2002, the Company received the \$4,000 subscription receivable.

2002

During 2002, the Company issued 2,541,935 shares of its common stock to Oleoyl-estrone Developments, S.L. (“OED”) in conjunction with a license agreement (the OED License Agreement”). We valued these shares at their then estimated fair value of \$1,000.

During 2002, the Company issued options to purchase 1,292,294 shares of its common stock in conjunction with several consulting agreements. The fair value of these options was \$60,589. The Company expensed \$22,721 in 2002 and \$37,868 in 2003.

During 2002 and 2003, the Company completed two private placements. During 2002, the Company issued 3,043,332 shares of its common stock at \$0.63 per share and warrants to purchase 304,333 of its common stock in a private placement. After deducting commissions and other expenses relating to the private placement, the Company received net proceeds of \$1,704,318.

2003

During 2003, the Company issued an additional 1,321,806 shares of its common stock at \$0.63 per share and warrants to purchase 132,181 shares of its common stock. After deducting commissions and other expenses relating to the private placement, the Company received net proceeds of \$743,691. In connection with these private placements, the Company issued to the placement agent warrants to purchase 1,658,753 shares of its common stock.

As described in Note 1, during 2003, the Company completed a reverse acquisition. The Company issued 6,287,582 shares of its common stock with a value of \$2,336,241 in the reverse acquisition.

In November 2003, the Company issued 1,000,000 shares of its newly-designated Series A Convertible Preferred Stock (the “Convertible Preferred”) at a price of \$10 per share in a private placement. After deducting commissions and other expenses relating to the private placement, the Company received net proceeds of \$9,046,176. Each share of Convertible Preferred was convertible at the holder’s election into shares of the Company’s common stock at a conversion price of \$1.10 per share. The conversion price of the Convertible Preferred was less than the market value of the Company’s common stock on the date of issuance. Accordingly for the year ended December 31, 2003 the Company recorded a separate charge to deficit accumulated during development stage for the beneficial conversion feature associated with the issuance of Convertible Preferred of \$418,182. The Convertible Preferred had a payment-in-kind annual dividend of five percent. Maxim Group, LLC of New York, together with Paramount Capital, Inc., a related party, acted as the placement agents in connection with the private placement.

2004

During 2004, the Company issued 3,368,952 shares of its common stock at a price of \$1.10 per share in a private placement. After deducting commissions and other expenses relating to the private placement, the Company received net proceeds of \$3,361,718. In connection with the common stock private placement and the Convertible Preferred private placement, the Company issued to the placement agents a warrant to purchase 1,235,589 shares of its common stock.



During 2004, the Company recorded a dividend on the Convertible Preferred of \$585,799. 24,901 shares of Convertible Preferred were issued in payment of \$282,388 of this in-kind dividend. Also during 2004, 170,528 shares of Convertible Preferred were converted into 1,550,239 shares of the Company's common stock at \$1.10 per share.

During 2004, the Company issued 27,600 shares of common stock upon the exercise of stock options.

During 2004, the Company issued warrants to purchase 110,000 shares of its common stock in conjunction with three consulting agreements. The fair value of these warrants was \$120,968. The Company expensed \$100,800 in 2004 and \$20,168 in 2005.

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2005

In August 2005, the Company issued 11,917,680 shares of its common stock and warrants to purchase 2,383,508 shares of its common stock in a private placement at \$1.11 and \$1.15 per share. After deducting commissions and other expenses relating to the private placement the Company received net proceeds of \$12,250,209. Paramount BioCapital, Inc. ("Paramount"), an affiliate of a significant stockholder of the Company, acted as placement agent and was paid cash commissions and expenses of \$967,968 of which \$121,625 was paid to certain selected dealers engaged by Paramount in the private placement. The Company also issued warrants to purchase 595,449 shares of common stock to Paramount and certain select dealers, of which Paramount received warrants to purchase 517,184 common shares. Timothy McInerney and Dr. Michael Weiser, each a director of the Company, were employees of Paramount BioCapital, Inc. at the time of the transaction.

During 2005, the Company recorded a dividend on the Convertible Preferred of \$175,663. 41,781 shares of Convertible Preferred were issued in payment of this \$175,663 in-kind dividend and the unpaid portion of the 2004 in-kind dividend, \$303,411. Also during 2005, the remaining 896,154 shares of Convertible preferred were converted into 8,146,858 shares of the Company's common stock.

During 2005, the Company issued 675,675 shares of its common stock at \$1.11 per share and warrants to purchase 135,135 shares of its common stock to Cato BioVentures, an affiliate of Cato Research, Inc., in exchange for satisfaction of \$750,000 of accounts payable owed by the Company to Cato Research, Inc. Since the value of the shares and warrants issued was approximately \$750,000, there is no impact on the statement of operations for this transaction.

During 2005, the Company issued 312,245 shares of common stock upon the exercise of stock options and warrants. As described in Note 1, in April 2005, the Company completed the Merger with Tarpan. In accordance with the Agreement, the stockholders of Tarpan received 10,731,052 shares of the Company's common stock with a value of \$11,052,984.

2006

During 2006, the Company issued 27,341 shares of common stock upon the exercise of warrants.

2007

On March 30, 2007, the Company entered into a series of subscription agreements with various institutional and other accredited investors for the issuance and sale in a private placement of an aggregate of 10,185,502 shares of its common stock for total net proceeds of approximately \$7.85 million, after deducting commissions and other costs of the transaction. Of the total amount of shares issued, 10,129,947 were sold at a per share price of \$0.84, and an additional 55,555 shares were sold to an entity affiliated with a director of the Company, at a per share price of \$0.90, the closing sale price of the common stock on March 29, 2007. Pursuant to the subscription agreements, the Company also issued to the investors 5-year warrants to purchase an aggregate of 3,564,897 shares of common stock at an exercise price of \$1.00 per share. The warrants are exercisable during the period commencing September 30, 2007 and ending March 30, 2012. Gross and net proceeds from the private placement were \$8,559,155 and \$7,852,185, respectively.

Pursuant to these subscription agreements the Company filed a registration statement on Form S-3 covering the resale of the shares issued in the private placement, including the shares issuable upon exercise of the investor warrants and the placement agent warrants, with the Securities and Exchange Commission on May 9, 2007, which was declared

effective by the Securities and Exchange Commission on May 18, 2007.

The Company engaged Paramount, an affiliate of a significant stockholder of the Company, as its placement agent in connection with the private placement. In consideration for its services, the Company paid aggregate cash commissions of approximately \$600,000 and issued to Paramount a 5-year warrant to purchase an aggregate of 509,275 shares at an exercise price of \$1.00 per share.

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2008

During 2008, the Company issued warrants to purchase 140,000 shares of its common stock to directors, officers and an employee in conjunction with the secured 10% notes.

During 2008, the Company issued a put for the issuance of 55.6 million shares of its common stock and a warrant to purchase 11.1 million shares of its common stock in conjunction with a joint venture transaction (see Notes 6 and 9).

During 2008, the Company issued warrants to purchase 50.4 million shares of its common stock to the investors and the placement agent in conjunction with the sale of the secured 12% notes.

2009

During 2009, the Company issued warrants to purchase 15.7 million shares of its common stock to the investors and the placement agent in conjunction with the sale of the secured 12% notes (see Note 7).

During 2009, the Company issued warrants to purchase 2.4 million shares of its common stock to the investors and the placement agent in conjunction with the sale of the convertible 12% notes (see Note 7).

2010

During 2010, the Company entered into subscription agreements with accredited investors pursuant to which the Company issued a total of 43.3 million shares of the Company's common stock at an issue price of \$0.07 (see Note 8).

On March 8, 2010, the Company entered into the Merger Agreement by and among the Company, Ariston and 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 the Company. Under the terms of the Merger Agreement, the consideration payable by Manhattan to the stockholders and note holders of Ariston consists of the issuance of 7,062,423 shares of Manhattan's common stock, par value \$0.001 per share (see Note 3).

(6) Joint Venture

In February 2008, the Company and Nordic Biotech Advisors ApS through its investment fund Nordic Biotech Venture Fund II K/S ("Nordic") entered into a 50/50 joint venture agreement (the "Hedrin JV Agreement") to develop and commercialize the Company's North American rights (under license) to its Hedrin product.

Pursuant to the Hedrin JV Agreement, Nordic formed a new Danish limited partnership, Hedrin Pharmaceuticals K/S, (the "Hedrin JV") and provided it with initial funding of \$2.5 million and the Company assigned and transferred its North American rights in Hedrin to the Hedrin JV in return for a \$2.0 million cash payment from the Hedrin JV and equity in the Hedrin JV representing 50% of the nominal equity interests in the Hedrin JV. At closing the Company recognized an investment in the Hedrin JV of \$250,000 and an exchange obligation of \$2,054,630. The exchange obligation represents the Company's obligation to Nordic to issue the Company's common stock in exchange for all or a portion of Nordic's equity interest in the Hedrin JV upon the exercise by Nordic of the put issued to Nordic in the Hedrin JV Agreement transaction. The put is described below.

The original terms of the Hedrin JV Agreement also provided that should the Hedrin JV be successful in achieving a payment milestone, namely that by September 30, 2008, the FDA determines to treat Hedrin as a medical device,

Nordic will purchase an additional \$2.5 million of equity in the Hedrin JV, whereupon the Hedrin JV will pay the Company an additional \$1.5 million in cash and issue additional equity in the JV valued at \$2.5 million, thereby maintaining the Company's 50% ownership interest in the Hedrin JV. These terms have been amended as described below.

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In June 2008, the Hedrin JV Agreement was amended (the "Hedrin JV Amended Agreement"). Under the amended terms Nordic invested an additional \$1.0 million, for a total of \$3.5 million, in the Hedrin JV and made an advance of \$250,000 to the Hedrin JV and the Hedrin JV made an additional \$1.0 million payment, for a total of \$3.0 million, to the Company. The Hedrin JV also distributed additional ownership equity sufficient for each of the Company and Nordic to maintain their ownership interest at 50%. The FDA classified Hedrin as a Class III medical device in February 2009. Under the amended terms, upon attaining this classification of Hedrin by the FDA, Nordic invested an additional \$1.25 million, for a total investment of \$5 million, into the Hedrin JV, the Hedrin JV paid an additional \$0.5 million, for a total of \$3.5 million, to the Company and the \$250,000 that Nordic advanced to the Hedrin JV in June became an equity investment in the Hedrin JV by Nordic. The Hedrin JV was obligated to issue to the Company and Nordic additional ownership interest in the Hedrin JV, thereby maintaining each of the Company's and Nordic's 50% ownership interest in the Hedrin JV.

In February 2009, the Company's exchange obligation increased by \$1,000,000 and the Company's investment in the Hedrin JV increased by \$500,000 as a result of the investment by Nordic of an additional \$1.25 million into the Hedrin JV, the reclassification of the advance made by Nordic in June 2008 to the Hedrin JV of \$250,000 into an equity interest and the payment of \$500,000 by the Hedrin JV to the Company. At both December 31, 2010 and 2009, the Company's exchange obligation is \$3,949,176.

During the years ended December 31, 2010 and 2009, the Company recognized \$0 and \$500,000, respectively, of equity in the losses of the Hedrin JV. This reduced the carrying value of its investment in the Hedrin JV to \$0 at both December 31, 2010 and 2009. As of December 31, 2010, the Company's estimated share of the losses is \$1,060,000; equity in losses of Hedrin JV previously recognized was \$500,000 leaving an estimated balance of \$560,000 of losses that were not recognized as of December 31, 2010, since the investment was already written down to zero and the Company has no obligation to provide additional equity financing for this amount.

Nordic had an option to put all or a portion of its equity interest in the Hedrin JV to the Company in exchange for the Company's common stock. The Company had an option to call all or a portion of Nordic's equity interest in the Hedrin JV in exchange for the Company's common stock. The put and call options terminated in January 2011 (see Note 14).

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 T&R, the licensor of Hedrin.

The Hedrin JV engaged the Company to provide management services to the Limited Partnership in exchange for a management fee. For the years ended December 31, 2010 and 2009, the Company has recognized \$300,000 and \$333,845, respectively, of other income from management fees earned from the Hedrin JV which is included in the Company's statements of operations for the years ended December 31, 2010 and 2009 as a component of interest and other income. The agreement to provide management services was terminated in January 2011 (see Note 14).

Nordic paid to the Company a non-refundable fee of \$150,000 at the closing for the right to receive a warrant covering shares of the Company's common stock. The warrant terminated in January 2011 (see Note 14).

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The Company granted Nordic registration rights for the shares to be issued upon exercise of the warrant, the put or the call. The Company filed an initial registration statement on May 1, 2008. The registration statement was declared effective on October 15, 2008. On June 2, 2009, the Company filed an additional Registration Statement registering the additional 28,769,841 shares of Common Stock that may be issued to Nordic upon exercise of a put right held by Nordic as a result of Nordic's additional investment of \$1,250,000 in Hedrin JV pursuant to the terms of the Partnership Agreement and as adjusted pursuant to the anti-dilution provisions of the put right (the "Put Shares") and the additional 3,968,254 shares issuable upon exercise of an outstanding warrant held by Nordic. The Securities and Exchange Commission ("SEC") has informed the Company that the Company may not register the Put Shares for resale until Nordic exercises its put right and such shares of Common Stock are outstanding. The Company believes that it has used commercially reasonable efforts to cause the registration statement to be declared effective and has satisfied its obligations under the registration rights agreement with respect to the registration of the Put Shares. The Company was required to file additional registration statements, if required, within 45 days of the date the Company first knows that such additional registration statement was required. As of January 2011 the Company is no longer required to file additional registration statements.

The profits of the Hedrin JV are to be shared by the Company and Nordic in accordance with their respective equity interests in the Limited Partnership, which, prior to the January 4, 2011 settlement and release agreement (see Note 14), were 55% to Nordic and 45% to Manhattan, except that Nordic will get a minimum distribution from the Hedrin JV equal to 6% on Hedrin sales, as adjusted for any change in Nordic's equity interest in the Limited Partnership. If the Hedrin JV realizes a profit equal to or greater than a 12% royalty on Hedrin sales, then profits will be shared by the Company and Nordic in accordance with their respective equity interests in the Limited Partnership. However, in the event of a liquidation of the Limited Partnership, Nordic's distribution in liquidation will be at least equal to the amount Nordic invested in the Hedrin JV (\$5 million) plus 10% per year, less the cumulative distributions received by Nordic from the Hedrin JV. If the Hedrin JV's assets in liquidation exceed the Nordic liquidation preference amount, then any excess shall be distributed to the Company until its distribution and the Nordic liquidation preference amount are in the same ratio as the respective equity interests in the Hedrin JV and the remainder, if any, shall be distributed to Nordic and the Company in the same ratio as the respective equity interests. Further, in no event shall Nordic's distribution in liquidation be greater than assets available for distribution in liquidation. After the January 4, 2011 settlement and release agreement (see Note 14) the respective equity interests in the Limited Partnership were 85% to Nordic and 15% to Manhattan.

On January 4, 2011 the Company entered into settlement and release agreement (the "Settlement and Release Agreement") with Nordic Biotech Venture Fund II K/S ("Nordic") and H Pharmaceuticals K/S (the "Joint Venture"). As previously reported, the Company and Nordic have had various disputes relating to the Joint Venture and to Nordic's option to purchase Company common stock in exchange for a portion of Nordic's interest in the Joint Venture (the "Put Right"), and Nordic's warrant to purchase Company common stock (the "Warrant"). The Settlement and Release Agreement resolves all disputes between the Company, on the one hand, and Nordic and the Joint Venture, on the other (see Note 14).

(7) Notes Payable

The following is a summary of Notes Payable:

At December 31, 2010			At December 31, 2009		
Current portion, net	Noncurrent portion, net	Total	Current portion, net	Noncurrent portion, net	Total

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Secured 12%						
Notes Payable	\$ 1,722,346	\$ -	\$ 1,722,346	\$ 1,247,062	\$ 384,473	\$ 1,631,535
8% Note						
Payable	-	-	-	27,000	-	27,000.00
Non-interest						
Bearing Note						
Payable	231,900	-	231,900	-	211,901	211,901
Convertible						
12% Note						
Payable	-	-	-	-	17,807	17,807
Convertible 5%						
Notes Payable	-	15,452,793	15,452,793	-	-	-
ICON						
Convertible						
Note Payable	100,000	677,778	777,778	-	-	-
Total	\$ 2,054,246	\$ 16,130,571	\$ 18,184,817	\$ 1,274,062	\$ 614,181	\$ 1,888,243

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a. Secured 12% Notes Payable

On November 19, 2008, December 23, 2008 and February 3, 2009, the Company completed the first, second and final closings on a financing transaction (the "Secured 12% Notes Transaction"). The Company sold \$1,725,000 of 12% senior secured notes (the "Secured 12% Notes") and issued warrants to the investors to purchase 57.5 million shares of the Company's common stock at \$0.09 per share. The warrants expire on December 31, 2013. Net proceeds of \$1.4 million were realized from the three closings. In addition, \$78,000 of issuance costs were paid outside of the closings.

National Securities Corporation ("National") was the placement agent for the Secured 12% Notes Transaction. National's compensation for acting as placement agent was a cash fee of 10% of the gross proceeds received, a non-accountable expense allowance of 1.5% of the gross proceeds, reimbursement of certain expenses and a warrant to purchase such number of shares of the Company's common stock equal to 15% of the shares underlying the warrants issued to the investors. The Company paid National a total of \$202,000 in placement agent fees, a non-accountable expense allowance and reimbursement of certain expenses. In addition, the Company issued warrants to purchase 8.6 million shares of the Company's common stock at \$0.09 per share. These warrants were valued at \$29,110 and are a component of Secured 12% notes payable issue costs. The warrants expire on December 31, 2013.

The Secured 12% Notes mature two years after issuance. Interest on the Secured 12% Notes is compounded quarterly and payable at maturity. At December 31, 2010 and December 31, 2009, accrued and unpaid interest on the Secured 12% Notes amounted to approximately \$481,000 and \$229,000, and is reflected in the accompanying consolidated balance sheets at December 31, 2010 and December 31, 2009, respectively, as part of interest payable. The Secured 12% Notes are secured by a pledge of all of the Company's assets except for its investment in the Hedrin JV. In addition, to provide additional security for the Company's obligations under the notes, the Company entered into a default agreement, which provides that upon an event of default under the notes, the Company shall, at the request of the holders of the notes, use reasonable commercial efforts to either (i) sell a part or all of the Company's interests in the Hedrin JV or (ii) transfer all or part of the Company's interest in the Hedrin JV to the holders of the notes, as necessary, in order to fulfill the Company's obligations under the notes, to the extent required and to the extent permitted by the applicable Hedrin joint venture agreements.

In connection with the private placement, the Company, 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 Securities and Exchange Commission). The registration statement was filed and declared effective on April 17, 2009.

The Company incurred a total of approximately \$424,000 of costs in the issuance of the \$1,725,000 of Secured 12% Notes sold in 2008 and 2009. These costs were capitalized and are being amortized over the life of the Secured 12% Notes into interest expense. During the years ended December 31, 2010 and 2009, the amount amortized into interest expense was approximately \$197,000 and \$206,000, respectively. The remaining unamortized balance of approximately \$4,400 and \$159,000 is reflected in the accompanying consolidated balance sheets as of December 31, 2010 and 2009, respectively, as debt issue costs.

The Company recognized an original issue discount (the "OID") of approximately \$194,000 on the issuance of the Secured 12% Notes sold for the value of the warrants issued to the investors. The OID is being amortized over the life

of the Secured 12% Notes into interest expense. During the years ended December 31, 2010 and 2009 the amount amortized into interest expense was approximately \$91,000 and \$94,000, respectively. The remaining unamortized balance of approximately \$2,700 and \$93,000 has been netted against the face amount of Notes Payable in the accompanying consolidated balance sheets as of December 31, 2010 and 2009, respectively.

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The principal amount of Secured 12% Notes plus interest thereon matured in three tranches beginning in November 2010. On February 9, 2011, the Company entered into a waiver and forbearance agreement with the requisite holders of the Secured 12% Notes whereby the holders of the Notes agreed to forbear the exercise of their rights under the Notes and waive the default thereof until December 31, 2011 (see Note 14).

b. 8% Note Payable

On December 21, 2009, the Company entered into a Future Advance Promissory Note (the "8% Note") with Ariston under which the Company may withdraw up to \$67,000 bearing interest at a rate of 8%. As of December 31, 2009, the Company had withdrawn \$27,000 from Ariston subject to the terms of the 8% Note. On January 13, 2010, the Company withdrew an additional \$20,000 subject to the 8% Note and on January 28, 2010, the Company withdrew an additional \$20,000 subject to the 8% Note.

On March 4, 2010, the Company repaid Ariston the \$67,000 withdrawn subject to the 8% Note and accrued interest of \$816.

c. Non-interest Bearing Note Payable

On October 27, 2009, the Company entered into a Settlement Agreement and Mutual Release with Swiss Pharma Contract LTD ("Swiss Pharma") pursuant to which the Company agreed to pay Swiss Pharma \$200,000 and issue to 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 note matures in October 2011. The amount of the Arbitration award was \$683,027 at September 30, 2009 and was included as a component of accrued expenses.

In connection with the non-interest bearing note, the Company recognized an original issue discount of \$40,000 of imputed interest on the note, which is being amortized into interest expense on a straight-line basis over the two-year term of the note. For the years ended December 31, 2010 and 2009, the Company amortized \$20,000 and \$1,900 of the OID into interest expense, respectively. The remaining unamortized balance of \$18,100 has been netted against the face amount of Notes Payable in the accompanying consolidated balance sheet as of December 31, 2010.

d. Convertible 12% Note Payable

In October 2009, the Company entered into a Subscription Agreement (the "Subscription Agreement") pursuant to which it sold a 12% Original Issue Discount Senior Subordinated Convertible Debenture with a stated value of \$400,000 (the "Convertible 12% Note") and a warrant to purchase 2,222,222 shares of the Company's common stock, par value \$.001 per share for a purchase price of \$200,000. The Convertible 12% Note is convertible into shares of Common Stock at an initial conversion price of \$0.09 per share, subject to adjustment, or, in the event the Company issues new securities in connection with a financing, the Convertible 12% Note 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 Company may also, in its sole discretion, elect to pay interest due on the Convertible 12% Note quarterly in shares of the Company's common stock provided such shares are subject to an effective registration statement. The Convertible 12% Note is subordinated to the Company's outstanding Secured 12% Notes. The Warrant is exercisable at an exercise price of \$0.11 per share, subject to adjustment. Because the Convertible 12% Note and the Warrant are convertible into shares of the Company, subject to adjustment, the conversion feature is subject to Derivative Liability accounting (see Note 10).

National was the placement agent for the Convertible 12% Note transaction. In connection with the issuance of the Securities, the Company issued warrants to purchase an aggregate of 222,222 shares of Common Stock at an exercise

price of \$0.11 per share, subject to adjustment, to the placement agent and certain of its designees. Because the warrant is convertible into shares of the Company, subject to adjustment, the warrants are subject to Derivative Liability accounting (see Note 10). The warrants expire on October 28, 2014.

The Convertible 12% Notes mature two years after issuance. Interest on the Convertible 12% Note is compounded quarterly and payable at maturity. At December 31, 2009, accrued and unpaid interest on the Convertible 12% Note amounted to approximately \$9,000, and is reflected in the accompanying consolidated balance sheet at December 31, 2009 as a component of interest payable.

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On April 8, 2010, the holder (the "Noteholder") of the outstanding Convertible 12% Note exercised its option to convert its note (including all accrued interest thereon into 16.88 Units (as described in Note 9). The conversion price was equal to the per Unit purchase price paid by the Investors in the private placement. As a result of this conversion, the Company accelerated the amortization of approximately \$30,000 in issue costs and \$160,000 original issue discount, which is reflected as a loss on early extinguishment of debt in the accompanying consolidated statement of operations for the year ended December 31, 2010.

e. Convertible 5% Notes Payable

Upon the Merger, Ariston issued \$15,452,793 of five-year 5% notes payable (the "5% Notes Payable") in satisfaction of several note payable issuances. The 5% Notes Payable mature in March 2015. The cumulative liability including accrued and unpaid interest of these several issuances of notes was \$15,452,793 as of the Merger date. Interest is payable at maturity and compounds annually. The 5% Notes Payable and accrued and unpaid interest thereon are convertible at the option of the holder into the Manhattan's common stock at the conversion price of \$0.40 per share. Ariston agreed to make quarterly payments on the 5% Notes Payable equal to 50% of the gross proceeds resulting from the revenues received from the exploitation or commercialization of Ariston's product candidates, AST-726 and AST-915. The 5% Notes Payable are solely the obligation of Ariston and have no recourse to Manhattan other than the conversion feature discussed above. For the year ended December 31, 2010, the Company recorded approximately \$627,000 in accrued interest, which is reflected as a component of interest payable in the accompanying balance sheet as of December 31, 2010.

f. ICON Convertible Note Payable

Upon the Merger, Ariston satisfied an account payable of \$1,275,188 to ICON Clinical Research Limited through the payment of \$275,188 in cash and the issuance of a three-year 5% note payable (the "ICON Note Payable"). The principal was to be repaid in 36 monthly installments of \$27,778 commencing in April 2010 and ending in March 2013. Interest was payable monthly in arrears. The ICON Convertible Note Payable is convertible at the option of the holder into the Company's common stock at the conversion price of \$0.20 per share. During the year ended December 31, 2010, the Company has paid approximately \$256,000 in principal and interest to ICON. For the year ended December 31, 2010, the Company recorded approximately \$37,000 in interest expense as reflected on the accompanying consolidated statement of operations for the year ended December 31, 2010. The ICON Note Payable was amended in March 2011 (see Note 14).

(8) Ariston Merger

On March 8, 2010, the Company entered into the Merger Agreement by and among the Company, Ariston and 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 the Company.

Under the terms of the Merger Agreement, the consideration payable by Manhattan to the stockholders and note holders of Ariston consists of the issuance of 7,062,423 shares of Manhattan's common stock, par value \$0.001 per share, ("Common Stock") at Closing (as defined in the Merger Agreement) plus the right to receive up to an additional 24,718,481 shares of Common Stock (the "Milestone Shares") upon the achievement of certain product-related milestones described below. In addition, Manhattan has reserved 38,630,723 shares of its Common Stock for possible future issuance in connection with the conversion of \$15.45 million of outstanding Ariston convertible promissory notes. The noteholders will not have any recourse to Manhattan for repayment of the notes (their sole recourse being

to Ariston), but the noteholders will have the right to convert the notes into shares of the Manhattan's Common Stock at the rate of \$0.40 per share. Further, Manhattan has reserved 5,000,000 shares of its Common Stock for possible future issuance in connection with the conversion of the \$1.0 million outstanding Ariston convertible promissory note issued in satisfaction of a trade payable. The noteholder will not have any recourse to Manhattan for repayment of the note (their sole recourse being to Ariston), but the noteholder will have the right to convert the note into shares of Manhattan's Common Stock at the rate of \$0.20 per share.

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

- Upon the affirmative decision of Manhattan’s Board of Directors, provided that such decision is made prior to March 8, 2011, to further develop the AST-915, either internally or through a corporate partnership, Manhattan would issue 8,828,029 of the Milestone Shares. This milestone was attained in January 2011 and the shares were issued in March 2011.
- Upon the acceptance by the FDA of the Ariston’s filing of the first New Drug Application for the AST-726 product candidate, Manhattan would issue 7,062,423 of the Milestone Shares.
- Upon the Company receiving FDA approval to market the AST-726 product candidate in the United States of America, Manhattan would issue 8,828,029 of the Milestone Shares.

Certain members and former members of Manhattan’s board of directors and principal stockholders of Manhattan at the time of the Merger owned Ariston securities as of the closing of the Merger:

- Timothy McInerney, a director of Manhattan, 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, a director of Manhattan, indirectly owned convertible promissory notes of Ariston with interest and principal in the amount of \$192,739.
- Michael Weiser, a former director of Manhattan, 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 Manhattan 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.

The Company 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-licensed, developed and planned to market novel therapeutics for the treatment of serious disorders of the central and peripheral nervous systems.

The Merger date fair value of the total consideration paid was \$1,491,937 which consisted of 7,062,423 shares of the Company’s common stock issued upon the Merger and 15,890,452 contingently issuable shares upon Ariston’s attaining certain milestones as described above. At the time of the Merger, the Company did not believe the attainment of the milestone for AST-915 was highly probable and, therefore, recorded no contingent consideration relative to it. The par value of the contingently issuable common shares is reflected in the accompanying consolidated balance sheets as of December 31, 2010 as a component of stockholders’ deficiency, contingently issuable shares. The Company incurred \$9,527 of acquisition related costs.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the Merger date:

Cash and cash equivalents	\$ 519,365
Other assets	120,870
Total identifiable assets	640,235
Accounts payable and accrued expenses	437,615
ICON convertible note payable	1,000,000

5% convertible notes payable	15,452,793
Total identifiable liabilities	16,890,408
Net identifiable assets (liabilities)	(16,250,173)
In-process research and development acquired	17,742,110
Net assets acquired	\$ 1,491,937

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The following supplemental pro forma information presents the financial results as if the acquisition of Ariston had occurred on January 1, 2009 for the year ended December 31, 2009 and on January 1, 2010 for the year ended December 31, 2010. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2009 or January 1, 2010, nor are they indicative of future results.

Pro forma consolidated results:

	Year Ended December 31,	
	2010	2009
Revenue	\$ -	\$ -
Net income (loss)	\$ 545,096	\$ (5,005,827)
Basic and diluted earnings (loss) per share	\$ 0.005	\$ (0.064 )

(9) Equity Financing

On March 2, 2010, the Company raised aggregate gross proceeds of approximately \$2,547,500 pursuant to a private placement of its securities (the "2010 Equity Financing"). The Company entered into subscription agreements (the "Subscription Agreements") with seventy-seven accredited investors (the "Investors") pursuant to which the Company sold an aggregate of 101.9 Units (as defined herein) for a purchase price of \$25,000 per Unit. Pursuant to the Subscription Agreements, the Company issued to each Investor units (the "Units") consisting of (i) 357,143 shares of common stock, \$0.001 par value per share (the "Common Stock" or "Shares") of the Company and (ii) 535,714 warrants (each a "Warrant" and collectively the "Warrants"), each of which will entitle the holder to purchase one additional share of Common Stock for a period of five years (each a "Warrant Share" and collectively the "Warrant Shares") at an exercise price of \$0.08 per share. Because the Warrant Shares are convertible into common shares of the Company, subject to adjustment, the conversion feature is subject to Derivative Liability accounting (see Note 10).

National was the placement agent for the 2010 Equity Financing transaction. In connection with the issuance of the Securities, the Company issued warrants to purchase an aggregate of 3,369,289 shares of Common Stock at an exercise price of \$0.08 per share, subject to adjustment, to the placement agent and certain of its designees. Because the warrant is convertible into shares of the Company, subject to adjustment, the warrants are subject to Derivative Liability accounting (see Note 10). The warrants expire on March 2, 2015.

All of the Investors 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 closing of the private placement, the Company, the placement agent acting in connection with the private placement (the "Placement Agent") and the Investors entered into a Registration Rights Agreement, dated as of March 2, 2010, and the Company agreed to file a registration statement to register the resale of the shares, 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).

The Company received net proceeds of approximately \$2.2 million after payment of an aggregate of approximately \$300,000 of commissions and expense allowance to the Placement Agent, and approximately \$100,000 of other offering and related costs in connection with the private placement. In addition, the Company issued a warrant to purchase 3,652,146 shares of Common Stock at an exercise price of \$0.08 per share to the Placement Agent as additional compensation for its services.

The Company did not use any form of advertising or general solicitation in connection with the sale of the Units. The Shares, the Warrants and the Warrant Shares are non-transferable in the absence of an effective registration statement under the Act, or an available exemption therefrom, and all certificates are imprinted with a restrictive legend to that effect.

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On April 8, 2010, the Company completed the final closing of the 2010 Equity Financing. In connection with the final closing, the Company sold an aggregate of 2.4 additional Units and received net proceeds of approximately \$51,700 after payment of an aggregate of \$8,300 of commissions and expense allowance to placement agent. In connection with the final closing, the Company also issued a warrant to purchase 12,857 shares of Common Stock at an exercise price of \$0.08 per share to the placement agent as additional compensation for its services.

In addition on April 8, 2010, the holder of the Convertible 12% Note (see Note 7) with a stated value of \$400,000 and \$22,000 of accrued interest, exercised its option to convert its 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.

The Company issued a total of 6,885,717 shares of common stock and warrants to purchase 10,328,566 shares of common stock at an exercise price of \$0.08 per share to the investors in the final closing of the 2010 Equity Financing, including the conversion of the 12% Convertible Note.

(10) Derivative Liability

In April 2008, the FASB issued ASC 815 which provides guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in the pronouncement on accounting for derivatives. This pronouncement was effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of these requirements can affect the accounting for warrants and many convertible instruments with provisions that protect holders from a decline in the stock price (or “down-round” provisions). For example, warrants with such provisions will no longer be recorded in equity. Down-round provisions reduce the exercise price of a warrant or convertible instrument if a company either issues equity shares for a price that is lower than the exercise price of those instruments or issues new warrants or convertible instruments that have a lower exercise price. We evaluated whether warrants to acquire stock of the Company contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price under the respective warrant agreements. We determined that the warrant issued to Nordic in April 2008 (the “Nordic Warrant”), contained such provisions, thereby concluding it was not indexed to the Company’s own stock and was reclassified from equity to derivative liabilities.

In accordance with ASC 815, the Company estimated the fair value of the Nordic Warrant as of January 1, 2009 to be \$22,222 by recording a reduction in additional paid-in capital of \$150,000 and a decrease in deficit accumulated during the development stage of \$127,778. The effect of this adjustment is recorded as a cumulative effect of change in accounting principle in our statements of stockholders’ equity (deficiency).

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We also determined that the Convertible 12% Note Payable issued in 2009, the warrants issued in connection with the Convertible 12% Note Payable, and the warrants issued in connection with the 2010 Equity Financing contained such provisions and therefore are derivatives. We determined the fair value based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 815. The fair values of these derivatives are as follows:

	December 31, 2010	December 31, 2009	Purchases, sales, issuances and settlements	Change in Fair Value During 2010
Nordic Warrant	\$ 71,429	\$ 483,333	\$ -	\$ (411,904 )
Convertible 12% Note	-	180,444	(225,778 )	45,334
Warrants issued with Convertible 12% Notes	15,644	121,000	-	(105,356 )
Warrants issued in 2010 Equity Financing	447,773	-	3,497,900	(3,050,127)
<b>Total</b>	<b>\$ 534,846</b>	<b>\$ 784,777</b>	<b>\$ 3,272,122</b>	<b>\$ (3,522,053)</b>

In accordance with ASC 815, the fair value of these derivatives were recorded in the accompanying consolidated balance sheets as of December 31, 2010 and 2009, as a component of a current liability, derivative liability. The change in fair value during the years ended December 31, 2010 and 2009 were (\$3,522,053) and \$560,065, respectively and are reported as a non-cash charge in the accompanying consolidated statements of operations as a component of other (income) expense.

(11) Stock Options and Warrants

Stock Options

A summary of the status of the Company's stock options as of December 31, 2010 and changes during the period then ended is presented below:

	Shares	Weighted average exercise price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2009	7,459,936	\$ 0.72		
Granted	4,125,000	\$ 0.07	5.70	
Exercised	-			
Canceled	10,000	\$ 0.28		
Forfeited	-			
Outstanding at December 31, 2010	11,594,936	\$ 0.49	6.97	\$ -
Exercisable at December 31, 2010	9,999,936	\$ 0.55	6.62	\$ -
	11,404,992	\$ 0.49	6.94	\$ -

Vested and expected to vest at  
December 31, 2010

Weighted-average fair value of  
options granted during the year  
ended December 31, 2010                      \$    0.0464

As of December 31, 2010 and 2009, the total compensation cost related to nonvested option awards not yet recognized is \$49,865 and \$55,249, respectively. The weighted average period over which it is expected to be recognized is approximately 2.17 and 0.26 years, respectively.

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The following table summarizes the information about stock options outstanding at December 31, 2010:

Exercise Price	Number of Options Outstanding	Weighted Average Remaining Life	Number of Options Exercisable
\$ 0.07 - \$0.12	4,175,000	8.55	2,600,000
\$ 0.17 - \$0.28	3,150,750	7.35	3,150,750
\$ 0.70 - \$1.35	3,047,186	5.35	3,047,186
\$ 1.38 - \$1.65	1,202,000	4.55	1,202,000
<b>Total</b>	<b>11,574,936</b>		<b>9,999,936</b>

#### Stock Warrants

The following table summarizes the information about warrants to purchase shares of our common stock outstanding at December 31, 2010:

Exercise Price	Number of Warrants Outstanding	Remaining Contractual Life (years)	Number of Warrants Exercisable
\$ 1.00	4,074,172	1.25	4,074,172
0.28	150,000	1.72	150,000
0.09	39,675,079	2.97	39,675,079
0.09	10,733,355	3.06	10,733,355
0.09	15,716,698	3.18	15,716,698
0.20	140,000	2.78	140,000
0.08	58,228,555	4.25	58,228,555
0.08	10,341,424	4.33	10,341,424
0.07	14,285,714	2.45	14,285,714
0.07	3,841,269	3.92	3,841,269
<b>Total</b>	<b>157,186,266</b>		<b>157,186,266</b>

#### (12) Income Taxes

There was no current or deferred income tax expense for the years ended December 31, 2010 or 2009.

The components of deferred tax assets as of December 31, 2010 and 2009 are as follows:

	2010	2009
<b>Deferred income tax assets:</b>		
Tax loss carryforwards	\$ 24,065,000	\$ 23,170,000
Research and development credit	1,826,000	1,799,000
In-process research and development charge	4,850,000	4,850,000
Share-based compensation	1,691,000	1,603,000
Other	(897,000 )	537,000
<b>Gross deferred income tax assets</b>	<b>31,535,000</b>	<b>31,959,000</b>

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Less valuation allowance	(31,535,000)	(31,959,000)
Net deferred income tax assets	\$ -	\$ -

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The reasons for the difference between actual income tax benefit for the years ended December 31, 2010 and 2009 and the amount computed by applying the statutory Federal income tax rate to losses before income tax benefit are as follows:

	2010		2009	
	Amount	% of Pre-tax loss	Amount	% of Pre-tax loss
Federal income tax benefit at statutory rate	\$ 212,000	34.0 %	\$ (944,000 )	(34.0 )%
State income taxes, net of federal tax	43,000	6.8 %	(188,000 )	(6.8 )%
Research and development credits	(75,000 )	(11.5 )%	(50,000 )	(3.0 )%
Other	-	0.0 %	-	0.0 %
Change in valuation allowance	(180,000)	(29.3 )%	1,182,000	43.8 %
	\$ -	0.0 %	\$ -	0.0 %

A valuation allowance is provided when it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The net change in the total valuation allowance for the years ended December 31, 2010 and 2009 was \$(180,000) and \$1,182,000, respectively. The income tax benefit assumed using the Federal statutory tax rate of 34% has been reduced to an actual benefit of zero due principally to the aforementioned valuation allowance.

At December 31, 2010, the Company had unused Federal and state net operating loss carryforwards of approximately \$60,716,000 and \$50,322,000, respectively. The net operating loss carryforwards expire in various amounts through 2029 for Federal and state income tax purposes. The Tax Reform Act of 1986 contains provisions which limit the ability to utilize net operating loss carryforwards in the case of certain events including significant changes in ownership interests. Accordingly, a substantial portion of the Company's net operating loss carryforwards above will be subject to annual limitations (currently approximately \$100,000) in reducing any future year's taxable income. At December 31, 2010, the Company also had research and development credit carryforwards of approximately \$1,826,000 for Federal income tax purposes which expire in various amounts through 2029.

The Company files income tax returns in the U.S. Federal, State and Local jurisdictions. With certain exceptions, the Company is no longer subject to U.S. Federal and state income tax examinations by tax authorities for years prior to 2007. However, net operating loss carryforwards and tax credits generated from those prior years could still be adjusted upon audit. Effective January 1, 2007, the Company adopted guidance under ASC Topic 740-10 (formerly FIN 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109") which clarifies the accounting and disclosure for uncertainty in income taxes. The adoption of this interpretation did not have a material impact to the financial statements. The Company recognizes interest and penalties to uncertain tax position in income tax expense in the statement of operations.

The Company had no unrecognized tax benefits at December 31, 2010 that would affect the annual effective tax rate. Further, the Company is unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next twelve months.



(13)

License Agreements

Altoderm License Agreement

On April 3, 2007, the Company entered into a license agreement for “Altoderm” (the “Altoderm Agreement”) with T&R. Pursuant to the Altoderm Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altoderm, a topical skin lotion product candidate using sodium cromoglicate for the treatment of atopic dermatitis.

In February 2009, the Company terminated the Altoderm Agreement. The Company has no further financial liability or commitment to T&R under the Altoderm Agreement.

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Altolyn License Agreement

On April 3, 2007, the Company and T&R also entered into a license agreement for "Altolyn" (the "Altolyn Agreement"). Pursuant to the Altolyn Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altolyn, an oral formulation product candidate using sodium cromoglicate for the treatment of mastocytosis, food allergies, and inflammatory bowel disorder.

In February 2009, the Company terminated the Altolyn Agreement for convenience. The Company has no further financial liability or commitment to T&R under the Altolyn Agreement.

(14) Subsequent Events

Nordic Settlement

On January 4, 2011 the Company entered into settlement and release agreement (the "Settlement and Release Agreement") with Nordic Biotech Venture Fund II K/S ("Nordic") and H Pharmaceuticals K/S (the "Joint Venture"). The Company and Nordic are partners in the Joint Venture for the development and commercialization in North America of Hedrin™, a non-pesticide, one-hour, treatment for pediculosis (head lice). As previously reported, the Company and Nordic have had various disputes relating to the Joint Venture and to Nordic's option to purchase Company common stock in exchange for a portion of Nordic's interest in the Joint Venture (the "Put Right"), and Nordic's warrant to purchase Company common stock (the "Warrant"). The Settlement and Release Agreement resolves all disputes between the Company, on the one hand, and Nordic and the Joint Venture, on the other.

The principal terms of the Settlement and Release Agreement are:

- The Put Right has been terminated. The Company believed the Put Right permitted Nordic to become the owner, upon exercise of the Put Right, of 71,428,571 shares of the Company's common stock. Nordic asserted that the Put Right would have permitted Nordic to become the owner of 183,333,333 shares of the Company's common stock.
- The Warrant has been terminated. The Company believed the Warrant covered 14,285,714 shares of the Company's common stock. Nordic asserted that the Warrant covered 33,333,333 shares of the Company's common stock.
- Nordic was required to make an additional, non-dilutive capital contribution to the Joint Venture of \$1,500,000, which includes \$300,000 contributed to the Joint Venture by Nordic on December 15, 2010.
- The Joint Venture has paid to the Company a settlement amount of \$500,000, less any "Excess Payment" (defined below). An "Excess Payment" is the amount by which Nordic's and the Joint Venture's reasonable out-of-pocket legal and other costs incurred with respect to the Settlement and Release Agreement exceed \$70,000. To date there have been no Excess Payments.
- Our equity interest in the Joint Venture was reduced to 15%, and further reductions in our equity interest are possible if and when Nordic makes additional capital contributions to the Joint Venture. In no event shall the capital contributions by Nordic reduce our ownership in the Joint Venture below 5%.
- The Joint Venture has paid \$75,000 to the Company under the Services Agreement, dated February 21, 2008, and that Services Agreement is terminated as of December 31, 2010.
- The Joint Venture Agreement, dated January 31, 2008, as amended on February 18, 2008, and as further amended by an Omnibus Amendment on June 9, 2008, between Manhattan and Nordic; the Shareholders' Agreement, dated February 21, 2008, as amended by an Omnibus Amendment on June 9, 2008, with respect to the Joint Venture, and the Registration Rights Agreement, dated February 25, 2009, are terminated.
- Messrs. Michael G. McGuinness and Douglas Abel resigned from the Board of Directors of the Joint Venture.

Ariston Milestone Shares On January 31, 2011 the Company announced that its Board of Directors has decided to continue development of AST-915, an orally delivered treatment for essential tremor. Under the terms of the merger agreement between the Company and Ariston Pharmaceuticals, Inc., the achievement of this milestone requires the company to issue 8,828,029 shares of its common stock to debt holders and former shareholders of Ariston. The shares were issued in March 2011.

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#### Extension of Maturity Date of Secured 12% Notes

On February 9, 2011, the Company entered into a waiver and forbearance agreement (the "Extension Agreement") with the requisite holders of the 12% senior secured notes whereby the holders of the Notes (the "Noteholders") agreed to forbear the exercise of their rights under the Notes and waive the default thereof until December 31, 2011. The Company issued a total of \$1,725,000 principal amount of the Notes in 2008 and 2009. \$1,035,000 of the Notes matured on November 19, 2010, \$280,000 of the Notes matured on December 22, 2010 and \$410,000 of the Notes matured on February 3, 2011.

As part of the Extension Agreement, the Company has agreed to take prompt steps to seek to reduce its outstanding indebtedness by permitting the Noteholders to convert the Notes into shares of the Company's common stock at a conversion price of \$0.01 per share, which will require the Company to obtain stockholder approval to, among other things, increase the number of its authorized common stock. If the Secured 12% Notes convert into common stock at a conversion price of \$0.01 the antidilution rights of the warrants issued with Secured 12% Notes, the warrants issued with the Convertible 12% Note and the warrants issued in the 2010 Equity Pipe transaction will be triggered causing significant potential dilution to our current stockholders. The following table illustrates the potential dilution:

	As of March 15, 2011		Conversion of Secured 12% Notes		After Conversion	
	Shares	%	Shares (1)	Shares	%	
<b>Shares outstanding:</b>						
Before conversion	129,793,289	45.66 %		129,793,289	8.78 %	
<b>Conversion of Secured 12% Notes</b>						
Total outstanding	129,793,289		231,826,600	231,826,600	15.67 %	
<b>Shares issuable:</b>						
Options	11,574,936	4.07 %		11,574,936	0.78 %	
<b>Warrants:</b>						
<b>With antidilution rights:</b>						
<b>Issued with Secured 12% Notes</b>						
Other	57,500,115	20.23 %	460,000,920	517,501,035	34.99 %	
	72,411,248	25.47 %	503,037,467	575,448,715	38.90 %	
<b>Without antidilution rights</b>						
Total issuable	12,989,189	4.57 %		12,989,189	0.88 %	
Total outstanding and issuable	154,475,488		963,038,387	1,117,513,875		
	284,268,777	100.00 %	1,194,864,987	1,479,133,764	100.00 %	

(1) Share conversion assumes conversion of principal and interest on May 31, 2011, the date on which we project the conversion will occur.

#### Amendment of ICON Note Payable

On March 1, 2011 Ariston entered into an amended and restated convertible promissory note (the "Amended Note") with ICON Clinical Research Limited. The principal terms of the Amended Note are that monthly payments of

principal and interest will be waived for the thirteen month period ended December 31, 2011 (the “Waiver Period”) in exchange for a single payment of \$100,000 on March 31, 2011, an increase in the interest on the Amended Note from 5% to 8% per annum during the Waiver Period and a balloon payment on January 31, 2012. The Amended Note will decrease the debt service requirements of the Company and Ariston by approximately \$300,000 during the thirteen-month period ended December 31, 2011.

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