

NYMOX PHARMACEUTICAL CORP  
Form 20-F  
March 15, 2011

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**United States**  
**Securities and Exchange Commission**  
**Washington, D.C. 20549**

**Form 20 F**

Registration Statement pursuant to section 12(b) or (g) of the Securities Exchange Act of 1934

or

Annual Report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2010

or

Transition Report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934

or

Shell Corporation Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of event requiring this Shell Corporation Report  
for the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-12033

**NYMOX PHARMACEUTICAL CORPORATION**

(Exact name of registrant as specified in its charter)

**Canada**

(Jurisdiction of incorporation or organization)

9900 Cavendish Blvd., Suite 306

St. Laurent, Quebec, Canada, H4M 2V2

(Address of principal executive offices)

Contact person: Roy Wolvin

Tel. 800-936-9669, e-mail: rwolvin@nymox.com, fax: 514-332-2227

(name, telephone, e-mail and/or facsimile number and address of company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class

Name of each exchange on which registered

Common Stock

The NASDAQ Stock Market LLC (NASDAQ Capital Market)

Securities registered or to be registered pursuant to Section 12(g) of the Act

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act

None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

32,573,856 shares as of December 31, 2010

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes [ ] No [ X ]

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Yes [ ] No [ X ]

Indicate by check mark whether the registrant (1) has 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.

Yes [ X ] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website; if any, every interactive Date 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 that the registrant was required to submit and post such files).

Yes [ ] No [ ]

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP <input type="checkbox"/>	International Financial Reporting Standards <input type="checkbox"/>	Other <input checked="" type="checkbox"/>
	as issued by the International Accounting Standards Board.	

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:

Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell Company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

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In this annual report, the terms Nymox , The Corporation , we and us refers to both Nymox Pharmaceutical Corporation and its subsidiaries, Nymox Corporation and Serex Inc. Unless otherwise indicated all dollar amounts are in United States Dollars.

### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

You should be aware that this report contains forward-looking statements about, among other things, the anticipated operations, product development, financial condition and operating results of Nymox, proposed clinical trials and proposed transactions, including collaboration agreements.

By forward-looking statements, we mean any statements that are not statements of historical fact, including (but not limited to) statements preceded by or that include the words, believes , expects , anticipates , hopes , targets or similar expressions.

In connection with the safe harbor provisions in the Private Securities Litigation Reform Act of 1995, we are including this cautionary statement to identify some of the important factors that could cause Nymox's actual results or plans to differ materially from those projected in forward-looking statements made by, or on behalf of, Nymox. These factors, many of which are beyond the control of Nymox, include Nymox's ability to:

- identify and capitalize on possible collaboration, strategic partnering or divestiture opportunities;
- obtain suitable financing to support its operations and clinical trials;
- manage its growth and the commercialization of its products;
- achieve operating efficiencies as it progresses from a development-stage to a later-stage biotechnology corporation;
- successfully compete in its markets;
- realize the results it anticipates from the clinical trials of its products;
- succeed in finding and retaining joint venture and collaboration partners to assist it in the successful marketing, distribution and commercialization of its products;
- achieve regulatory clearances for its products;
- obtain on commercially reasonable terms adequate product liability insurance for its commercialized products and avoid product liability claims;
- adequately protect its proprietary information and technology from competitors and avoid infringement of proprietary information and technology of its competitors;
- assure that its products, if successfully developed and commercialized following regulatory approval, are not rendered obsolete by products or technologies of competitors; and
- not encounter problems with third parties, including key personnel, upon whom it is dependent.

Although Nymox believes that the forward-looking statements contained in this annual report are reasonable, it cannot ensure that its expectations will be met. These statements involve risks and uncertainties. Actual results may differ materially from those expressed or implied in these statements. Factors that could cause such differences include, but are not limited to, those discussed under Risk Factors.

**PART I****ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS**

Not Applicable

**ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

Not Applicable

**ITEM 3. KEY INFORMATION****Selected Financial Data**

The following table sets forth selected consolidated financial data for Nymox for the periods indicated, derived from financial statements prepared in accordance with generally accepted accounting principles ( GAAP ). We prepare our basic financial statements in accordance with Canadian GAAP and include, as a note to the statements, a reconciliation of material differences to United States GAAP. The financial statements have been audited by KPMG LLP, Montreal, Canada as at and for the years ended December 31, 2006, 2007, 2008, 2009 and 2010 and are reported in U.S. dollars. The data set forth below should be read in conjunction with the Corporation's consolidated financial statements and notes thereto included in Part I, Item 8 of this report.

**NYMOX PHARMACEUTICAL CORPORATION****Selected Consolidated Financial Data**

(In U.S. dollars)

	Dec. 31, <u>2010</u>	Dec. 31, <u>2009</u>	Dec. 31, <u>2008</u>	Dec. 31, <u>2007</u>	Dec. 31, <u>2006</u>
<b>CANADIAN GAAP</b>					
Current Assets	\$ 13,470,096	\$ 1,074,279	\$ 480,505	\$ 430,960	\$ 379,194
Property & Equipment	14,730	16,152	21,525	19,710	7,839
Patents & Intellectual Property	0	0	220,855	441,708	662,564
Total Assets (3)	13,502,222	1,090,431	749,879	989,372	1,155,590
Total Liabilities	15,556,836	1,742,597	1,256,885	1,294,745	2,144,312
Share Capital	62,855,147	57,955,147	53,850,147	50,155,147	44,443,350
Shareholders' Equity	(2,854,614 )	(1,452,166 )	(1,307,006 )	(1,105,373 )	(1,788,722 )
Total Revenues	692,641	415,980	428,409	433,933	442,861
Sales	582,383	415,980	426,675	412,923	437,440
Research & Development Expenditures (1) (3)	4,551,719	3,043,219	2,388,911	3,468,273	3,171,428
Net Loss (3)	6,956,033	5,130,074	4,637,103	5,746,149	5,282,231
Loss per Share (basic & diluted) (3)	\$ 0.22	\$ 0.17	\$ 0.16	\$ 0.20	\$ 0.19
Weighted Avg. No. of Common Shares	31,940,584	30,717,822	29,749,000	29,005,342	27,644,749

## U.S. GAAP (2)

Net Loss	\$ 7,190,670	\$ 5,282,534	\$ 4,590,345	\$ 5,290,431	\$ 4,893,685
Loss per Share	0.23	0.17	0.15	0.18	0.18
Shareholders Equity (2)	465,912	2,102,997	2,400,617	2,555,492	1,416,424

- (1) We earn research tax credits by making qualifying research and development expenditures. These amounts shown are net of research tax credits.
- (2) Reference is made to Note 15 of Nymox's audited financial statements as at and for the years ended December 31, 2010, 2009 and 2008 for a reconciliation of differences between Canadian and U.S. GAAP.
- (3) Net loss, loss per share (basic & diluted), research and development expenditures, patents and intellectual property, total assets and shareholders' equity reflect the impact of the change in accounting policy as described in Note 3 (a) to the audited consolidated financial statements.

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## **Risk Factors**

Investing in our securities involves a significant degree of risk. You should carefully consider the risks described below, together with all of the other information in our publicly filed documents, before making an investment decision. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected. In such an event, the trading price of our Common Shares could decline and shareholders may lose part or all of their investment in our securities.

### **Our Clinical Trials for our Therapeutic Products in Development, Such as NX-1207, May Not Be Successful and We May Not Receive the Required Regulatory Approvals Necessary to Commercialize These Products**

Products requiring regulatory approval, such as NX-1207, will be approved for commercial sale only if governmental regulatory authorities are satisfied that our clinical trials are properly designed and conducted and that the results of those trials provide valid and acceptable evidence that the product is safe and effective for the conditions or diseases it is intended to treat. We do not know whether our pending or any future clinical trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products. Clinical trials are lengthy, complex, expensive and uncertain processes and failure can occur at any stage of testing. Results attained in pre-clinical testing or in early clinical trials may not be indicative of results that are obtained in later studies. We may suffer significant setbacks in advanced clinical trials, even after promising results in earlier studies. Based on results at any stage of clinical trials, we may decide to repeat or redesign a trial or discontinue development of one or more of our product candidates. If we fail to adequately demonstrate the safety and efficacy of our products under development, we will not be able to obtain the required regulatory approvals to commercialize our product candidates. Failure to obtain such approval could cause the price of our shares to decline and adversely affect our business, operations, product development programs and financial condition.

### **Our Clinical Trials for Our Therapeutic Products, Such as NX-1207, May Be Delayed, Making it Impossible to Achieve Anticipated Development or Commercialization Timelines**

Delays in the initiation, conduct or completion of clinical trials are not uncommon. If one or more of our clinical trials is delayed, we may be unable to meet our anticipated development or commercialization timelines. Either circumstance could cause the price of our shares to decline, increase clinical trial and product development costs, and affect the Corporation's business, operations, product development programs and financial condition.

The design, conduct and completion of clinical trials is a complex process involving many third parties, including governmental authorities, institutional review boards, contract manufacturers, contract research organizations (CROs), consultants, investigators, patients, and data monitoring committees. The initiation, progress, completion and success of a clinical trial is in part dependent on third parties providing necessary approvals, agreements and consents, performing necessary tasks in a timely, competent manner, and complying with protocols, good clinical practices and applicable laws, rules and regulations. Failure of a third party to perform as expected or agreed upon may result in delays or failure in initiating or completing a clinical trial.

Our clinical trials are subject to prior approvals and continuing oversight by governmental regulatory authorities and institutional review boards. We must meet and comply with their requirements in order to start, continue and successfully complete a clinical trial. We may not be able to comply with one or more of these requirements or there may be delays in doing so. A clinical trial may be put on hold or halted altogether due to concerns about patient safety. Governmental regulatory authorities may change approvals or requirements, resulting in changes to the design or conduct of a clinical trial or the need for new or further clinical trials.

Clinical trials for our product candidates require that we identify and enroll a large number of patients with the disorder under investigation. We may not be able to enroll a sufficient number of patients to complete our clinical trials in a timely manner. Patient enrollment is a function of many factors including:

- design of the protocol;
- the size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the drug under study;
- availability of competing therapies;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- availability of clinical trial sites.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing clinical trials.



### **A Setback in Any of Our Clinical Trials Would Likely Cause a Drop in the Price of Our Shares**

We have successfully completed several Phase 1 and Phase 2 multi-center, blinded and controlled clinical trials, and follow-up studies, in the U.S. for NX-1207, our drug candidate for the treatment of enlarged prostate (benign prostatic hyperplasia or BPH), and we are currently in Phase 3. The clinical testing of drug candidates is fraught with uncertainties and positive results from earlier clinical trials may not be repeated in later trials. As well, government regulators such as the U.S. Food and Drug Administration, or FDA, may require additional testing or further documentation relating to the preclinical testing, clinical studies, manufacturing or other issues at any time. These requirements may result in substantial delays in obtaining regulatory approval or make obtaining such approval much more difficult. Setbacks in any phase of the clinical development of our product candidates could have a negative impact on our business, operations, product development programs and financial condition, could jeopardize FDA or other regulatory approval and would likely cause a drop in the price of our shares.

### **We May Not be Able to Make Adequate Arrangements with Third Parties for the Commercialization of Our Product Candidates, such as NX-1207**

In order to commercialize our product candidates successfully, we intend, on a product-by-product basis, either to make arrangements with third parties to perform some or all of these services or to expand our existing sales, marketing and distribution capabilities. We currently have limited sales and marketing capabilities and limited experience in developing, training or managing a large marketing or sales force. We currently rely primarily upon distributors for the sales of our existing products. The cost of establishing and maintaining a larger sales force would be substantial and may exceed its cost effectiveness. In addition, in marketing our products, we would likely compete with many companies that currently have extensive and well-funded marketing and sales operations. Despite our marketing and sales efforts, we may be unable to compete successfully against these companies. We may make arrangements with third parties to market and sell some or all of our products under development in certain territories, rather than establish our own sales force. We may not be able to do so on favorable terms. If we contract with third parties for the sales and marketing of our products, our revenues will depend upon the efforts of these third parties, whose efforts may not be successful.

We anticipate entering into co-development and co-marketing agreements with one or more partners with established sales, marketing and regulatory capabilities in order to assist in the completion of the development and commercialization of NX-1207. We may not be able to do so on favourable terms. If we fail to establish or make adequate arrangements with third parties for such purposes, our business, operations, product development programs and financial condition will be materially adversely affected.

In December 2010, the Corporation signed a license and collaboration agreement with Recordati, a European pharmaceutical group, for the development and commercialization of NX-1207 in Europe including Russia and the CIS, the Middle East, the Maghreb area of North Africa and South Africa (the Licensed Territory). The license and collaboration agreement covers the use of NX-1207 for the treatment of BPH as the initial indication for development and commercialization. The success of this agreement is contingent on Recordati's ability to secure marketing approval from the European Medicines Agency (EMA) and other government regulatory agencies in the Licensed Territory. Failure to secure such approvals, inability to establish satisfactory reimbursement prices for sale of approved products, and difficulties with commercialization in the Licensed Territory could significantly impact our revenues from this agreement.

### **We May Not Achieve Our Projected Development Goals in the Time Frames We Announce and Expect**

We make public statements regarding our estimates and projections for meeting milestones, such as the commencement and completion of clinical trials, anticipated regulatory submission and approval dates and time of product launch. The actual timing of these events can vary dramatically due to factors such as delays or failures in our clinical trials, the uncertainties inherent in the regulatory approval process and delays in achieving manufacturing or marketing arrangements sufficient to commercialize our products. There can be no assurance that our clinical trials will be completed, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the launch of any of our products. If we fail to achieve one or more of these milestones as planned, the price of our shares could decline.

**Even If We Obtain Regulatory Approvals for Our Product Candidates, We Will be Subject to Stringent Ongoing Government Regulation**

Even if regulatory authorities approve any of our product candidates, the manufacture, marketing and sale of such products will be subject to strict and ongoing regulation. Compliance with such regulation will be expensive and consume substantial financial and management resources. For example, an approval for a product may be conditioned on our conducting costly post-marketing follow-up studies. In addition, if based on these studies, a regulatory authority does not believe that the product demonstrates a benefit to patients, such authority could limit the indications for which the product may be sold or revoke the product's regulatory approval.

We and our contract manufacturers will be required to comply with applicable current Good Manufacturing Practice ( cGMP ) regulations for the manufacture of our products. These regulations include requirements relating to quality assurance, as well as the corresponding maintenance of records and documentation. Manufacturing facilities must be approved before we can use them in commercial manufacturing of our products and are subject to subsequent periodic inspection by regulatory authorities. In addition, material changes in the methods of manufacturing or changes in the suppliers of raw materials are subject to further regulatory review and approval.

If we or any marketing collaborators or contract manufacturers fail to comply with applicable regulatory requirements, we may be subject to sanctions including fines, product recalls or seizures, injunctions, total or partial suspension of production, civil penalties, withdrawals of previously granted regulatory approvals and criminal prosecution. Any of these penalties could delay or prevent the development, marketing or sale of our products.

### **It is Uncertain When, if Ever, We Will Make a Profit**

We first began operations in 1995 and are only in the early stages of commercial marketing of our diagnostic products, AlzheimerAlert<sup>®</sup>, NicAlert<sup>®</sup> and TobacAlert<sup>®</sup>. We have never made a profit. We incurred a net loss of approximately \$4.6 million in 2008, \$5.1 million in 2009 and \$7.0 million in 2010. As of December 31, 2010, Nymox's accumulated deficit was approximately \$62.9 million.

We cannot say when, if ever, Nymox will become profitable. Profitability will depend on our uncertain ability to generate revenues from the sale of our products and the licensing of our technology that will offset the significant expenditures required for us to advance our research, protect and extend our intellectual property and develop, manufacture, license, market, distribute and sell our technology and products successfully. Similar types of expenditures in the past have contributed to the net losses reported above.

### **We May Not Be Able to Raise Enough Capital to Develop and Market Our Products**

Nymox has funded its operations primarily by selling shares of its common stock. Since late 1998, a small portion of the funds came from sales. However, sales have not been, and may not be in the foreseeable future, sufficient to meet our anticipated financial requirements. In December 2010, the Corporation received an upfront payment of \$10 million (US\$13.1 million) pursuant to a license and collaboration agreement with Recordati for the development and commercialization of NX-1207 in the Licensed Territory. Future payments under this agreement are contingent in part on Recordati's ability to secure regulatory approvals in the licensed territory and may be delayed or not occur.

We will continue to need to raise substantial amounts of capital for our business activities including our research and development programs, the conduct of clinical trials needed to obtain regulatory approvals and the marketing and sales of our products. We anticipate being able to fund our current total annual budgeted expenditures of approximately \$5.5 - 7 million per year over the next year through our current cash position and additional financing, including draw downs through our Common Stock Private Purchase agreement with Lorros-Greyse Investments, Inc. (Lorros-Greyse). The Corporation must comply with general covenants in order to draw on its facility including maintaining its stock exchange listing and registration requirements and having no material adverse effects, as defined in the agreement, with respect to the business and operations of the Corporation. Clinical trials will substantially increase cash requirements. We anticipate being able to meet these requirements as they arise. We plan to raise capital either through a new round of financing and/or through partnering with a major pharmaceutical corporation. The financial crisis in the United States and the global economic recession has had a negative impact on the availability of liquidity in the market and may have an effect on the liquidity of Lorros-Greyse. Additional financing may not be available when needed, or, if available, may not be available on acceptable terms. If adequate funds on acceptable terms are not available, we may have to curtail or eliminate expenditures for research and development, testing, clinical trials, promotion and marketing for some or all of our products.

### **We Face Challenges in Developing, Manufacturing and Improving Our Products**

Our success depends on our ability to develop or acquire rights to new products or to improve our existing products. We are still developing many of our products and have not yet brought them to market. We cannot assure you that we will be able to develop or acquire rights to such products and to market them successfully.

Developing a treatment for Alzheimer's disease is particularly challenging. Many pharmaceutical companies, institutions and researchers are working on many different approaches and treatments. There is no consensus among researchers about the cause of this fatal illness and no guarantee that our drug development programs in this area are targeting significant factors in its cause, progression or symptoms. It is difficult to design drug candidates that can cross from the bloodstream into the brain, where the damage from Alzheimer's disease is occurring. Clinical trials to establish efficacy for drugs that slow down the progression of Alzheimer's disease over a period of months or years often require that a large number of subjects be tracked over many months or years, making them very expensive to conduct. The potentially long period from discovery and patenting through development and regulatory approval to the market can significantly reduce the patent life of an Alzheimer's disease treatment. Any marketed treatment in this area may well eventually face competition from me-too drugs developed by other pharmaceutical companies based on our research. We will be under constant competitive pressure to improve our products and to develop new treatments in order to protect our position in the field.

Developing and improving our diagnostic products is also challenging. The science and technology of the detection and measurement of very small amounts of biochemicals in bodily fluids and tissue is evolving rapidly. We may need to make significant expenditures in research and development costs and licensing fees in order to take advantage of new technologies. If any major changes to our testing technologies used in our AlzheimerAlert and NicAlert and TobacAlert tests are made, further validation studies will be required. Developing new diagnostic products is more challenging, requiring identification and validation of the biochemical marker being detected by the new product in the clinical context and the development and validation of the product designed to detect the marker.

We anticipate outsourcing at least some of the manufacturing required for new products we may develop in order to control start-up and operating costs and to take advantage of the existing manufacturing capabilities and capacity in the large contract manufacturing sectors in the pharmaceutical and diagnostic industries. There are risks associated with this strategy, including difficulties in the transfer of manufacturing, the possibility of production interruption due to causes beyond our control and the need to arrange alternative suppliers. We currently out-source some of the manufacturing services required for our NicAlert and TobacAlert products to a contract manufacturer. We do not anticipate any significant risk of long-term interruption of manufacture due to this arrangement. The services supplied are not unique or unduly complicated and other contract manufacturers are available to provide similar services. The manufacture of therapeutics is more challenging and capital-intensive and may require us to partner with a major pharmaceutical corporation or other partner in order to manufacture a therapeutic for market.

### **Our Products and Services May Not Receive Necessary Regulatory Approvals**

Our diagnostic products, AlzheimerAlert, NicAlert and TobacAlert, and our products in development, are subject to a wide range of government regulation governing laboratory standards, product safety and efficacy. The actual regulatory schemes in place vary from country to country and regulatory compliance can take several years and involve substantial expenditures.

We cannot be sure that we can obtain necessary regulatory approvals on a timely basis, if at all, for our products in development and all of the following could have a material adverse effect on our business:

- failure to obtain or significant delays in obtaining requisite approvals;
- loss of or changes to previously obtained approvals; and
- failure to comply with existing or future regulatory requirements.

Any changes in the Centers for Medicare and Medicaid Services ( CMS ) or state law requirements or in the U.S. Food and Drug Administration ( FDA ) regulations could have a detrimental impact on our ability to offer or market any reference laboratory services and/or on our ability to obtain reimbursement from the Medicare and Medicaid programs and providers.

We have developed a diagnostic kit based on AlzheimerAlert for sale to third parties. We will require prior approval from the FDA before we can market, distribute or sell this product in the United States. In July 2005, an FDA advisory panel voted 5-2 against approval of our kit, citing the need for further studies, such as long term follow-up and autopsy confirmation.

Similar requirements exist in many other countries. Obtaining these approvals and complying with the subsequent regulatory requirements can be both time-consuming and expensive.

In the United States, our drugs in development will require final FDA approval before their sale or distribution. Such approval comes only at the end of a lengthy, expensive and often arduous process. In September, 2006, we announced the successful completion of a multi-center, double-blind, placebo-controlled Phase 2 trial of NX-1207, our lead candidate for the treatment of BPH, a common disorder of older men. The Corporation reported positive results in 2007 and 2008 in several follow-up studies of BPH patients. In February 2008, the Corporation reported positive results in a 32 site U.S. Phase 2 prospective randomized clinical trial, with statistically significant improvement compared to an approved BPH drug (finasteride). In February 2009, the Corporation reported concluding a positive and productive End of Phase 2 ( EOP2 ) meeting with the FDA concerning the Phase 3 program for NX-1207. In June 2009, the Corporation began conducting the first of two pivotal double blind placebo controlled Phase 3 trials for NX-1207 that incorporate the specific protocol design recommendations provided to the Corporation by the FDA. The

two pivotal Phase 3 studies for NX-1207 are being conducted at well known investigational sites across the U.S. with planned enrollment of 1,000 patients. We cannot predict with any certainty the outcome of this program, what further steps may be required in order to apply for final FDA approval for this drug or whether the FDA will ultimately grant us such approval. Similar requirements exist in many other countries.

### **We Face Significant and Growing Competition**

The modern pharmaceutical and biotechnology industries are intensely competitive, particularly with respect to Alzheimer's disease where there is a large unmet need for an effective treatment. Currently there are five drugs with similar mechanisms of action approved for sale in the United States (Aricept®, Cognex®, Exelon®, Razadyne® and Namenda®). These drugs offer some relatively short-term symptomatic relief, but do not treat the underlying causes of the illness. Over the past decade, there has been an intense research effort both in the non-profit sectors such as universities, government agencies and research institutes and in the pharmaceutical and biotechnology industry to develop new treatments for Alzheimer's disease. Treatment candidates under development include:

- vaccines and other immunotherapies for Alzheimer's disease. A number of pharmaceutical and biotechnology companies including Wyeth, Elan, Novartis, and Baxter are working on such therapies.

- enzyme-blocking therapies intended to block the production of the protein found in the senile plaques characteristic of Alzheimer's disease. A number of pharmaceutical and biotechnology companies including Bristol-Myers Squibb and Merck are working on such therapies.
- drugs aimed at reducing, blocking or clearing the aggregation or accumulation of the protein found in senile plaques. A number of pharmaceutical and biotechnology companies including Elan, Lilly, Pfizer and Prana Biotechnology are working on such therapies.
- drugs designed to enhance cognition from AstraZeneca and Roche among others.
- antihistamines such as Dimebon from Medivation.

There is also ongoing research into possible methods of preventing Alzheimer's disease such as taking certain cholesterol-lowering drugs called statins, estrogen replacement therapies, anti-oxidants such as vitamin E and ginkgo biloba, nutraceuticals such as resveratrol and docosahexanoic acid (DHA) (an omega 3 fatty acid), or anti-inflammatory drugs such as ibuprofen (*e.g.*, Advil® or Motrin®). The successful development of a treatment or method of preventing Alzheimer's disease could significantly impact on our ability to develop or market a competing treatment for Alzheimer's disease.

Our treatments under development for enlarged prostate (benign prostatic hyperplasia or BPH) face significant competition from existing products. There are eight drugs approved for treatment of BPH: four proprietary drugs (dutasteride (Avodart®), tamsulosin (Flomax®), alfuzosin (Uroxatral®), and silodosin (Rapaflo®)), a combination of two drugs (dutasteride and tamsulosin) (Jalyn ), and four generics (finasteride, terazosin, doxazosin, and prazosin). There are a number of thermal treatments on the market designed to shrink the enlarged prostate by heating its tissue with a device inserted through the urethra (the passage leading from the bladder through the penis through which men urinate). The devices on the market use microwave energy (Prostatron®, Targis Therapy® or TherMatrx®), low level radiowaves (TUNA System®), lasers (Indigo LaserOptic Treatment System® or Laserscope GreenLight PVP ), direct heat, energy or hot water to heat or burn away prostate tissue. A variety of surgical procedures exist to surgically reduce or remove the prostate or to widen the urethra. These include procedures to cut away prostate tissue such as TURP (transurethral resection of the prostate) and using a resectoscope with an electrical loop inserted through the penis to cut the prostate tissue. A small device used to widen the constricted urethra called a prostatic stent can also be inserted.

The diagnostic testing industry is also highly competitive. In the area of Alzheimer's disease, Athena Diagnostics, Inc. markets diagnostic tests for different biochemical indicators found in blood and spinal fluid and for genetic predispositions for the illness. Other companies are attempting to develop and market other diagnostic products in this area. The introduction of other diagnostics products for Alzheimer's disease or tobacco product use that are cheaper, easier to perform, more accurate or otherwise more attractive to the physicians, health care payers or other potential customers would have a significant impact on the sales of our AlzheimAlert , NicAlert or TobacAlert products.

### **We May Not Be Able to Successfully Market Our Products**

To increase our marketing, distribution and sales capabilities both in the United States and around the world, we will need to enter into licensing arrangements, contract sales agreements and co-marketing deals. We cannot assure you that we will be able to enter into agreements with other companies on terms acceptable to us, that any licensing arrangement will generate any revenue for the Corporation or that the costs of engaging and retaining the services of a contract sales organization will not exceed the revenues generated.

### **Protecting Our Patents and Proprietary Information is Costly and Difficult**

We believe that patent and trade secret protection is important to our business, and that our success will depend, in part, on our ability to obtain strong patents, to maintain trade secret protection and to operate without infringing the proprietary rights of others.

Obtaining and maintaining our patent position is costly. We pay for the filing, prosecution and fees of several hundred patents and patent applications in countries around the world, including the United States, Europe, Japan, Canada, Australia, New Zealand and South Korea. In the United States alone, Nymox has twenty-three patents issued or allowed relating to its technology. Our subsidiary, Serex, Inc. has thirteen patents.

While we believe that we have strong patent protection for the products we sell and for our product development programs and we are in the process of extending that patent protection to cover more countries or new discoveries or products, we cannot assure you that additional patents covering new products or improvements will be issued or that any new or existing patents will be of commercial benefit or be valid and enforceable if challenged.

Many companies have patents covering various drugs, methods and discoveries in the fields of diagnostics and therapeutics for Alzheimer's disease and related conditions and of new anti-infective agents. We believe that the patents issued to date should not preclude Nymox from developing and marketing our products; however, it is impossible to predict the extent to which licenses from third parties will be necessary. If Nymox were to need licenses from third parties there can be no assurance that we could obtain such licenses on commercially reasonable terms, if at all.



In the fields of diagnostic methods and diagnostic tests for common human diseases and conditions, where Serex has many of its patents, there are many patents issued covering many areas of diagnostic methods, tests and technologies. We believe that these patents issued to date to other companies will not preclude Serex from developing and marketing its products but you should be aware that it is often difficult to determine the nature, breadth and validity of competing patent claims in these fields, that there has been significant litigation in some of these areas (not involving Serex) and that, if and when Serex's products become more commercially successful, Serex's products or patents may become the subject matter of litigation. If Serex were to need licenses from third parties there can be no assurance that it could obtain such licenses on commercially reasonable terms, if at all.

We are not currently involved in patent litigation. In the pharmaceutical and biotechnology industry patent disputes are frequent and can preclude the commercialization of products. Patent litigation is costly and the outcome often difficult to predict. It can expose us to significant liabilities to third parties and may require us to obtain third-party licenses at a material cost or cease using the technology or product in dispute.

### **We Face Changing Market Conditions**

The healthcare industry is in transition with a number of changes that affect the market for therapeutic and diagnostic test products. The U.S. federal and various state governments have under consideration a number of proposals that may have the effect of directly or indirectly limiting drug prices in the U.S. markets. In March 2010, the United States enacted health care reform legislation. Important market reforms began this year and will continue through full implementation in 2014. The new law is expected to expand access to health care to more than 32 million Americans by the end of the decade. These changes may adversely affect the prices we may charge for any therapeutic drug we develop. Funding changes and budgetary considerations can lead major health care payers and providers to make changes in reimbursement policies for our products. These changes can seriously impact the potential for growth for the market for our products, either favorably when the decision is to offer coverage for our products at a reasonable price or negatively when the decision is to deny coverage altogether. Changes in the healthcare delivery system have resulted in consolidations and in the formation of multi-hospital alliances, reducing the number of institutional customers for therapeutic and diagnostic test products. There can be no assurance that Nymox will be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with these institutional customers.

### **Health Care Plans May Not Cover or Adequately Pay for Our Products and Services**

Throughout the developed world, both public and private health care plans are under considerable financial and political pressure to contain their costs. The two principal methods of restricting expenditures on drugs and diagnostic products and services are to deny coverage or, if coverage is granted, to limit reimbursement. For single-payer government health care systems, a decision to deny coverage or to severely restrict reimbursement for one of our products can have an adverse effect on our business and revenues.

In the United States, where, to a significant degree, the patient population for our products is elderly, Medicare and Medicaid are sources of reimbursement. In general, any restriction on reimbursement, coverage or eligibility under either program could adversely affect reimbursement to Nymox for products and services provided to beneficiaries of the Medicare and/or Medicaid programs. Many elderly people are covered by a variety of private health care organizations either operating private health care plans or Medicare or Medicaid programs subject to government regulation. These organizations are also under considerable financial constraints and we may not be able to secure coverage or adequate reimbursement from these organizations. Without coverage, we will have to look to the patients themselves who may be unwilling or unable to pay for the product; in turn, doctors may be reluctant to order or prescribe our products in the absence of coverage of the product for the patient.

**We Are Subject to Continuing Potential Product Liability Risks, Which Could Cost Us Material Amounts of Money.**

We may be subject to product liability which could task our critical resources, delay the implementation of our business strategy, result in products being recalled or removed from the market, and materially and adversely harm our business and financial condition due to the costs of defending such legal actions or the payment of any judgments or settlements relating to such actions or both. Our business exposes us to the risk of product liability claims that is inherent in the development and marketing, distribution, and sale of pharmaceutical and diagnostic products. If any of our product candidates or marketed products harms people, or is alleged to be harmful, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, patients, health care providers, corporate partners or others.

We have product liability insurance covering our ongoing clinical trials and marketed products. Our insurance coverage may not be sufficient to cover fully all potential claims, nor can we guarantee the solvency of any of our insurers. If our claims experience results in higher rates, or if product liability insurance otherwise becomes costlier because of general economic, market or industry conditions, then we may not be able to maintain product liability coverage on acceptable terms. If sales of our products increase materially, or if we add significant products to our portfolio, then we will require increased coverage and may not be able to secure such coverage at reasonable rates or terms. If our insurance coverage is not sufficient to cover fully all potential claims, the Corporation would be exposed to the risk that our litigation costs and liability could exceed our total assets and our ability to pay.

### **The Issuance of New Shares May Dilute Nymox's Stock**

The Corporation relies almost exclusively on financing to fund its operations. In order to achieve the Corporation's business plan and realization of its assets and liabilities in the normal course of operations, the Corporation anticipates the need to raise additional capital and/or achieve sales and other revenue generating activities. The issuance of further shares and the eligibility of issued shares for sale will dilute our common stock and may lower its share price. There were 32,588,856 common shares of Nymox issued and outstanding as of March 15, 2011. In addition, 5,328,000 share options are outstanding, of which 4,618,625 are currently vested. Expiry dates for Nymox options range from 1 month to 9.3 years (see note 8(b) to our consolidated financial statements). These options have been granted to employees, officers, directors and consultants of the Corporation. Moreover, Nymox may use its shares as currency in acquisitions. The Corporation depends on financing under the Common Stock Private Purchase Agreement to fund its operations. In order to achieve its business plan and the realization of its assets and liabilities in the normal course of operations, the Corporation anticipates the need to raise additional capital to meet the Corporation's requirements.

### **We Face Potential Losses Due to Foreign Currency Exchange Risks**

Nymox incurs certain expenses, principally relating to salaries and operating expenses at its Canadian head office, in Canadian dollars. All other expenses are derived in U.S. dollars. As a result, we are exposed to the risk of losses due to fluctuations in the exchange rates between the U.S. dollar and the Canadian dollar. We protect ourselves against this risk by maintaining cash balances in both currencies. We do not currently engage in hedging activities. The Corporation may suffer losses as a result of unfavorable fluctuations in the exchange rates between the United States dollar and Canadian dollar.

### **We Have Never Paid a Dividend and are Unlikely to do so in the Foreseeable Future**

Nymox has never paid any dividends and does not expect to do so in the foreseeable future. We expect to retain any earnings or positive cash flow in order to finance and develop Nymox's business.

## **ITEM 4. INFORMATION ON THE CORPORATION**

### **History of the Corporation**

Nymox Pharmaceutical Corporation was incorporated under the Canada Business Corporations Act in May, 1995 to acquire all of the common shares of DMS Pharmaceutical Inc., a private Corporation which had been carrying on research and development since 1989 on diagnostics and drugs for brain disorders and diseases of the aged with an emphasis on Alzheimer's disease. Nymox has two subsidiaries: one wholly-owned subsidiary named Nymox Corporation and the other a majority owned subsidiary named Serex, Inc., acquired in 2000. Both subsidiaries are based in the same building in Hasbrouck Heights, New Jersey. Nymox Corporation conducts some research and development, while Serex conducts research and development, and some of the manufacturing for NicAlert and TobacAlert.

Nymox's principal executive offices are located at:

Nymox Pharmaceutical Corporation  
9900 Cavendish Boulevard, Suite 306, St. Laurent, Quebec, Canada, H4M 2V2  
Phone: (800) 936-9669 Fax: (514) 332-2227

Nymox's registered agent in the United States is:

CT Corporation System  
111 Eighth Avenue, 13<sup>th</sup> Floor  
New York, NY, 10011

Nymox's two subsidiaries are located at:

Nymox Corporation  
777 Terrace Avenue  
Hasbrouck Heights, NJ, USA 07604

Serex, Inc.  
777 Terrace Avenue  
Hasbrouck Heights, NJ, USA 07604

Nymox Pharmaceutical Corporation is a biopharmaceutical Corporation with three proprietary products on the market, and a significant R&D pipeline of products in development for the treatment of such conditions and diseases as enlarged prostate (benign prostatic hyperplasia or BPH), Alzheimer's disease (AD), *E. coli* O157:H7 contamination of food and drink products, and bacterial infections and for the diagnosis of AD and other indications. Nymox also has U.S. and global patent rights for the use of statin drugs for the treatment and prevention of Alzheimer's disease.

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### **Acquisition of a Majority Interest in Serex, Inc.**

In March 2000, we acquired a controlling interest in Serex, Inc., a privately held diagnostic Corporation based in New Jersey and now own approximately 99% of its common stock.

Serex's patented diagnostic technologies include its particle valence technology, a highly sensitive, new method to detect very small amounts of biochemical indicators in body fluids such as blood, urine and saliva. This technology can be adapted to detect a wide range of biochemical indicators for diseases, conditions and drug use. Our NicAlert and TobacAlert employ this technology to measure levels of one of the metabolic products of nicotine in human urine, in order to determine whether a person is using or has been exposed to a tobacco product. NicAlert and TobacAlert are currently being distributed by Nymox and Jant Pharmacal Corporation.

### **Products**

#### ***NicAlert for Tobacco Product Use and TobacAlert for Second-Hand Smoke Exposure***

Nymox has developed and markets NicAlert and TobacAlert, which are inexpensive, simple-to-use test strips for determining whether a person is using tobacco products (NicAlert) or has been recently exposed to second-hand smoke (TobacAlert). Both NicAlert and TobacAlert employ Serex, Inc.'s patented technology to provide an accurate read-out of levels of cotinine, a by-product of the body's breakdown of nicotine and generally regarded as the best indicator of tobacco exposure for smokers and nonsmokers. The technology can be used with saliva as well as urine samples in order to detect tobacco product use. NicAlert and TobacAlert do not require instruments or special training to use and offer a quick, convenient means to test on-site whether a person, such as a child, teenager, student athlete or insurance applicant, is using a tobacco product or has been exposed to second-hand smoke.

Smoking and other tobacco product use is a serious public health problem around the world. Smoking kills. According to the Centers for Disease Control and Prevention, cigarette smoking is responsible for more than 430,000 deaths per year in the United States alone. Smoking can cause cancer of the lung, mouth, bladder, larynx, esophagus and other organs, as well as heart disease and stroke and chronic lung disease. Every year, exposure to second-hand smoke (environmental tobacco smoke or ETS) causes an estimated 3,000 nonsmoking Americans to die of lung cancer and up to 300,000 American infants and small children to suffer from lower respiratory tract infections.

NicAlert received clearance from the FDA in October 2002 for medical use to determine if an individual has been exposed to tobacco products. In January, 2006, Nymox announced the certification of the urine-based version of NicAlert with a CE Mark making it eligible for sale in the European Union and in May, 2006 the certification of the saliva-based version of NicAlert with a CE Mark. In September, 2003, Nymox launched TobacAlert for nonmedical testing for second hand smoke exposure in the U.S.

We market the NicAlert and TobacAlert tests through our own marketing arm and distributors in North America, Europe and Asia. TobacAlert is also available online at [www.tobacalert.com](http://www.tobacalert.com). Nymox has entered into distribution and marketing agreements with companies and organizations in the U.S., the U.K., and Spain for these products.

Our NicAlert and TobacAlert products face competition from clinical laboratories such as LabCorp and Quest Diagnostics which provide off-site lab testing for cotinine, the by-product of the body's breakdown of nicotine measured by NicAlert and TobacAlert, and from assay suppliers, including immunoassay developers such as OraSure Technologies Inc. and Abraxis LLC, and diagnostic system manufacturers such as Roche Diagnostics, Abbott and Diagnostic Products Corporation. NicAlert and TobacAlert also face competition from distributors who supply yes-no smoking status tests such as NicQuick, and QuickScreen, from NicCheck I, an FDA-cleared smoking status test being

marketed by Mossman & Associates Ltd, from SmokeScreen, a chemical color-based tobacco test being marketed by Mermaid Diagnostics, Ltd. in the United Kingdom, and from carbon monoxide (CO) monitors such as SmokeCheck.

NicAlert and TobacAlert products are currently partly manufactured through out-sourcing arrangements with contract manufacturers. To date, we have not experienced any significant interruptions in the manufacture of these products and the cost of the manufacturing services has not been volatile. The manufacturing services supplied by our current contract manufacturers are not unique or unduly complicated and other contract manufacturers are available to provide similar services in the event that our current contract manufacturers fail to meet our needs.

The technology used in these products is covered by patents and patent applications held by Nymox's subsidiary, Serex, Inc., both in the U.S. and elsewhere in the world with expiry dates no earlier than 2012.

Independent studies published in peer-reviewed medical and scientific journals reported finding that the Corporation's NicAlert Saliva product provides an accurate, convenient and cost-effective way to verify self-reported smoking status with broad potential applications both in the clinic and in large research trials and surveys. In 2008, one such study, Fiona Cooke et al. Diagnostic accuracy of NicAlert cotinine test strips in saliva for verifying smoking status, *Nicotine Tob Res.* 2008;10:607-12, was published in *Nicotine & Tobacco Research*, the official journal of the Society for Research on Nicotine and Tobacco (SRNT).

Other published studies include *Cancer Epidemiol Biomarkers Prev.* 2007; 16:1858-62 and *Int J Circumpolar Health.* 2007; 66 Suppl 1:29-38.

NicAlert Saliva was also reported used in research studies where there was a need to verify or monitor smoking status or nicotine replacement therapy (NRT): see, for example, *Am J Prev Med.* 2007; 33:297-305 (monitoring NRT in smoking cessation research involving pregnant women), *Int J Behav Med.* 2006; 13:16-25 (verifying smoking status in a smoking study of cancer patients), and *Neuropsychopharmacology* 2008; 33:480-490 (confirming non-smoking status for entry into the study).

### ***AlzheimAlert ; an Aid to the Diagnosis of Alzheimer's Disease***

We have developed AlzheimAlert , a proprietary urine assay that can aid physicians in the diagnosis of Alzheimer's disease. We have developed a kit version of the AlzheimAlert assay for sale in Europe. The AlzheimAlert kit has the CE Mark. The kit allows clinical reference laboratories to perform the AlzheimAlert assay on site with urine samples sent directly to the laboratory. We filed a premarket approval (PMA) application for the diagnostic kit version of the AlzheimAlert test with the FDA in February 2004. On July 15, 2005, an FDA advisory panel voted 5-2 against approval of the kit, citing the need for further studies, such as long term follow-up and autopsy confirmation.

The AlzheimAlert assay is based on research by scientists at the Massachusetts General Hospital and Brown University and on years of clinical studies to establish and confirm the accuracy of the assay technology as an aid to the diagnosis of Alzheimer's disease. In 1997, Nymox succeeded in developing a commercial assay that used spinal fluid samples. Subsequently, Nymox was able to develop an assay that used more easily obtained first morning urine samples. The AlzheimAlert assay represents the latest generation of development of this testing technology.

Nymox licensed the technology that led to the development of the AlzheimAlert assay in 1997 from the Massachusetts General Hospital as part of a sponsored research and licensing agreement, under which Nymox sponsored the research of the principal investigators into the use of neural thread protein ( NTP ), its antibodies or genes for diagnostic or therapeutic purposes. Nymox also paid the patent costs for the patent applications filed arising out of this research. In return, Nymox received an exclusive worldwide license of the patents to sell products and to use processes encompassed by them. Nymox is to pay the Massachusetts General Hospital a 4% royalty of the net sales price of any product developed and sold under the license. Nymox currently pays this royalty on its sales of its AlzheimAlert product. The license and the obligation to pay patent costs and royalties continue for the life of the patents, which run until November 2014 at the earliest. The Massachusetts General Hospital has the right to terminate the license in any country where, after the first commercial sale of the product in the country, there is a continuous two year period in which no product is sold in such country. There are eight issued U.S. patents under license and a larger number of patents and patent applications in Europe, Japan, Canada, Australia, New Zealand and South Korea. The sponsored research portion of this agreement terminated in March 1999. Nymox retained the exclusive license to the rights to the AlzheimAlert -related patents owned by the Massachusetts General Hospital.

Effective March 1999, Nymox entered into a similar sponsored research and licensing agreement with Brown University and the Rhode Island Hospital. Under the terms of this agreement, Nymox continued to sponsor research into the uses of neural thread proteins, their antibodies or genes for diagnostic, therapeutic and research purposes and to pay the patent costs for any patent applications filed arising out of this research. In return, Nymox received an exclusive worldwide license of any such patents to sell products and to use processes encompassed by them. The Rhode Island Hospital has the right to terminate the license in any country where, after the first commercial sale of the product in the country, there is a continuous two year period in which no product is sold in such country. Nymox is to pay the Rhode Island Hospital a 4% royalty of the net sales price of any product developed and sold under the license. The sponsorship of this agreement expired in March 2005; however, Nymox retains the exclusive license to patent

rights on certain NTP-based technology including a license to two issued U.S. patents.

The successful results of a multi-center double blind independent clinical study of the Corporation's urinary AlzheimerAlert test were published in the January 2007 issue of the *Journal of the American Medical Directors Association* (*J Am Med Dir Assoc.* Jan 2007; 8:21-30; A multi-center blinded prospective study of urine neural thread protein measurements in patients with suspected Alzheimer's disease, Goodman I et al.). The independent peer-review study from 8 prestigious centers across the U.S. found the level of accuracy of the AlzheimerAlert urine test to be over 90%. The study was double-blind and involved expert assessments and state of the art clinical correlations and continued evaluations.

In January 2007, a second peer-reviewed report was published in the *Journal of Clinical Laboratory Analysis* providing further positive data on the accuracy and utility of the Corporation's urinary AlzheimerAlert test (*J Clin Lab Anal.* Jan 2007;21:24-33, Competitive ELISA studies of neural thread protein in urine in Alzheimer's disease ). The paper reported excellent performance in laboratory studies and impressive reproducibility of clinical test results for patients and controls who were re-tested at intervals ranging from 2 days to 4.5 years.

Recent publications in the peer-reviewed literature concerning the clinical utility of the assay in the diagnosis of Alzheimer's disease include, for example, the *Journal of Clinical Investigation* (1997; 100: 3093-3104); *Journal of Contemporary Neurology* (1998; art. 4a); *Journal of Clinical Laboratory Analysis* (1998; 12: 285-288) and (1998; 12: 223-226); *Alzheimer's Reports* (1999; 2: 327-332), (2000; 3: 177-184), (2001; 4: 61-65) and (2002; 5: 1-6); *Neurology* (2000; 54: 1498-1504) and (2000; 55: 1068); *Journal of Alzheimer's Disease* (2001; 3: 345-353) and (2004; 6(3): 231-42); *Cellular and Molecular Life Sciences* (2001; 58: 844-849) and (2003; 60: 2679-91); *Neurology and Clinical Neurophysiology* (2002; 1: 2-7); *Journal of Neuropathology and Experimental Neurology* (2001; 60: 195-207) and (1996; 55: 1038-1050), *Frontiers in Bioscience* (2002; 7: d989-96), *Journal of the American Medical Directors Association* (Jan 2007; 8:21-30), *Journal of Clinical Laboratory Analysis* (Jan 2007;21:24-33), *Expert Review of Molecular Diagnostics* (January 2008; 8:21-28) and *Journal of the American Medical Directors Association* (Article in press; published online October 1, 2010; doi:10.1016/j.jamda.2010.03.004).



Nymox believes that its AlzheimerAlert test can assist a physician faced with the task of diagnosing whether a patient has Alzheimer's disease. A recently published independent peer-reviewed double blind study from 8 prestigious centers across the U.S. found the level of accuracy of the AlzheimerAlert urine test to be over 90% (*Journal of the American Medical Directors Association* Jan 2007; 8:21-30; A multi-center blinded prospective study of urine neural thread protein measurements in patients with suspected Alzheimer's disease, Goodman I *et al.*). This study confirmed several earlier Corporation funded trials of the AlzheimerAlert technology. In earlier studies, the test results were positive for over 87% of the patients with verified Alzheimer disease and negative in over 89% of subjects without the disease (known as a low false positive rate). The low rate of positive results for patients without the disease is important for doctors investigating patients with subtle or marginal symptoms of mental, emotional, cognitive, or behavioral changes. If the doctor can rule out Alzheimer's with more assurance, a great deal of patient and family anguish and anxiety will be avoided. A low test score will help the doctor to be more certain that Alzheimer's disease is not the cause of the patient's symptoms and to target the other, often reversible causes of the patient's symptoms, such as depression. There can be no assurance that further studies will repeat the same level of success experienced to date.

There is a large need for a simple, non-invasive test that can aid in the diagnosis of Alzheimer's disease. According to 2010 Alzheimer's Disease Facts and Figures, U.S. Alzheimer's Association, Alzheimer's disease is the most common cause of dementia and is the seventh leading cause of death in the United States. It is estimated that as many as 5.3 million people have Alzheimer's disease in the United States alone. By 2050 this number is projected to increase to between 11 and 16 million Americans. The annual national direct and indirect costs of caring for Alzheimer patients in the U.S. alone are estimated to be over \$200 billion a year. The human toll on patients, families and caregivers is incalculable. Despite the need for an accurate clinical test, the definitive diagnosis of the disease is possible only after the death of the patient by expert, pathologic examination of brain tissue.

The U.S. Surgeon General's Report on Mental Health, released on December 13, 1999, identified the importance and the need for the early detection and diagnosis of Alzheimer's disease. The report described the current approach to Alzheimer's disease diagnosis, clinical examination and the exclusion of other common causes of its symptoms, as time- and labor-intensive, costly and largely dependent on the expertise of the examiner. As a result, the illness is currently under-recognized, especially in primary care settings, where most older patients seek care. The report joined other experts writing in the field in recognizing the need for a better, more reliable method for diagnosing the disease in living patients and in particular, the need for a simple, accurate and convenient test that could detect a biochemical change early in patients with Alzheimer's disease. We believe our AlzheimerAlert product provides such a test.

The early diagnosis of Alzheimer's disease is important to physicians, patients and their families and enables them to make informed and early social, legal and medical decisions about treatment and care. Early diagnosis of Alzheimer's disease has become increasingly important with new improvements in drug treatment and care. Even a modest delay in institutionalization can mean substantial social and financial savings. Conversely, any testing procedure that could rule out Alzheimer's disease would eliminate the tremendous uncertainty and anxiety patients and their families otherwise face and would allow physicians to focus on the other, often reversible, causes of cognitive changes.

Early diagnosis as facilitated by the AlzheimerAlert test represents a potentially large cost-savings in the form of a reduced number of office visits, lab tests, scans and other procedures required by the traditional methods of diagnosis.

In the field of Alzheimer's disease diagnosis, our AlzheimerAlert test faces growing competition which could detrimentally impact on our ability to successfully market and sell our diagnostic test. Our competitors include:

- Athena Diagnostics, Inc., which is currently marketing three tests claimed to aid in the diagnosis of Alzheimer's disease: a genetic test for the rare cases of familial, early-onset Alzheimer's disease; a genetic test

for a relatively common mutation of a gene said to increase the likelihood of a person with at least one of the genes contracting the disease; and a test for two proteins in the spinal fluid of patients.

- Innogenetics NV, a Solvay Pharmaceuticals Corporation, which currently markets tests and kits for two proteins and a variant of one of these proteins in the spinal fluid of patients and a genetic test for a relatively common mutation of a gene said to increase the likelihood of a person developing the disease.
- Amorfix Life Sciences Ltd. currently markets a research test to detect aggregated amyloid protein in brain test and has under development related blood and CSF test.

There are also a number of other proposed biochemical signs of the disease that could potentially be developed into a commercial diagnostic test as well as various scanning and imaging technologies which compete for a portion of the diagnostic market for Alzheimer's disease. On January 20, 2011, an FDA Advisory Committee panel recommended against the approval at that time of Lilly's Amyvid (florbetapir), a molecular imaging tool developed to detect beta-amyloid plaque in the brain. The Committee's decision left open the possibility of approval at a later time after a further study is completed. A number of companies, including GE, are actively working to develop imaging technologies for the diagnosis of Alzheimer's disease. In June 2004, the CMS approved limited coverage of a Positronic Emission Tomography (PET) imaging procedure for helping to more precisely distinguish Alzheimer's disease from a rarer type of dementia when clinical evaluation has been inconclusive. In October 2004, the National Institute on Aging in conjunction with other Federal agencies, private companies and organizations launched the Alzheimer's disease Neuroimaging Initiative, a \$60 million initiative to test whether various scanning and imaging technologies, biochemical markers, and clinical and neuropsychological testing can be combined to help diagnose early Alzheimer's disease.

**Products in Development:**

***NX-1207 for Enlarged Prostate (BPH)***

We are developing treatments for enlarged prostate (benign prostatic hyperplasia or BPH), using novel compounds. Our lead candidate NX-1207, which successfully completed a multi-center, double-blind, placebo-controlled Phase 2 trial in September 2006, is presently in Phase 3. We cannot predict with any certainty the outcome of this trial, what further steps may be required in order to apply for final FDA approval for this drug or whether the FDA will ultimately grant us such approval.

There is a significant need for an effective treatment for BPH. More than half of men in their sixties and as many as 90% of men in their seventies and eighties have the symptoms or signs of BPH according to the 2010 AUA Guideline on the Management of Benign Prostatic Hyperplasia, American Urological Association. Symptoms include more frequent urination (especially at night), difficulty urinating, incomplete emptying of the bladder and sometimes complete inability to urinate. More serious cases may require surgical intervention to reduce the size of the prostate. There is a need for a simple, effective treatment for BPH, particularly in cases where existing drug treatments have proven to be ineffective and where more intrusive procedures such as surgery may be inadvisable or bring unacceptable risks.

NX-1207 showed positive results for the treatment of BPH in Phase 1 and 2 clinical trials in the U.S. The Corporation successfully completed a 43 site prospective randomized double-blinded placebo controlled Phase 2 U.S. clinical trial of NX-1207 in 2006, which showed statistically significant efficacy and a good safety profile. In February 2008, the Corporation reported positive results in a 32 site U.S. Phase 2 prospective randomized blinded clinical trial, with statistically significant improvement compared to an approved BPH drug (finasteride). Nymox reported positive results in twelve follow-up studies of available subjects from the completed Phase 1 and 2 clinical trials.

In February 2009, the Corporation reported concluding a positive and productive EOP2 meeting with the FDA concerning the Phase 3 program for NX-1207. In June 2009, the Corporation began conducting the first of two pivotal double blind placebo controlled Phase 3 trials for NX-1207 that incorporate the specific protocol design recommendations provided to the Corporation by the FDA. The two pivotal Phase 3 studies for NX-1207 are being conducted at well known investigational sites across the U.S. with planned enrollment of 1,000 patients.

Our treatments under development for enlarged prostate (benign prostatic hyperplasia or BPH) face significant competition from existing products. There are eight drugs approved for treatment of BPH: four proprietary drugs (dutasteride (Avodart®), tamsulosin (Flomax®), alfuzosin (Uroxatral®), and silodosin (Rapaflo®)) a combination of two drugs (dutasteride and tamsulosin) (Jalyn ), and four generics (finasteride, terazosin, doxazosin, and prazosin). There are a number of thermal treatments on the market designed to shrink the enlarged prostate by heating its tissue with a device inserted through the urethra (the passage leading from the bladder through the penis through which men urinate). The devices on the market use microwave energy (Prostatron®, Targis Therapy® or TherMatrx®), low level radiowaves (TUNA System®), lasers (Indigo LaserOptic Treatment System® or Laserscope GreenLight PVP ), direct heat or hot water to heat or burn away prostate tissue. A variety of surgical procedures exist to surgically reduce or remove the prostate or to widen the urethra. These include procedures to cut away prostate tissue such as TURP (transurethral resection of the prostate) and using a resectoscope with an electrical loop inserted through the penis to cut the prostate tissue. A small device used to widen the constricted urethra called a prostatic stent can also be inserted.

***NX-1207 for Prostate and Liver Cancer***

We are also developing NX-1207 as a focal treatment for certain types of cancer. On August 26, 2009, Nymox announced that NX-1207 has been shown to produce strongly positive results when given to animals with hepatocellular carcinoma (HCC). In the experimental studies, the cancers were significantly reduced in size after 2 local injections of NX-1207. On October 14, 2009, we announced that NX-1207 had been shown to produce strongly positive results in laboratory studies of human prostate cancer. In addition, local injection of NX-1207 showed activity in animals with transplanted human prostate carcinoma. The NX-1207 used in these studies is a higher dosage from that of NX-1207 used to treat benign prostatic hyperplasia (BPH).

The Corporation intends to advance NX-1207 into human clinical trials for the treatment of HCC and for the focal treatment of localized prostate cancer. We cannot predict with any certainty whether the use of NX-1207 for any oncological indication will successfully complete preclinical testing, whether government regulatory agencies, such as the FDA, will permit such products to proceed to human trials, or whether ultimately the use of NX-1207 for any such indications will be granted approval for sale and marketing in the U.S., Canada, or elsewhere in the world. The development of cancer therapeutics in particular is associated with high risks and many uncertainties and a drug candidate that shows efficacy in pre-clinical testing and in animal models may fail in human trials or take a long period (7 years or more) to achieve regulatory approval.

***NXC-4720 for E. coli Contamination of Meat***

We are developing novel antibacterial agents for the treatment of *E. coli* O157:H7 bacterial contamination in hamburger meat and other food and drink products and for the treatment of urinary tract and other bacterial infections in humans which have proved highly resistant to conventional antibiotic treatments.

*E. coli* contamination of food and drink is a serious public health problem worldwide and a major concern for meat processors in particular. *E. coli* bacteria occur normally and usually harmlessly in the gastrointestinal tracts of humans, cows and other animals. However, one mutant variety of the *E. coli* bacteria, *E. coli* O157:H7, can cause life-threatening illness and has been implicated in cases of severe diarrhea, intestinal bleeding and kidney failure, leading, in some cases, to death in children and the elderly. *E. coli* contamination in hamburger meat and other food products and in drinking water affects about 70,000 people in the United States a year.

There is a well-recognized need in the beef industry to address the problem of *E. coli* contamination in meat processing and in livestock. *E. coli* contamination has triggered massive recalls of ground beef in the U.S. Cattle are a natural reservoir for the deadly strain of *E. coli*. Water contamination from cattle operations have led to public health tragedies.

Nymox developed a potent new antibacterial agent, NXC-4720. Tests of NXC-4720 show it to be highly effective against all known substrains of *E. coli* O157:H7, destroying the bacteria efficiently, rapidly and at a very low dose. In 1999, we began further laboratory trials for this agent as a treatment for food and drink contamination and entered into agreements with various collaborators. NXC-4720, which is being developed as a treatment of meat at the processing stage, has been shown to be capable of substantially reducing the level of potentially fatal *E. coli* O157:H7 contamination on fresh beef according to laboratory studies. Other projects in this area, such as treating *E. coli* O157:H7 infection in livestock, are in preliminary stages of development. Further pre-clinical testing and development is required before we can apply for regulatory approval for use of this agent on the processing of food and drink for human consumption.

The problem of *E. coli* O157:H7 contamination of hamburger meat and other food products is also well-known and a number of companies and researchers have been pursuing various potential solutions, including irradiation with x-rays, better detection of contamination, electronic pasteurization, vaccination and competitive exclusion of the pathogenic *E. coli* bacteria by harmless bacteria. The development of alternative solutions to the problem of *E. coli* infection may adversely affect the market for our treatment for *E. coli* O157:H7 infection in cattle and contamination of food products.

Nymox has also developed three other novel antibacterial agents, NXB-4221 for the treatment of difficult chronic and persistent urinary tract infections; NXB-5886 for the treatment of streptococcal infection; and NXT-1021 for the treatment of staphylococcal infection. Urinary tract infections in women caused by bacteria such as *E. coli* are a common and significant infection often resistant to conventional antibiotic treatment. Some varieties of streptococcus and staphylococcus bacteria, a common source of infection in humans, have acquired a broad immunity to antibiotic treatments. Infections from these antibiotic resistant bacteria are difficult to treat and can be life threatening.

Nymox's three antibacterial agents for the treatment of infectious disease have all shown the ability to kill their bacterial targets in culture with no signs of toxicity. Further pre-clinical testing and development is required before we can apply for regulatory approval to begin initial testing in humans.

A similar competitive reality prevails in the field of novel anti-infectives. Over the past ten years, there has been an increasing awareness of the medical need and of emerging market opportunities for new treatments for antibiotic

resistant bacterial infections. Many of the major pharmaceutical companies are developing anti-infective drugs that either modify their existing drugs or involve new anti-bacterial properties. Many biotechnology companies are developing new classes of anti-bacterial drugs. At least three major pharmaceutical companies have vaccines against bacterial infections in development. To the extent that these companies are able to develop drugs or vaccines that offer treatment for some or all of the indications for our anti-infectives, the market for our products may be adversely affected.

Nymox has patent rights to these and other antibacterial agents.

### ***The Use of Statin Drugs for the Treatment or Prevention of Alzheimer's Disease***

In October 2002, we were issued a United States patent for the use of statin drugs to treat, prevent or reduce the risk of the onset of Alzheimer's disease and have issued patents or pending patent applications elsewhere, including Europe, Japan, Canada and Australia. Statins are a class of commonly prescribed cholesterol lowering drugs that have a well-established safety record and are widely available. The potential of statin drugs for AD has been featured in a cover story in *Newsweek*, as well as in the *New York Times*, *Fortune*, *Los Angeles Times*, and *The Wall Street Journal*. Some of the recent scientific studies and reviews concerning the potential for statin drugs to treat or reduce the risk of AD or loss of cognitive function include *Neurology*. 2007; 69:1873-80; *Expert Opinion on Ther Targets*. 2007; 11:1257-60; *CNS Drugs*. 2007;21:449-62; *Neurosci Lett*. 2007;416:279-84; *Curr Med Chem*. 2007;14:103-12; *Neurol Res*. 2006; 28:630-6, *Acta Neurol Scand* 2006; 114 (Suppl. 185): 78-86, *Acta Neurol Scand* 2006; 114 (Suppl. 185): 3-7, *J.Neurochem*. 2006; 97:716-723; *Restor. Neurol. Neurosci* 2006; 24:79-95; *Neuromolecular Med*. 2006; 8:319-328, *Neurology* 2005; 65:1388-1394, *J. Neurol. Neurosurg. Psychiatry* 2005; 76:1624-1629, *The American Journal of Medicine* 2005; 118: 48S-53S; *The Lancet Neurology* 2005; 4:841-852; *Current Opinions in Lipidology* 2005;16: 619-623; *The Lancet Neurology* 2005; 4: 521-2, *Arch Neurol* 2005; 62:1047-51, *Neurology* 2005; 64:1531-8, *Arch Neurol* 2005; 62:753-7, *J Neurol Sci* 2005; 229-230:147-50, *Arch Gen Psychiatry* 2005; 62:217-24. *International Journal of Geriatric Psychiatry* (2004; 19:327-32), *Neuroepidemiology* (2004; 23:94-8); *Neuron* (2004; 41:7-10); *Archives of Neurology* (2000; 57:1439-1443); *Lancet* (2000; 356:1627-1631); *Archives of Neurology* (2002; 59:223-227); *Journals of Gerontology: Biological Sciences and Medical Sciences* (2002; 57:M414-M418); and *Journal of the American Geriatrics Society* (2002;50:1852-1856). Some studies, however, have not found evidence that statins may help treat or prevent Alzheimer's disease and research in this area is ongoing. No statin drug has been approved for use in the treatment or prevention of Alzheimer's disease.

## **Research and Development of New Products**

### ***New Therapeutics for Alzheimer's Disease***

Nymox has a number of proprietary drug development programs aimed at treatments for Alzheimer's disease and other indications. One program targets NTP and its role in the extensive brain cell loss associated with AD. Another program is based on spherons, which Nymox researchers regard as a source of senile plaques, the characteristic abnormality found in abundance in the brains of patients with AD and widely believed to play a major role in the cause and course of the illness. A third program is based on a novel drug candidate, NXD-5150, for neurodegenerative disease.

At present, there is no cure for Alzheimer's disease. There are five drugs approved by the FDA, tacrine (brand-name Cognex®), donepezil HCl (brand-name Aricept®), rivastigmine (brand-name Exelon®), galantamine hydrobromide (brand name Razadyne®) and memantine (brand name Namenda®) for the treatment of Alzheimer's disease. However, at most these drugs offer symptomatic relief for the loss of mental function associated with the disease and possibly help to delay the progression. There is no consensus as to the cause of Alzheimer's disease or even whether it is one disease or many.

There is an urgent need for an effective treatment for the illness, caused in part by the rising health care, institutional and social costs for the treatment and care of Alzheimer's disease sufferers. The Surgeon General's Report on Mental Health released on December 13, 1999, put the direct health care costs for the illness in the United States at almost \$18 billion for 1996. In April 2002, the National Institute on Aging reported that the cost of care to family, caregivers and society in general was estimated to exceed \$100 billion per year.

These costs are expected to rise sharply as the baby boom generation ages and more people become at risk for the disease. According to the National Institute on Aging's *2009 Progress Report on Alzheimer's Disease: Discovery and Hope*, experts agree that the number of people with AD will increase significantly if current population trends continue and no preventive treatments become available. As people live longer, they become more at risk of developing Alzheimer's disease. The U.S. Census Bureau estimates that the number of people in the U.S. aged 65 and older is expected to double to about 72 million people in the next 25 years. Moreover, the 85-and-older age group is now the fastest growing segment of the U.S. population.

Nymox's research into drug treatments for Alzheimer's disease is aimed at compounds that could arrest the progression of the disease and therefore are targeted for long term use.

### ***Drugs Targeting Spherons***

We are a leader in research and development into drugs for the treatment of Alzheimer's disease that target spherons. Nymox researchers believe that spherons are a cause of senile plaques, the characteristic lesion found abundantly in the brains of patients with Alzheimer's disease and believed by many researchers to play a pivotal role in the fatal illness. Spherons are tiny balls of densely packed protein found in brain cells scattered throughout the brains of all humans from age one. Nymox researchers have found that as humans age the spherons grow up to a hundred times larger until they become too large for the cells that hold them. Once released from the cells, the researchers believe that the spherons burst, creating senile plaques, contributing to the cellular damage and biochemical changes pivotal to the symptoms and signs of Alzheimer's disease.

The substantial evidence linking spherons to senile plaques and Alzheimer's disease has been published in journals such as the

*Journal of Alzheimer's Disease, Drug News & Perspectives* and *Alzheimer Reports*. There are 20 important criteria of validity which have been set forth correlating the disappearance of spherons in old age with the appearance of senile plaques and implicating spherons as a major cause in Alzheimer's disease. In 2000, Nymox researchers published important findings in *Alzheimer Reports* (2000; 3: 177-184) confirming that spherons contain key proteins that are also known to be in senile plaques and showing that, like senile plaques, spherons contain unusually old proteins in terms of the human body's metabolism, with an average age of 20 to 40 years. In 2003, Nymox announced the discovery that spherons contain toxic molecules termed spherotoxins which its researchers believe contribute significantly to the cell death and symptoms characteristic of Alzheimer's disease.

Nymox researchers believe that stopping or inhibiting the transformation of spherons into senile plaques will help stop or slow the progress of this illness. However, there is no consensus among researchers about the causes or possible treatments of Alzheimer's disease and not all researchers share this belief that spherons are a causative factor in Alzheimer's disease or are a target for the development of treatments for the disease.

Based on the research findings discussed above and the spheron-based approach to the treatment of the disease, we have developed novel, proprietary drug screening methods based on spherons and used them to discover, develop and test drug candidates to inhibit the formation of Alzheimer plaques from spherons. We believe these candidates have the potential to slow or stop the progression of the disease.



We have two distinct new drug candidates, NXD-3109 and NXD-1191, neither of which demonstrate significant toxicity and both of which had positive animal testing results. These candidates are at the stage of pre-clinical testing.

Such drug candidates will require regulatory approval in order to begin clinical studies for humans, but there is no guarantee that any of these drug candidates will ever be approved for marketing as a treatment for Alzheimer's disease. Drug candidates that look promising in early studies in the laboratory or with animals often prove on further testing to be unsafe, ineffective or impractical to use with human patients. The cost of bringing a drug candidate through the necessary clinical trial and regulatory approvals is very high and may require us to seek substantial financing through various sources including the issuing of more stock, the borrowing of funds secured by financial instruments such as bonds or agreements with major pharmaceutical companies. We risk not being able to secure such funding in the necessary amounts or on sufficiently favorable terms.

Nymox holds global patent rights covering both methods for using spherons as targets for developing drugs and for the actual drug candidates discovered.

### ***Neural Thread Protein Based Drugs***

Nymox developed a drug screening system, based on the research that led to its AlzheimerAlert test, to identify other potential drug candidates for the treatment of Alzheimer's disease. There is a substantial body of evidence showing that NTP may play a key role in Alzheimer's disease, including such published studies as *Journal of the Neurological Sciences* (1996; 138: 26-35), *Journal of Neuropathology and Experimental Neurology* (1996; 55: 1038-50) and (2001; 60: 195-207), *Journal of Clinical Investigation* (1997; 100: 3093-3104), *Alzheimer's Reports* (1999; 2: 327-332), *Journal of Alzheimer's Disease* (2001; 3: 345-353) and (2005; 7(1): 45-61), and *Cellular and Molecular Life Sciences* (2001; 58: 844-849) and (2003; 60:2679-91).

Nymox licensed the NTP technology in 1997 from Harvard University and the Massachusetts General Hospital as part of a sponsored research and licensing agreement. Under the terms of this agreement, Nymox sponsored the research of the principal investigators into the use of neural thread protein, its antibodies or genes for diagnostic or therapeutic purposes. Nymox also paid the patent costs for the patent applications filed arising out of this research. In return, Nymox received an exclusive worldwide license of the patents to sell products and to use processes encompassed by them. Nymox is to pay the Massachusetts General Hospital a 4% royalty of the net sales price of any product developed and sold under the license. Nymox currently pays this royalty on its sales of its AlzheimerAlert product. The license and the obligation to pay patents costs and royalties continue for the life of the patents, which run until November, 2014 at the earliest. The Massachusetts General Hospital has the right to terminate the license in any country where, after the first commercial sale of the product in the country, there is a continuous two year period in which no product is sold in such country. There are eight issued U.S. patents under license and a larger number of patents and patent applications in Europe, Japan, Canada, Australia, New Zealand and South Korea. The sponsored research portion of this agreement terminated in March, 1999. Nymox retained the exclusive license to the rights to the NTP-related patents owned by the Massachusetts General Hospital.

Effective March 1999, Nymox entered into a similar sponsored research and licensing agreement with Brown University and the Rhode Island Hospital. Under the terms of this agreement, Nymox continued to sponsor research into the uses of neural thread proteins, their antibodies or genes for diagnostic, therapeutic and research purposes and to pay the patent costs for any patent applications filed arising out of this research. In return, Nymox received an exclusive worldwide license of any such patents to sell products and to use processes encompassed by them. The Rhode Island Hospital has the right to terminate the license in any country where, after the first commercial sale of the product in the country, there is a continuous two year period in which no product is sold in such country. Nymox is to pay the Rhode Island Hospital a 4% royalty of the net sales price of any product developed and sold under the license.

The sponsorship agreement expired in March 2005; however, Nymox retains the exclusive license to patent rights on certain NTP-based technology including a license to two issued U.S. patents.

Nymox has screened compounds for their ability to impede the process of premature cell death and thus potentially help slow or halt the loss of brain cells in the Alzheimer's disease brain. This screening process identified promising drug candidates. The Corporation has developed a candidate, NXD-9062, which has shown significant progress in preclinical studies but successful completion of other pre-clinical studies is necessary before it can move into formal regulatory studies.

The Corporation's third program is based on a new drug candidate for neurodegenerative disease, NXD-5150, which successfully completed important pre-clinical milestones. Nymox has exclusive rights to two patent applications covering NXD-5150 as well as other related drug candidates for neurodegenerative disorders.

Nymox faces intense competition for the development of an effective treatment for Alzheimer's disease. The market conditions for an Alzheimer's disease drug strongly favor the entry of other corporations into the area. This market is expected to grow rapidly as new drugs enter the market and as the baby boom generation becomes more at risk for developing Alzheimer's disease. As a result, most of the major pharmaceutical companies and many biotechnology companies have ongoing research and development programs for drugs and treatments for Alzheimer's disease. Many of these companies have much greater scientific, financial and marketing resources than we have and may succeed in developing and introducing effective treatments for Alzheimer's disease before we can. At present, four drugs for Alzheimer's disease are being widely marketed in the United States, Aricept® by Pfizer, Exelon® by Novartis, Razadyne® by Janssen and Namenda® by Forest. These four drugs only treat some of the symptoms of Alzheimer's disease by enhancing memory and other mental functions and not the underlying causes of the illness.

### ***Oncology products***

We are in the preclinical stage of developing therapeutic products for oncological indications based on technology licensed from the Massachusetts General Hospital. We cannot predict with any certainty whether any such product will successfully complete preclinical testing, whether government regulatory agencies, such as the FDA, will permit such products to proceed to human trials, or whether ultimately any such product will be granted approval for sale and marketing in the U.S., Canada, or elsewhere in the world.

### ***New Diagnostic Products***

Nymox has a number of proprietary diagnostic markers and technologies, including a patented platform for point-of-care testing, and has tests utilizing these technologies in the early stages of development. Nymox also has U.S. patents for a method and device for using saliva to determine cholesterol levels and for a method of testing for osteoporosis. The Corporation also owns patent rights to several novel biochemical indicators for Alzheimer's disease.

### **Manufacturing Arrangements**

Our NicAlert and TobacAlert products and AlzheimerAlert kits are currently partly manufactured through out-sourcing arrangements with contract manufacturers. To date, we have not experienced any significant interruptions in the manufacture of these products and the cost of the manufacturing services has not been volatile. The manufacturing services supplied by our current contract manufacturer are not unique or unduly complicated and other contract manufacturers are available to provide similar services in the event that our current contract manufacturer fails to meet our needs.

### **Property and Equipment**

Nymox and Serex laboratory facilities in Hasbrouck Heights, New Jersey comprise 4,799 square feet of leased space. That lease agreement expires October 31, 2013. Nymox office and research facilities in St. Laurent, Quebec, Canada comprise 11,210 square feet of leased space. The lease agreement expires on August 31, 2012. Nymox Pharmaceutical Corp. and its two US subsidiaries Nymox Corp. and Serex, Inc. own a full complement of equipment used in all aspects of their research and development work. Nymox believes that its facilities are adequate for its current needs and that additional space, if required, would be available on commercially reasonable terms.

### **Governmental Regulation**

Our AlzheimerAlert test is subject to extensive government regulation in the United States. Any changes in CMS or state law requirements or in the FDA regulations could have an impact on our future ability to offer or market any reference laboratory services and/or on our ability to obtain reimbursement from the Medicare and Medicaid programs and providers.

We have developed a diagnostic kit version of the AlzheimerAlert test. We will need to obtain FDA approval before we can market or sell such a diagnostic kit version outside of the clinical reference laboratory setting in the United States. Such approval for this type of commercial development is necessary for all in vitro diagnostic kits. On July 15, 2005, an FDA advisory panel voted 5-2 against recommending approval of our PMA application for the kit, citing the need for further studies, such as long term follow-up and autopsy confirmation. We cannot predict with any certainty when or if FDA approval will be forthcoming and we anticipate that more clinical testing or further documentation will be required before approval. If approved, the diagnostic kit would then be subject to postmarketing record and reporting obligations and manufacturing requirements.

Similar requirements exist in many other countries. In November 2004, Nymox satisfactorily completed the testing and registration required by European regulatory, environmental and quality standards in order to obtain a CE Mark for the AlzheimerAlert kit. The CE Mark makes the AlzheimerAlert kit eligible for sale in the European Union and enables European clinical and hospital laboratories to perform the AlzheimerAlert test in their own facilities in Europe.

The regulatory process leading to such approval can be time-consuming and expensive and can result in an outright denial or a very limited approval only. AlzheimerAlert will be subject to premarketing and postmarketing requirements applicable to such devices, including those governing:

- clinical testing;
- design control procedures;
- prior FDA approval of a 510(k) application, where the FDA has determined that our diagnostic device is substantially equivalent to a marketed device, or a premarket approval application, where the FDA has been satisfied with clinical studies demonstrating the safety and efficacy of our device;
- postmarketing record and reporting obligations; and
- good manufacturing practices.

The requirements for a premarket approval application are analogous to those for the approval of a new drug and include four categories of information: indications for use, device description and manufacturing methods, alternative practices and procedures for the diagnosis of the disease and clinical and nonclinical studies. The requirements for a 510(k) application are generally less onerous but still include indications for use, safety and effectiveness data as well as manufacturing and quality assurance data and information. There can be no assurance that the AlzheimerAlert test or any other medical device that we may develop in the future will obtain the necessary approvals within a specified time framework, if ever. In addition, the FDA may impose certain postmarketing requirements that may significantly increase the regulatory costs associated with our product. The FDA has recourse to a wide range of administrative sanctions and civil and criminal penalties in order to enforce the applicable laws, rules and regulations.

Our therapeutic products under development by Nymox would also have to receive regulatory approval. This is a costly, lengthy and risky process. In the United States, in order for a product to be marketed, it must go through four distinct development and evaluation stages:

#### Product Evaluation

We must conduct preliminary studies of potential drug candidates using various screening methods to evaluate them for further testing, development and marketing.

#### Optimization of Product Formulation

The activities in this stage of development involve consultations between us and investigators and scientific personnel. Preliminary selection of screening candidates to become product candidates for further development and further evaluation of drug efficacy is based on a panel of research based biochemical measurements. Extensive formulation work and in vitro testing are conducted for each of various selected screening candidates and/or product candidates.

#### Clinical Screening and Evaluation

During this phase of development, portions of which may overlap with product evaluation and optimization of product formulation, initial clinical screening of product candidates is undertaken and full scale clinical trials commence. The FDA must approve any clinical testing on healthy subjects (Phase 1) and on patients (Phase 2 and 3).

#### Final Product Development

The activities to be undertaken in final product development include performing final clinical evaluations, conducting large-scale experiments to confirm the reproducibility of clinical responses, making clinical lots for any additional extensive clinical testing that may be required, performing any further safety studies required by the FDA, carrying out process development work to allow pilot scale production of the product, completing production demonstration runs for each potential product, filing new drug applications, product license applications, investigational device exemptions (and any necessary supplements or amendments) and undergoing comprehensive regulatory approval programs and processes.

We cannot assure you that we will successfully complete the development and commercialization of any therapeutic products.

In the United States, obtaining the necessary FDA approval for any drug is a lengthy, expensive and often arduous process. We cannot predict with any certainty the amount of time the FDA will take to approve one of our drugs or even whether any such approval will be forthcoming. Similar requirements exist in many other countries.

In the United States, the FDA approval procedure is a two-step process. We must file an investigational new drug (IND) application for each product with the FDA before beginning the initial (Phase 1) clinical testing of the new drug in healthy subjects. If the FDA has not commented on or questioned the application within 30 days of its filing, initial clinical studies may begin. If, however, the FDA has comments or questions, the questions must be answered to the satisfaction of the FDA before initial clinical testing can begin. In some instances, this process could result in substantial delay and expense. Phase I studies are intended to demonstrate the functional characteristics and safety of a product.

After Phase 1 testing, we must conduct extensive clinical trials with patients in order to establish the efficacy and safety of our drug. Once we complete the required clinical testing, we expect to have to file a new drug application for FDA approval in order to market most, if not all, of our new drugs. The application is complicated and detailed and must include the results of extensive clinical and other testing, the cost of which is substantial. The FDA conducts an extensive and often lengthy review of such applications. The agency is required to review applications within 180 days of their filing, but, during the review, frequently requests that additional information be submitted. This starts the 180-day regulatory review period anew when the requested additional information is submitted and, as a result, can significantly extend the review period. Until the FDA actually approves the new drug application, there can be no assurance that the agency will consider the information requested and submitted to justify approval. The packaging and labeling of products are also subject to FDA regulation. Accordingly, it is impossible to anticipate when the FDA will approve a new drug application.

Our lead candidate is NX-1207, a treatment for benign prostatic hyperplasia. We cannot predict with any certainty the outcome of future trials, what further steps may be required in order to apply for final FDA approval for this drug or whether the FDA will ultimately grant us such approval.

We must also obtain approval for our drugs or diagnostic devices from the comparable regulatory authority in other countries before we can begin marketing our product in that country. The approval procedure varies from country to country and can involve additional testing. The time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general each country has its own procedures and requirements, many of which are time-consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed.

After such approvals are obtained, further delays may be encountered before the products become commercially available. If, subsequent to approval, new information becomes available concerning the safety or effectiveness of any approved product, the regulatory authority may require the labeling for the affected product to be revised or the product to be withdrawn. Our manufacturing of any approved drug must conform with the FDA's good manufacturing practice regulations which govern the production of pharmaceutical products and be subject to inspections and compliance orders.

Government regulation also affects our ability to receive an appropriate level of reimbursement for our products. Throughout the developed world, both public and private health care plans are under considerable financial and political pressure to contain their costs. The two principal methods of restricting expenditures on drugs and diagnostic products and services are to deny coverage or, if coverage is granted, to limit reimbursement. For single-payer government health care systems, a decision to deny coverage or to severely restrict reimbursement for one of our products can have an adverse effect on our business and revenues.

In the United States, where, to a significant degree, the patient population for our products is elderly, Medicare and Medicaid are sources of reimbursement. In general, any restriction on reimbursement, coverage or eligibility under either program could adversely affect reimbursement to Nymox for products and services provided to beneficiaries of the Medicare and/or Medicaid programs. Many elderly people are covered by a variety of private health care organizations either operating private health care plans or Medicare or Medicaid programs subject to government regulation. These organizations are also under considerable financial constraints and we may not be able to secure coverage or adequate reimbursement from these organizations. Without coverage, we will have to look to the patients themselves who may be unwilling or unable to pay for the product; in turn, doctors may be reluctant to order or prescribe our products in the absence of coverage of the product for the patient.

In response to rising health care costs, there have been a number of legislative and administrative proposals in the U.S. for the reform of the healthcare system. In 1997 the U.S. Congress implemented sweeping changes to the U.S. Medicare and Medicaid systems. Under Part C: Medicare + Choice programs, beneficiaries can opt for a variety of health delivery models, including coordinated care plans, HMOs, preferred provider organizations and provider sponsored organizations, private fee-for-service plans and medical savings account plans. In addition, states have the option to require Medicaid recipients to enroll with managed health care plans without first obtaining a waiver, making it substantially easier for the states to meet their Medicaid obligations through private managed care organizations. All these health care delivery systems, including the original Medicare and Medicaid systems, are subject to funding formulas and spending caps and may compensate for these restrictions by limiting coverage, eligibility and/or payments. In 2003, the U.S. government added insurance coverage to help pay for prescription drugs to Medicare. In March 2010, the United States enacted health care reform legislation. Important market reforms began this year and will continue through full implementation in 2014. The new law is expected to expand access to health care to more than 32 million Americans by the end of the decade. These changes may adversely affect the prices we may charge for any therapeutic drug we develop. The long-term impact of legislative changes in terms of their efficiency, effectiveness and financial viability in delivering health care services to an aging population is uncertain at present. Any legislative or regulatory actions to reduce or contain federal spending under either the Medicare or

Medicaid programs could adversely affect our ability to participate in either program as a provider or supplier of services or products and the amount of reimbursement under these programs potentially available to us.

Our AlzheimerAlert test, and any of the new diagnostic and therapeutic products and services that we may develop, will be subject to coverage determinations by health care providers and payers. Federal and state regulations and law and internal coverage policies of health care organizations affect our ability to obtain payments for our products and services. The Medicare program will not pay for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Historically, CMS interpreted this provision in order to exclude from Medicare coverage those medical and health care services that are not demonstrated to be safe and effective by acceptable clinical evidence. CMS recently revised both its national coverage policies and procedures in general and specifically its coverage of diagnostic laboratory tests and constituted a Medicare Coverage Advisory Committee to provide advice on the effectiveness and appropriateness of medical items and services that are eligible for coverage under Medicare. It is unknown how these changes will affect our ability to obtain Medicare coverage for our products and services. However, an adverse national coverage decision with respect to one of our products or services will make it impossible to receive reimbursement from Medicare for that product and more difficult to convince private health care organizations to provide coverage for it. Even if we receive a favorable coverage decision for one of our products or services, there is no guarantee that the level of reimbursement for it will be close to our retail price for it or commensurate with the costs of developing and marketing it.

#### **Patents and Proprietary Information**

We believe that patent and trade secret protection is important to our business, and that our success will depend, in part, on our ability to obtain strong patents, to maintain trade secret protection and to operate without infringing the proprietary rights of others.



The commercial success of products incorporating our technologies may depend, in part, upon our ability to obtain strong patent protection. We cannot assure you that additional patents covering new products or improvements will be issued or that any new or existing patents will be of commercial benefit or be valid and enforceable if challenged.

We pursue a policy of seeking patent protection for valuable patentable subject matter of our proprietary technology and require all employees, consultants and other persons who may have access to its proprietary technology to sign confidentiality agreements.

The Corporation currently owns or has licensed exclusive rights to several hundred patents and patent applications in the U.S. and other countries around the world in support of its proprietary product development programs. Nymox has twenty-three U.S. patents issued or allowed and a corresponding larger number of patents and patent applications worldwide. Nymox has issued patents in the main European markets, including Great Britain, Germany, France, Italy, The Netherlands, Sweden and Spain among others and in other countries such as Japan, Canada and Australia. These patents and patent applications cover much of our current product development and technologies, including new drug candidates, proprietary screening technologies for finding drugs, promising diagnostic markers, new diagnostic assay methods, methods of treating meat and other food products; and anti-infective agents. The earliest expiry date for our issued patents was July 2010 and the rest range from 2013 through 2021.

Nymox's subsidiary, Serex, has thirteen patents issued or allowed in the United States and a corresponding larger number of patents and patent applications worldwide. These patents and patent applications cover such areas as Serex's proprietary diagnostic technologies and methodologies. The expiry dates for its patents range from 2012 to 2017.

Nymox also has exclusive rights to twelve issued U.S. patents as well as a corresponding larger number of patents and patent applications worldwide through research and license agreements. The earliest of these patents expires in 2014.

Many companies have patents covering various drugs, methods and discoveries in the fields of diagnostics and therapeutics for Alzheimer's disease and related conditions and of new anti-infective agents. We believe that the patents issued to date will not preclude Nymox from developing and marketing our products; however, it is impossible to predict the extent to which licenses from third parties will be necessary. If Nymox were to need licenses from third parties there can be no assurance that we could obtain such licenses on commercially reasonable terms, if at all.

In the fields of diagnostic methods and diagnostic tests for common human diseases and conditions, where Serex has many of its patents, there are many patents issued covering many areas of diagnostic methods, tests and technologies. We believe that these patents issued to date to other companies will not preclude Serex from developing and marketing its products but you should be aware that it is often difficult to determine the nature, breadth and validity of competing patent claims in these fields, that there has been significant litigation in some of these areas (not involving Serex) and that, if and when Serex's products become more commercially successful, Serex's products or patents may become the subject matter of litigation. If Serex were to need licenses from third parties there can be no assurance that it could obtain such license on commercially reasonable terms, if at all.

Neither Nymox nor Serex are currently involved in litigation over patent and other intellectual property rights but significant litigation over these matters in the pharmaceutical and biotechnology industry is not uncommon. The validity and extent of patent rights can be very difficult to determine and involve complex legal, factual and scientific questions. Important legal issues about patent protection in the field of biotechnology have not been resolved. Patent litigation is costly and time-consuming and can consume substantial resources. An adverse decision can preclude the marketing of a product, expose us to significant liabilities or require us to obtain third party licenses, which may not be available at commercially reasonable prices.

We also rely upon trade secrets, know-how, and continuing technological advancement to develop and maintain our competitive position. We control the disclosure and use of our know-how and confidential information through agreements with the parties involved. In addition, we have confidentiality agreements with our key employees, consultants, officers and directors. There can be no assurance, however, that all confidentiality agreements will be honored, that others will not independently develop equivalent technology, that disputes will not arise as to the ownership of intellectual property, or that disclosure of our trade secrets will not occur. Furthermore, there can be no assurance that others have not obtained or will not obtain patent protection that will exclude us from using our trade secrets and confidential information. To the extent that consultants or research collaborators use intellectual property owned by others in their work with us, disputes may also arise as to the rights to related or resulting know-how or inventions.

### **Competition**

Rapidly evolving technology and intense competition are the hallmarks of modern pharmaceutical and biotechnology industries.

Our competitors include:

- major pharmaceutical, diagnostic, chemical and biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours;
- biotechnology companies, either alone or in collaborations with large, established pharmaceutical companies to support research, development and commercialization of products that may be competitive with ours; and

- academic institutions, government agencies and other public and private research organizations which are conducting research into Alzheimer's disease and which increasingly are patenting, licensing and commercializing their products either on their own or through joint ventures.

In the field of Alzheimer's disease diagnosis, our AlzhemAlert test faces growing competition which could detrimentally impact on our ability to successfully market and sell our diagnostic test. Our competitors include:

- Athena Diagnostics, Inc., a wholly owned subsidiary of Thermo Fischer Scientific, which is currently marketing three tests claimed to aid in the diagnosis of Alzheimer's disease: a genetic test for the rare cases of familial, early-onset Alzheimer's disease; a genetic test for a relatively common mutation of a gene said to increase the likelihood of a person with at least one of the genes contracting the disease; and a test for two proteins in the spinal fluid of patients.
- Innogenetics NV which currently markets tests and kits for two proteins and a variant of one of these proteins in the spinal fluid of patients and a genetic test for a relatively common mutation of a gene said to increase the likelihood of a person developing the disease.
- Amorfix Life Sciences Ltd. currently markets a research test to detect aggregated amyloid protein in brain test and has under development related blood and CSF test.

There are also a number of other proposed biochemical signs of the disease that could potentially be developed into a commercial diagnostic test as well as various scanning and imaging technologies which compete for a portion of the diagnostic market for Alzheimer's disease. On January 20, 2011, an FDA Advisory Committee panel recommended against the approval at that time of Lilly's Amyvid (florbetapir), a molecular imaging tool developed to detect beta-amyloid plaque in the brain. The Committee's decision left open the possibility of approval at a later time after a further study is completed. A number of companies, including GE, are actively working to develop imaging technologies for the diagnosis of Alzheimer's disease. In June 2004, the CMS approved limited coverage of a Positronic Emission Tomography ( PET ) imaging procedure for helping to more precisely distinguish Alzheimer's disease from a rarer type of dementia when clinical evaluation has been inconclusive. In October 2004, the National Institute of Aging in conjunction with other Federal agencies, private companies and organizations launched the Alzheimer's Disease Neuroimaging Initiative, a \$60 million initiative to test whether various scanning and imaging technologies, biochemical markers, and clinical and neuropsychological testing can be combined to help diagnose early Alzheimer's disease.

Our NicAlert and TobacAlert products face competition from clinical laboratories such as LabCorp and Quest Diagnostics which provide off-site lab testing for cotinine, the by-product of the body's breakdown of nicotine measured by NicAlert and TobacAlert, and from assay suppliers, including immunoassay developers such as OraSure Technologies Inc. and Abraxis LLC, and diagnostic system manufacturers such as Roche Diagnostics, Abbott and Diagnostic Products Corporation. NicAlert and TobacAlert also face competition from distributors who supply simple yes-no smoking status tests such as NicQuick, and QuickScreen, from NicCheck I, an FDA-cleared smoking status test being marketed by Mossman & Associates Ltd, from SmokeScreen, a chemical color-based tobacco test being marketed by Mermaid Diagnostics, Ltd. in the United Kingdom, and from carbon monoxide (CO) monitors such as SmokeCheck.

We also face intense competition for the development of an effective treatment for Alzheimer's disease. The market conditions for an Alzheimer's disease drug strongly favor the entry of other corporations into the area. This market is expected to grow rapidly as new drugs enter the market and as the baby boom generation becomes more at risk for developing Alzheimer's disease. As a result, most of the major pharmaceutical companies and many biotechnology companies have ongoing research and development programs for drugs and treatments for Alzheimer's disease. Many

of these companies have much greater scientific, financial and marketing resources than we have and may succeed in developing and introducing effective treatments for Alzheimer's disease before we can. At present, four drugs for Alzheimer's disease are being widely marketed in the United States, Aricept® by Pfizer, Exelon® by Novartis, Razadyne® by Janssen and Namenda® by Forest. These four drugs only treat some of the symptoms of Alzheimer's disease by enhancing memory and other mental functions and not the underlying causes of the illness.

A similar competitive reality prevails in the field of novel anti-infectives. Over the past ten years, there has been an increasing awareness of the medical need and of emerging market opportunities for new treatments for antibiotic resistant bacterial infections. Many of the major pharmaceutical companies are developing anti-infective drugs that either modify their existing drugs or involve new anti-bacterial properties. Many biotechnology companies are developing new classes of anti-bacterial drugs. At least three major pharmaceutical companies have vaccines against bacterial infections in development. To the extent that these companies are able to develop drugs or vaccines that offer treatment for some or all of the indications for our anti-infectives, the market for our products may be adversely affected.

Our treatments under development for enlarged prostate (benign prostatic hyperplasia or BPH) face significant competition from existing products. There are eight drugs approved for treatment of BPH: four proprietary drugs (dutasteride (Avodart®), tamsulosin (Flomax®), alfuzosin (Uroxatral®), and silodosin (Rapaflo®)) a combination of two drugs (dutasteride and tamsulosin) (Jalyn ), and four generics (finasteride, terazosin, doxazosin, and prazosin). There are a number of thermal treatments on the market designed to shrink the enlarged prostate by heating its tissue with a device inserted through the urethra (the tube leading from the bladder through the penis through which men urinate) or through the abdomen. The devices on the market use microwave energy (Prostatron®, Targis Therapy® or TherMatrx®), low level radiowaves (TUNA System®), lasers (Indigo LaserOptic Treatment System® or Laserscope GreenLight PVP ), direct heat or hot water to heat or burn away prostate tissue. A variety of surgical procedures exist to surgically reduce or remove the prostate or to widen the urethra. These include procedures to cut away prostate tissue such as TURP (transurethral resection of the prostate) and using a resectoscope with an electrical loop inserted through the penis to cut the prostate tissue. A small device used to widen the constricted urethra called a prostatic stent can also be inserted.

The problem of *E. coli* O157:H7 contamination of hamburger meat and other food products is also well-known and a number of companies and researchers have been pursuing various potential solutions, including irradiation with x-rays, better detection of contamination, electronic pasteurization, vaccination and competitive exclusion of the pathogenic *E. coli* bacteria by harmless bacteria. The development of alternative solutions to the problem of *E. coli* infection may adversely affect the market for our treatment for *E. coli* O157:H7 infection in cattle and contamination of food products.

## Marketing

Our AlzheimerAlert test is certified with a CE Mark, making the device eligible for sale in the European Union.

At present, we do most of our marketing ourselves. To increase our marketing, distribution and sales capabilities both in the United States and around the world, we will need to enter into licensing arrangements, contract sales agreements and co-marketing deals. We cannot assure you that we will be able to enter into agreements with other companies on terms acceptable to us, that any licensing arrangement will generate any revenue for the Corporation or that the costs of engaging and retaining the services of a contract sales organization will not exceed the revenues generated.

If successfully developed and approved, we plan to market and sell our therapeutic and diagnostic products directly or through co-promotion arrangements or other licensing arrangements with third parties. In cases where we have sole or shared marketing rights, we plan to build a small, focused sales force if and when such products approach marketing approval in some markets, including Europe. Implementation of this strategy will depend on many factors, including the market potential of any products we develop as well as on our financial resources. To the extent we will enter into co-promotion or other licensing arrangements, any revenues received by us will be dependent on the efforts of third parties.

## Principal Markets

The Corporation markets its products for sale principally in the United States, Canada and overseas. Set forth below is a breakdown of the Corporation's revenues by geographic market for the last three years.

Revenues:	Canada	United States	Europe & Other
2010	\$ 17,091	\$ 505,897	\$ 169,653
2009	\$ 11,386	\$ 328,564	\$ 76,030
2008	9,637	347,764	71,008

## ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

### General

Nymox Pharmaceutical Corporation is a biopharmaceutical Corporation with three proprietary products on the market, and an R&D pipeline of drug and diagnostic products in development.

We have developed the AlzheimerAlert test as an aid to the diagnosis of Alzheimer's disease. The kit version of the AlzheimerAlert test is certified with a CE Mark in Europe. AlzheimerAlert is an improved version of our AD7C test, from which we began generating revenue from sales in 1997. In July 2005, an FDA advisory panel voted 5-2 against approval of our kit, citing the need for further studies, such as long term follow-up and autopsy confirmation.

We also market NicAlert and TobacAlert, our two products which determine a person's level of exposure to tobacco products. These products are also certified with a CE Mark, making the devices eligible for sale in the European Union.

We have under development therapeutic agents for the treatment of Alzheimer's disease, the treatment of enlarged prostate (BPH) and of certain antibiotic-resistant infections as well as antibacterial agents for E. coli contamination of food and drink products.

In September, 2006, we announced the successful completion of a multi-center, double-blind, placebo-controlled Phase 2 trial of NX-1207, our lead candidate for the treatment of BPH. In February 2009, the Corporation reported concluding a positive and productive End of Phase 2 ( EOP2 ) meeting with the FDA concerning the Phase 3 program for NX-1207. In June 2009, the Corporation began conducting the first of two pivotal double blind placebo controlled Phase 3 trials for NX-1207 that incorporate the specific protocol design recommendations provided to the Corporation by the FDA.

We also have the rights to a U.S. patent for the use of statin drugs for the treatment or prevention of Alzheimer's disease.

We have incurred operating losses throughout our history. Management believes that such operating losses will continue for at least the next few years. The costs relating to clinical trials for our potential therapeutic products will increase expenditures and delay profitability, despite anticipated increases in sales revenue in the coming years.

All figures are presented in U.S. dollars, unless otherwise stated.

Similar requirements exist in many other countries. Obtaining these approvals and complying with the subsequent regulatory requirements can be both time-consuming and expensive.

### **History of Capital Funding**

We have funded our operations and projects primarily by selling shares of Nymox's common stock. However, since 1997, a small portion of our funding also comes from sales. Since its incorporation in May, 1995, Nymox raised the capital necessary to fund its on-going research and development work and its marketing and sales operations primarily through private placements of its shares.

On December 1, 1997, our common shares began trading on the Nasdaq Stock Market. Nymox's common shares also traded on the Montreal Exchange from December 18, 1995 to November 19, 1999.

On January 27, 2003 we entered into a Common Stock Private Purchase Agreement with an investment corporation, Lorros-Greyse, for the future issuance and purchase of Nymox's common shares.

Under the terms of this agreement, which has since been replaced annually by new agreements with Lorros-Greyse, we may give notice to Lorros-Greyse requiring it to purchase a specified dollar amount of our shares. The amount specified in any one notice may be up to \$500,000 but not less than \$100,000. The maximum amount can be higher if both parties agree. The number of shares Nymox will issue to Lorros-Greyse in return for that money will be equal to the amount specified in the notice divided by 97% of the average market price of our common shares for the five trading days preceding the giving of the notice. The Corporation must comply with general covenants in order to draw on its facility, including maintaining its stock exchange listing and registration requirements and having no material adverse effects, as defined in the agreement, with respect to the business and operations of the Corporation. The Corporation may terminate the agreement before the 24-month term, if it has issued at least \$8 million of common shares under the agreement.

Under the agreement dated November 16, 2007, we received a total of \$3,695,000 during 2008 and under the agreement dated November 10, 2008, we received \$4,105,000 during 2009.

On November 2, 2009, we signed a new Common Stock Private Purchase Agreement, whereby Lorros-Greyse is committed to purchase up to \$15 million of Nymox's common shares over the twenty-four month period beginning in November 2009, subject to the same terms and conditions as before.

Under this agreement dated November 2, 2009, which became effective December 10, 2009, we received a total of \$4,700,000 for the following shares under this Common Stock Private Purchase Agreement:

- January 22, 2010, 117,925 common shares were issued at a price of \$4.24 per share.
- March 1, 2010, 298,913 common shares were issued at a price of \$3.68 per share.

- May 4, 2010, 91,743 common shares were issued at a price of \$3.27 per share.
- June 3, 2010, 34,965 common shares were issued at a price of \$4.29 per share
- June 14, 2010, 47,059 common shares were issued at a price of \$4.25 per share.
- June 28, 2010, 64,935 common shares were issued at a price of \$3.85 per share.
- July 23, 2010, 34,247 common shares were issued at a price of \$2.92 per share.
- August 4, 2010, 24,450 common shares were issued at a price of \$4.09 per share.
- August 13, 2010, 46,729 common shares were issued at a price of \$4.28 per share.
- August 27, 2010, 25,445 common shares were issued at a price of \$3.93 per share.
- September 2, 2010, 54,201 common shares were issued at a price of \$3.69 per share.
- September 13, 2010, 41,436 common shares were issued at a price of \$3.62 per share.
- September 23, 2010, 35,112 common shares were issued at a price of \$3.56 per share.
- September 29, 2010, 124,269 common shares were issued at a price of \$3.42 per share.
- October 26, 2010, 49,261 common shares were issued at a price of \$4.06 per share.
- November 4, 2010, 50,251 common shares were issued at a price of \$3.98 per share.
- November 15, 2010, 49,751 common shares were issued at a price of \$4.02 per share.
- November 24, 2010, 50,125 common shares were issued at a price of \$3.99 per share.

On November 1, 2010, we signed a new Common Stock Private Purchase Agreement, whereby Lorros-Greyse is committed to purchase up to \$15 million of Nymox's common shares over the twenty-four month period beginning in November 2010, subject to the same terms and conditions as before.



Under this agreement dated November 1, 2010, which became effective November 25, 2010, we received a total of \$200,000 for the following shares under this common stock private purchase agreement:

- December 9, 2010, 49,261 common shares were issued at a price of \$4.06 per share.

As of March 15, 2011, Nymox had approximately \$14.8 million of financing available under the facility. We expect this Common Stock Private Purchase Agreement to provide sufficient financing to enable us to advance our research and product development for the next two years.

Also, the Corporation has received total proceeds of approximately \$1.03 million from the exercise of 346,400 options since 1995. No options were exercised in 2010 and no options have been exercised since May 2007.

Pursuant to the share purchase agreement we entered into in March 2000 to acquire a controlling interest of Serex, Inc., a total of 257,607 additional shares and 158,526 warrants were issued in exchange for the shares of Serex. Since January 2004, 131,940 of these warrants have been exercised under a cashless exercise, whereby the warrant holder receives a number of shares equivalent in value to the net difference between the strike price on the warrant and the average market price on the day before the date of the cashless exercise, according to a formula contained in the warrant agreement. The net effect of these cashless exercises has been the issuance of 22,061 shares of Nymox common stock. Another 1,090 of these warrants were exercised resulting in the issuance of 1,090 shares of Nymox, for proceeds of \$4,033.

In total, Nymox has raised over \$62.9 million through the issuance of common stock or securities exercisable for shares of common stock, since its incorporation in May 1995.

We have no financial obligations of significance other than long-term lease commitments for our premises in the United States and Canada of \$31,793 per month in 2011. Total commitments in 2011 and beyond are summarized in note 9 to the consolidated financial statements.

## MANAGEMENT'S DISCUSSION AND ANALYSIS

(in US dollars)

This Management's discussion and analysis ("MD&A") comments on the Corporation's operations, performance and financial condition as at and for the years ended December 31, 2010, 2009 and 2008. This MD&A should be read together with the audited Consolidated Financial Statements and the related notes. This MD&A is dated March 15, 2011. All amounts in this report are in U.S. dollars, unless otherwise noted.

All financial information contained in this MD&A and in the Consolidated Financial Statements has been prepared in accordance with Canadian generally accepted accounting principles (GAAP). The audited Consolidated Financial Statements and this MD&A were reviewed by the Corporation's Audit and Finance Committee and were approved by our Board of Directors.

Additional information about the Corporation can be obtained on EDGAR at [www.sec.gov](http://www.sec.gov) or on SEDAR at [www.sedar.com](http://www.sedar.com).

### Overview

#### Corporate Profile

Nymox Pharmaceutical Corporation is a biopharmaceutical company with a significant R&D pipeline in development. Nymox is developing NX-1207, a novel treatment for benign prostatic hyperplasia which is in Phase 3 trials in the U.S. In December 2010, the Corporation signed a license and collaboration agreement with Recordati, a European pharmaceutical group, for the development and commercialization of NX-1207 in Europe including Russia and the CIS, the Middle East, the Maghreb area of North Africa and South Africa. The licensing and collaboration agreement covers the use of NX-1207 for the treatment of BPH as the initial indication for development and commercialization. NX-1207 showed positive results for the treatment of BPH in Phase 1 and 2 clinical trials in the U.S. The Corporation successfully completed a 43 site prospective randomized double-blinded placebo controlled Phase 2 U.S. clinical trial of NX-1207 in 2006, which showed statistically significant efficacy and a good safety profile. In February 2008, the Corporation reported positive results in a 32 site U.S. Phase 2 prospective randomized blinded clinical trial, with statistically significant improvement compared to an approved BPH drug (finasteride). Nymox reported positive results in twelve follow-up studies of available subjects from the completed Phase 1 and 2 clinical trials. In February 2009, the Corporation reported concluding a positive and productive End of Phase 2 (EOP2) meeting with the FDA concerning the Phase 3 program for NX-1207. In June 2009, the Corporation began conducting the first of two pivotal double blind placebo controlled Phase 3 trials for NX-1207 that incorporate the specific protocol design recommendations provided to the Corporation by the FDA. The two pivotal Phase 3 studies for NX-1207 are being conducted at well known investigational sites across the U.S. with planned enrollment of 1,000 patients. The Corporation is also developing new treatments for bacterial infections in humans and for the treatment of *E. coli* O157:H7 contamination in food products. Nymox has candidates which are under development as drug treatments aimed at the causes of Alzheimer's disease, and has several other drug candidates in development. Nymox has U.S. and global patent rights for the use of statin drugs for the treatment and prevention of Alzheimer's disease. Nymox developed the AlzheimerAlert™ test, which is certified with a CE Mark in Europe. AlzheimerAlert™ is an accurate, non-invasive aid in the diagnosis of Alzheimer's disease. Nymox developed and markets NicAlert™ and TobacAlert™; which are tests that use urine or saliva to detect use of and exposure to tobacco products. NicAlert™ has received clearance from the U.S. Food and Drug Administration (FDA) and is also certified with a CE Mark in Europe. TobacAlert™ is the first test of its kind to accurately measure second and third hand smoke exposure in individuals.

#### Risk Factors

The business activities of the Corporation since inception have been devoted principally to research and development. Accordingly, the Corporation has had limited revenues from sales and has not been profitable to date. We refer to the Risk Factors section of our Form 20-F filed on EDGAR and of our Annual Information Form filed on SEDAR for a discussion of the management and investment issues that affect the Corporation and our industry. The risk factors that could have an impact on the Corporation's financial results are summarized as follows:

- Our Clinical Trials for our Therapeutic Products in Development, such as NX-1207, May Not be Successful and We May Not Receive the Required Regulatory Approvals Necessary to Commercialize These Products
- Our Clinical Trials for our Therapeutic Products, such as NX-1207, May be Delayed, Making it Impossible to Achieve Anticipated Development or Commercialization Timelines
- A Setback in Any of our Clinical Trials Would Likely Cause a Drop in the Price of our Shares
- We May Not be Able to Make Adequate Arrangements with Third Parties for the Commercialization of our Product Candidates, such as NX-1207
- We May Not Achieve our Projected Development Goals in the Time Frames We Announce and Expect
- Even If We Obtain Regulatory Approvals for our Product Candidates, We Will be Subject to Stringent Ongoing Government Regulation
- It is Uncertain When, if Ever, We Will Make a Profit
- We May Not Be Able to Raise Enough Capital to Develop and Market Our Products
- We Face Challenges in Developing, Manufacturing and Improving Our Products
- Our Products and Services May Not Receive Necessary Regulatory Approvals
- We Face Significant and Growing Competition

- We May Not Be Able to Successfully Market Our Products
- Protecting Our Patents and Proprietary Information is Costly and Difficult
- We Face Changing Market Conditions
- Health Care Plans May Not Cover or Adequately Pay for our Products and Services
- We Are Subject to Continuing Potential Product Liability Risks, Which Could Cost Us Material Amounts of Money
- We Face Potential Losses Due to Foreign Currency Exchange Risks

### **Critical Accounting Policies**

The consolidated financial statements of the Corporation have been prepared under Canadian generally accepted accounting principles and include a reconciliation to accounting principles generally accepted in the United States (see Canadian/US reporting differences in the Notes to the Consolidated Financial Statements). The Corporation's functional and reporting currency is the United States dollar. Our accounting policies are described in the notes to our annual audited consolidated financial statements. We consider the following policies to be the most critical in understanding the judgments that are involved in preparing our financial statements and the matters that could impact our results of operations, financial condition and cash flows. Revenue Recognition The Corporation has generally derived its revenue from product sales, collaboration agreements and interest. Revenue from product sales is recognized when the product has been delivered or obligations as defined in the agreement are performed. Collaboration agreements that include multiple deliverables are considered to be multiple-element arrangements. Under this type of arrangement, the identification of separate units of accounting is required and revenue is allocated among the separate units based on their relative fair values.

Payments received under a collaboration agreement may include upfront payments, milestone payments, sale of goods, royalties and license fees. Revenue for each unit of accounting are recorded as described below:

(i) Upfront payments:

Upfront payments are deferred and recognized as revenue on a systematic basis over the estimated service period.

Changes in estimates are recognized prospectively when changes to the expected term are determined.

(ii) Milestone payments:

Revenue subject to the achievement of milestones is recognized only when the specified events have occurred and collectibility is reasonably assured.

Specifically, the criteria for recognizing milestone payments are that (i) the milestone is substantive in nature, (ii) the achievement was not reasonably assured at the inception of the agreement, and (iii) the Corporation has no further involvement or obligation to perform associated with the achievement of the milestone, as defined in the related collaboration arrangement.

(iii) Sale of goods:

Revenue from the sale of goods is recognized when the Corporation has transferred to the buyer the significant risks and rewards of ownership of the goods, there is no continuing management involvement with the goods, and the amount of revenue can be measured reliably.

(iv) Royalties and license fees:

Royalties and license fees are recognized when conditions and events under the license agreement have occurred and collectibility is reasonably assured.

Valuation of Long-lived Assets

Property and equipment are stated at cost and are amortized on a straight-line basis over the estimated useful lives. The Corporation reviews the unamortized balance of property and equipment, and recognizes any impairment in carrying value when it is identified. Factors we consider important, which could trigger an impairment review include:

- Significant changes in the manner of our use of the acquired assets or the strategy for our overall business;  
and
- Significant negative industry or economic trends.

Impairment is assessed by comparing the carrying amount of an asset with its expected future net undiscounted cash flows from use together with its residual value (net recoverable value). If such assets are considered impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds its fair value. Management's judgment regarding the existence of impairment indicators is based on legal factors, market conditions and operating performances. Future events could cause management to conclude that impairment indicators exist and that the carrying values of the Corporation's property and equipment are impaired.

Stock-based Compensation

Stock-based compensation is recorded using the fair value based method for stock options issued to employees and non-employees. Under this method, compensation cost related to employee awards is measured at fair value at the date of grant, net of forfeitures, and is expensed over the award's vesting period. The Corporation uses the Black-Scholes options pricing model to calculate stock option values, which requires certain assumptions, including the future stock price volatility and expected time to exercise. Changes to any of these assumptions, or the use of a different option pricing model, could produce different fair values for stock-based compensation, which could have a material impact on the Corporation's earnings. The Corporation has no unvested non-employee awards.

Valuation of Future Income Tax Assets

Management judgment is required in determining the valuation allowance recorded against future tax assets. We have recorded a full valuation allowance as of December 31, 2010, due to uncertainties related to our ability to utilize all of our future tax assets, primarily consisting of net operating losses carried forward and other unclaimed deductions, before they expire. In assessing the realizability of future tax assets, management considers whether it is more likely than not that some portion or all of the future tax assets will not be realized. The ultimate realization of future tax assets is dependent upon the generation of future taxable income and tax planning strategies. The generation of future taxable income is dependent on the successful commercialization of the Corporation's products and technologies.

**Results of Operations**

<b>Selected Annual Information</b>	<b>2010</b>	<b>2009</b>	<b>2008</b>
Total revenues	\$692,641	\$415,980	\$428,409
Net loss (i)	\$(6,956,033)	\$(5,130,074)	\$(4,637,103)
Loss per share (basic & diluted) (i)	\$(0.22)	\$(0.17)	\$(0.16)
Total assets (i)	\$13,502,222	\$1,090,431	\$749,879

<b>Quarterly Results</b>	<b>Q1 – 2010</b>	<b>Q2 – 2010</b>	<b>Q3 – 2010</b>	<b>Q4 - 2010</b>
Total revenues	\$247,443	\$104,550	\$26,950	\$313,698
Net loss (i)	\$(1,269,550)	\$(1,745,798)	\$(1,760,474)	\$(2,180,211)
Loss per share (basic & diluted) (i)	\$(0.04)	\$(0.05)	\$(0.05)	\$(0.07)
	<b>Q1 - 2009</b>	<b>Q2 - 2009</b>	<b>Q3 - 2009</b>	<b>Q4 - 2009</b>
Total revenues	\$96,226	\$80,341	\$71,904	\$167,509
Net loss (i)	\$(1,004,259)	\$(1,220,152)	\$(1,362,840)	\$(1,542,823)
Loss per share (basic & diluted) (i)	\$(0.03)	\$(0.04)	\$(0.04)	\$(0.05)

(i) Net loss, loss per share (basic & diluted) and the total assets reflect the impact of the change in accounting policy as described in Note 3 (a) to the audited consolidated financial statements.

Results of Operations – 2010 compared to 2009

Net losses were \$2,180,211, or \$0.07 per share, for the quarter and \$6,956,033, or \$0.22 per share, for the year ended December 31, 2010, compared to \$1,542,823 or \$0.05 per share, for the quarter and \$5,130,074 or \$0.17 per share for the year ended December 31, 2009. Net losses include stock compensation charges of \$898,585 for the year ended December 31, 2010 and \$1,085,164 for the same period in 2009. The increase in net losses is attributable to higher clinical trial expenditures compared to 2009. The weighted average number of common shares outstanding for the year ended December 31, 2010 was 31,940,584 compared to 30,717,822 for the same period in 2009.

Revenues

Revenues from sales amounted to \$204,076 for the quarter and \$582,383 for the year ended December 31, 2010, compared with \$167,509 for the quarter and \$415,980 for the year ended December 31, 2009. Sales to new clients explain the increase in sales for the quarter and the year ended December 31, 2010 compared to the same period in 2009. The development of therapeutic candidates and moving therapeutic product candidates through clinical trials is a priority for the Corporation at this time. The growth of sales will become more of a priority once these candidates have reached the marketing stage. The Corporation expects that revenues will increase if and when product candidates pass clinical trials and are launched on the market.

For the year ended December 31, 2010, an amount of \$109,067 was recognized as revenue related to the upfront payment received from Recordati in December 2010. At December 31, 2010, the deferred revenue related to this transaction recorded on the balance sheet amounted to \$12,978,933.

### Research and Development

Research and development expenditures were \$1,330,216 for the quarter and \$4,787,820 for the year ended December 31, 2010, compared with \$1,172,863 for the quarter and \$3,183,134 for the year ended December 31, 2009. Research and development expenditures include costs incurred in advancing Nymox's BPH product candidate NX-1207 through clinical trials, as well as costs related to its R&D pipeline in development. The increase in expenses is attributable to higher expenditures on the clinical trial for NX-1207 compared to 2009. Expenditures in 2010 were increased principally on payroll by approximately \$317,000 and clinical site and laboratory services by approximately \$1,390,000 compared to the same period in 2009 with corresponding increases for the quarter. Research tax credits amounted to \$236,101 compared to \$139,915 in 2009 as a result of additional expenditures claimed for refundable tax credits in 2010 compared to 2009. The Corporation expects that research and development expenditures will decrease as product candidates finish development and clinical trials. However, because of the early stage of development of the Corporation's R&D projects, it is impossible to outline the nature, timing or estimated costs of the efforts necessary to complete these projects, nor the anticipated completion dates for these projects. The facts and circumstances indicating the uncertainties that preclude us from making a reasonable estimate of the costs and timing necessary to complete projects include the risks inherent in any field trials, the uncertainty as to the nature and extent of regulatory requirements both for safety and efficacy, and the ability to manufacture the products in accordance with current good manufacturing requirements (cGMP) and in sufficient quantities both for large scale trials and for commercial use. A drug candidate that shows efficacy can take a long period (7 years or more) to achieve regulatory approval. There is also uncertainty whether we will be able to successfully adapt our patented technologies or whether any new products we develop will pass proof-of-principle testing both in the laboratory and in clinical trials, and whether we will be able to manufacture such products at a commercially competitive price. In addition, given the very high costs of development of therapeutic products, we anticipate having to partner with larger pharmaceutical companies to bring therapeutic products to market. The terms of such partnership arrangements along with our related financial obligations cannot be determined at this time and the timing of completion of the approval of such products will likely not be within our sole control.

### Marketing Expenses

Marketing expenditures amounted to \$41,631 for the quarter and \$147,609 for the year ended December 31, 2010, compared with \$37,326 for the quarter and \$138,396 for the year ended December 31, 2009. The increase for the quarter and the year is due to an increase in costs of communications in 2010 compared to 2009. The Corporation expects that marketing expenditures will increase if and when new products are launched on the market.

### General and Administrative Expenses

General and administrative expenses amounted to \$915,814 for the quarter and \$1,716,515 for the year ended December 31, 2010, compared with \$182,024 for the quarter and \$799,784 for the year ended December 31, 2009. The increase for the year is due to higher expenditures on shareholder relations by approximately \$80,000, travel by approximately \$40,000, other professional fees by approximately \$97,000 and by \$705,000 in professional fees incurred related to entering into the license agreement compared to 2009 with corresponding increases for the quarter. The Corporation expects that general and administrative expenditures will increase as new product development leads to expanded operations.

### Stock-based Compensation

The Corporation accounts for stock option grants using the fair value method, with compensation cost measured at the date of grant and amortized over the vesting period. In 2010, stock-based compensation costs of \$780,880 were recorded for the 3,565,500 options granted in 2006 which vest quarterly over six years as well as costs of \$117,705



relating to the issuance of new options to an employee and to the directors of the Corporation. In 2009, stock-based compensation costs of \$815,280 were recorded relating to the 2006 option grant mentioned above as well as costs of \$269,884 relating to the issuance of new options to employees and directors of the Corporation.

Foreign Exchange

The Corporation incurs expenses in the local currency of the countries in which it operates, which include the United States and Canada. Approximately 78% of 2010 expenses (76% in 2009) were in U.S. dollars. Foreign exchange fluctuations had no meaningful impact on the Corporation's results in 2010 or 2009.

Inflation

The Corporation does not believe that inflation has had a significant impact on its results of operations. Results of Operations – 2009 compared to 2008

Net losses were \$1,542,823, or \$0.05 per share, for the quarter and \$5,130,074, or \$0.17 per share, for the year ended December 31, 2009, compared to \$922,915 or \$0.03 per share, for the quarter and \$4,637,103 or \$0.16 per share for the year ended December 31, 2008. The increase of the net loss for the quarter and for the year ended December 31, 2009 is mainly attributable to expenses relating to the launch of the Phase 3 clinical trial. The weighted average number of common shares outstanding for the year ended December 31, 2009 was 30,717,822 compared to 29,749,000 for the same period in 2008.

### Revenues

Revenues from sales amounted to \$167,509 for the quarter and \$415,980 for the year ended December 31, 2009, compared with \$119,826 for the quarter and \$426,675 for the year ended December 31, 2008. The increase for the quarter ended December 31, 2009 is due to an increase in the number of customers for NicAlert/TobacAlert in the US compared to the same period in 2008. The decrease for the year ended December 31, 2009 is due to a decrease in the sales of NicAlert/TobacAlert attributable to the economic slowdown during that period.

### Research and Development

Research and development expenditures were \$1,172,863 for the quarter and \$3,183,134 for the year ended December 31, 2009, compared with \$449,458 for the quarter and \$2,500,154 for the year ended December 31, 2008. Research and development expenditures include costs incurred in advancing Nymox's BPH product candidate NX-1207 through clinical trials, as well as costs related to its R&D pipeline in development. The increase in expenditures for the quarter and for the year compared to the same period last year is attributable to the increase in expenditures relating to the Phase 3 clinical trial. In 2009, research tax credits amounted to \$139,915 compared to \$111,243 in 2008 as a result of additional expenditures claimed for refundable tax credits in 2009 compared to 2008.

### Marketing Expenses

Marketing expenditures amounted to \$37,326 for the quarter and \$138,396 for the year ended December 31, 2009, compared with \$44,530 for the quarter and \$187,868 for the year ended December 31, 2008. The decrease for the quarter and the year is primarily due to reduced expenditures year-to-date on publicity by approximately \$22,000, and promotional activities by approximately \$27,000 during 2009 with proportional reductions for the quarter.

### General and Administrative Expenses

General and administrative expenses amounted to \$182,024 for the quarter and \$799,784 for the year ended December 31, 2009, compared with \$267,311 for the quarter and \$1,064,903 for the year ended December 31, 2008. The decrease for the quarter and for the year compared to 2008 is due primarily to reduced expenditures on shareholder relations and related activities by approximately \$175,000, travel by approximately \$30,000, salaries and professional fees by approximately \$38,000 and insurance premiums by approximately \$14,000 during 2009 with proportional reductions for the quarter.

### Stock-based Compensation

The Corporation accounts for stock option grants using the fair value method, with compensation cost measured at the date of grant and amortized over the vesting period. In 2009, stock-based compensation costs of \$815,280 were recorded for the 3,565,500 options granted in 2006 which vest quarterly over six years, as well as costs of \$269,884 relating to the issuance of new options to employees and directors of the Corporation. In 2008, stock-based compensation was \$817,000 relating to the 2006 option grant mentioned above. An additional \$108,220 was recorded in 2008 for options granted to the Corporation's directors, and a consultant, and which were fully vested at the date of grant.

### **Contractual Obligations**

Nymox has no financial obligations of significance other than long-term lease commitments and other operating leases as follows:

<b>Contractual Obligations</b>	<b>Total</b>	<b>Current</b>	<b>2-4 years</b>
Rent	\$730,335	\$354,218	\$376,117
Operating Leases	\$32,346	\$10,853	\$21,493
Total Contractual Obligations	\$762,681	\$365,071	\$397,610

The Corporation has no binding commitments for the purchase of property, equipment or intellectual property. The Corporation has no commitments that are not reflected in the balance sheet except for operating leases.

### **Transactions with Related Parties**

The Corporation had no transactions with related parties in 2010 or 2009.

### **Financial Position**

#### Liquidity and Capital Resources

As of December 31, 2010, cash totalled \$13,174,999 and receivables including tax credits totalled \$277,649. In December 2010, the Corporation received an upfront payment of €10 million (US\$13.1 million) pursuant to a license and collaboration agreement with Recordati for the development and commercialization of NX-1207 in Europe and other countries. In November 2009, the Corporation signed a common stock private purchase agreement, whereby Lorros-Greyse Investments Limited (the "Purchaser") is committed to purchase up to \$15 million of the Corporation's common shares over a twenty-four month period. The agreement became effective December 10, 2009. As at December 31, 2010, eighteen drawings were made under this purchase agreement, for total proceeds of \$4,700,000. On January 22, 2010, 117,925 common shares were issued at a price of \$4.24 per share. On March 1, 2010, 298,913 common shares were issued at a price of \$3.68 per share. On May 4, 2010, 91,743 common shares were issued at a price of \$3.27 per share. On June 3, 2010, 34,965 common shares were issued at a price of \$4.29 per share. On June 14, 2010, 47,059 common shares were issued at a price of \$4.25 per share. On June 28, 2010, 64,935 common shares were issued at a price of \$3.85 per share. On July 23, 2010, 34,247 common shares were issued at a price of \$2.92 per share. On August 4, 2010, 24,450 common shares were issued at a price of \$4.09 per share. On August 13, 2010, 46,729 common shares were issued at a price of \$4.28 per share. On August 27, 2010, 25,445 common shares were issued at a price of \$3.93 per share. On September 2, 2010, 54,201 common shares were issued at a price of \$3.69 per share. On September 13, 2010, 41,436 common shares were issued at a price of \$3.62 per share. On September 23, 2010, 35,112 common shares were issued at a price of \$3.56 per share. On September 29, 2010, 124,269 common shares were issued at a price of \$3.42 per share. On October 26, 2010, 49,261 common shares were issued at a price of \$4.06 per share. On November 4, 2010, 50,251 common shares were issued at a price of \$3.98 per share. On November 15, 2010, 49,751 common shares were issued at a price of \$4.02 per share. On November 24, 2010, 50,125 common shares were issued at a price of \$3.99 per share.

The Corporation negotiated a new agreement with the Purchaser on November 1, 2010, which became effective November 25, 2010, under the same terms and conditions of the previous agreement. The Corporation can draw down \$15,000,000 over 24 months under the new agreement. As at December 31, 2010, one drawing was made under this purchase agreement, for total proceeds of \$200,000. On December 9, 2010, 49,261 common shares were issued at a price of \$4.06 per share. At December 31, 2010, the Corporation can draw down \$14,800,000 over the remaining 22 months under the agreement. The Corporation intends to access financing under this agreement when appropriate to fund its research and development. The Corporation believes that cash balances, funds from operations as well as from existing financing agreements will be sufficient to meet the Corporation's cash requirements for the next twelve months.

The Corporation must comply with general covenants in order to draw on its facility including maintaining its stock exchange listing and registration requirements and having no material adverse effects, as defined in the agreement, with respect to the business and operations of the Corporation.

The Corporation relies almost exclusively on this financing to fund its operations. In order to achieve the Corporation's business plan and realization of its assets and liabilities in the normal course of operations, the Corporation anticipates the need to raise additional capital and/or achieve sales and other revenue generating activities.

In October 2010, the Corporation was informed that it had been awarded a grant of \$244,479 from the U.S Government under the Qualifying Therapeutic Discovery Project for its ongoing Phase III clinical trial program for NX-1207 for the treatment of BPH. The Corporation anticipates receiving the grant sometime in 2011. The Corporation will record this amount in its consolidated financial statements when it is received.

### **Capital Disclosures**

The Corporation's objective in managing capital is to ensure a sufficient liquidity position to finance its research and development activities, general and administrative expenses, working capital and overall capital expenditures, including those associated with patents.

The Corporation defines capital as total shareholders' equity. To fund its activities, the Corporation has followed an approach that relies almost exclusively on the issuance of common equity and most recently during 2010, entered into a collaboration agreement. Since inception, the Corporation has financed its liquidity needs primarily through private placements and since 2003 through a financing agreement with the Purchaser that has been replaced annually by a new agreement with the same investor. The Corporation intends to access financing under this agreement when appropriate to fund its research and development activities. The financial crisis in the United States and the global economic environment has had a negative impact on the availability of liquidity in the market. Since 2003 through to December 2010, the Purchaser has always complied with the drawdowns made pursuant to the agreement. The Corporation is not aware of any information that would lead it to believe that the Purchaser will not be able to meet its commitments under the current agreement. The Corporation believes that cash balances, funds from operations, as well as from existing financing agreements will be sufficient to meet the Corporation's cash requirements for the next twelve months.

The capital management objectives remain the same as for the previous fiscal year. When possible, the Corporation tries to optimize its liquidity needs by non-dilutive sources, including sales, collaboration agreements, investment tax credits and interest income. The Corporation's general policy on dividends is to retain cash to keep funds available to finance its research and development and operating expenses. The Corporation has no debt. The Corporation is not subject to any capital requirements imposed by external parties.

### **Outstanding Share Data**

As at March 15, 2011, there were 32,588,856 common shares of Nymox issued and outstanding. In addition, 5,328,000 share options are outstanding, of which 4,618,625 are currently vested. There are no warrants outstanding.

## **Disclosure Controls and Procedures**

Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to senior management on a timely basis so that appropriate decisions can be made regarding public disclosure. The Corporation's Chief Executive Officer and its Chief Financial Officer are responsible for establishing and maintaining disclosure controls and procedures. They are assisted in this responsibility by the Corporation's disclosure committee, which is composed of members of senior management. Based on an evaluation of the Corporation's disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures were effective as of December 31, 2010.

## **Internal Control over Financial Reporting**

### Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. 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 the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with 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.

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting, as of December 31, 2010, based on the framework set forth in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its evaluation under this framework, management concluded that our internal control over financial reporting was effective as of December 31, 2010.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

KPMG LLP, an independent registered public accounting firm, which audited and reported on our financial statements in this Annual Report, has issued an unqualified audit report on the effectiveness of our internal control over financial reporting as of December 31, 2010.

### Changes in Internal Controls Over Financial Reporting

There have been no changes during fiscal 2010 in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Future Accounting Policies**

International Financial Reporting Standards

In February 2008, Canada's Accounting Standards Board (AcSB) confirmed that Canadian generally accepted accounting principles, as used by publicly accountable enterprises, will be fully converged into International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board (IASB). The changeover date is for interim and annual financial statements relating to fiscal years beginning on or after January 1, 2011. Therefore the Corporation will be required to report under IFRS for its 2011 interim and annual financial statements. The Corporation will convert to these new standards according to the timetable set within these new rules. The Corporation is currently finalizing its assessment of the future impact of these new standards on its consolidated financial statements and progressing towards implementation.

As at December 31, 2010, Management has almost completed the process of change-over to IFRS as follows: (1) the significant accounting policy choices have been assessed, (2) expert outside consultants have been engaged and the training program is in progress, (3) the scoping study has been prepared, (4) the review of GAAP related covenants and contracts has been completed, and (5) the accounting policy review and IFRS implementation plan process is underway.

**Potential Impact of the Conversion**

The need for the US GAAP reconciliation will no longer be required upon IFRS conversion.

The detailed comparison of IFRS with Canadian GAAP has helped identify a number of areas of differences.

International Financial Reporting Standard ("IFRS") 1, *First-time Adoption of International Financial Reporting Standards*, provides entities adopting IFRS for the first time with a number of optional exemptions and mandatory exceptions, in certain areas, to the general requirement for full retrospective application of IFRS. The Corporation completed its analyses of the various accounting policy choices available based on what Management believed to be most appropriate in the circumstances.

The Corporation has concluded that it will apply the following available elective exemptions:

- it will not retrospectively restate the accounting of past business combinations; and
- it will not retrospectively apply IFRS 2, *Share-based Payment*, for equity instruments granted on or before November 7, 2002, and for equity instruments granted after November 7, 2002 that have vested before the transition date to IFRS.

The remaining elective exemptions have limited or no applicability to the Corporation.

The Corporation also followed the mandatory exemptions applicable to the Corporation as described below:

Estimates – Hindsight cannot be used to create or revise estimates. Estimates previously made under Canadian GAAP cannot be revised for application of IFRS, except where necessary, to reflect any difference in accounting policies.

Therefore, most adjustments required on transition to IFRS will be made retrospectively against opening retained earnings as of the date of the first comparative balance sheet presented based on standards applicable at December 31, 2011. Transitional adjustments relating to those standards where comparative figures are not required to be restated will only be made as of the first day of the year of adoption.

Set out below are the main areas where changes in accounting policies in conversion to IFRS may impact the Corporation's consolidated financial statements. The list and comments should not be construed as a comprehensive list of changes that will result from transition to IFRS, but rather highlights those areas of accounting differences Management currently believes to be most significant. Notwithstanding, analysis of changes is still in progress and will be completed during the first quarter of fiscal 2011.

Management has identified an IFRS / Canadian GAAP difference related to the presentation of the Corporation's preferred shares of a subsidiary which, based on the current IFRS standards, a portion of the \$800,000 related to the convertible preferred shares of a subsidiary currently reported outside of shareholders' equity, would need to be presented as a separate component of equity for IFRS purposes, based on International Accounting Standard 27, *Consolidated and Separate Financial Statements* (IAS 27).

Another IFRS/Canadian GAAP difference was identified by Management, which relates to the measurement of the Corporation's stock-based compensation expense. Based on IFRS 2, *Share-based Payment*, the Corporation's stock options that vest in installments need to be accounted for as though each installment is a separate stock option grant, and therefore the fair value will be required to be measured separately for each installment and recognized over the vesting period of each installment. The Corporation will complete the calculation of this difference and record the necessary adjustment at the transition date as an increase to deficit and an increase to additional paid-in capital.

In addition, the Corporation is currently working on its preliminary annual IFRS financial statements in accordance with International Accounting Standard 1, *Presentation of Financial Statements* (IAS 1), and on its preliminary interim IFRS financial statements in accordance with International Accounting Standard 34, *Interim Financial Reporting* (IAS 34). Certain additional disclosures will be required in the notes to the financial statements and the statement of operations will be modified to reflect a presentation by nature or by function, of which the Corporation has elected for a presentation by function.

#### **Impact on Information Systems and Technology**

The transition had no impact on the Corporation's IT system.



### **Impact on Internal Control over Financial Reporting and Disclosure Controls and Procedures**

The Corporation's internal control over financial reporting will not be significantly affected by the transition to IFRS. The IFRS differences will mostly require presentation changes to report more detailed information in the notes to the consolidated financial statements, and it is not expected to lead to many differences in the accounting treatments of the Corporation. The Corporation's disclosure controls and procedures are adapted to take into consideration the changes in recognition, measurement and disclosures practices, but the impact is expected to be minimal.

#### **General**

An update regarding the progress of the Corporation's conversion plan was provided to the Audit Committee of the Corporation prior to the release of these consolidated financial statements.

Based upon the work completed to date, the Corporation cannot reasonably determine the full impact that adopting IFRS may have on its financial position and future results.

## Forward Looking Statements

Certain statements included in this MD&A may constitute “forward-looking statements” within the meaning of the U.S. *Private Securities Litigation Reform Act of 1995* and Canadian securities legislation and regulations, and are subject to important risks, uncertainties and assumptions. This forward-looking information includes amongst others, information with respect to our objectives and the strategies to achieve these objectives, as well as information with respect to our beliefs, plans, expectations, anticipations, estimates and intentions. Forward-looking statements generally can be identified by the use of forward-looking terminology such as “may”, “will”, “expect”, “intend”, “estimate”, “anticipate”, “plan”, “foresee”, “believe” or “continue” or the negatives of these terms or variations of them or similar terminology. We refer you to the Corporation’s filings with the Canadian securities regulatory authorities and the U.S. Securities and Exchange Commission, as well as the “Risk Factors” section of this MD&A, and of our Form 20-F and of our Annual Information Form, for a discussion of the various factors that may affect the Corporation’s future results. The results or events predicted in such forward-looking information may differ materially from actual results or events.

Forward-looking statements do not take into account the effect that transactions or non-recurring or other special items announced or occurring after the statements are made have on the Corporation’s business. For example, they do not include the effect of business dispositions, acquisitions, other business transactions, asset writedowns or other charges announced or occurring after forward-looking statements are made. The financial impact of such transactions and non-recurring and other special items can be complex and necessarily depends on the facts particular to each of them.

We believe that the expectations represented by our forward-looking statements are reasonable, yet there can be no assurance that such expectations will prove to be correct. Furthermore, the forward-looking statements contained in this report are made as of the date of this report, and we do not undertake any obligation to update publicly or to revise any of the included forward-looking statements, whether as a result of new information, future events or otherwise unless required by applicable legislation or regulation. The forward-looking statements contained in this report are expressly qualified by this cautionary statement.

## Research and Development, Patents and Licenses

Nymox's research and development policies are targeted at the development of novel therapeutic and diagnostic proprietary products that are subject to patent rights either directly owned by the Corporation or licensed to the Corporation through exclusive licensing agreements of patent rights. Over the last three financial years, the Corporation's major research and development activities were in the following program areas:

- *Diagnostic products for Alzheimer's disease.* The major project in this area, the development and validation of a kit version of our AlzheimerAlert™ product for sale to laboratories and hospitals was completed in 2004 and the kit subsequently received the CE mark in Europe, allowing it to be marketed there. The FDA has not approved our kit version for sale in the U.S. We are continuing to pursue further kit development and regulatory approvals. At this time, we cannot provide an estimate of the costs and timing to obtain FDA approval for such a kit as it is uncertain at this stage the nature and extent of FDA requirements for approval based on discussions with us.
- *Therapeutic products for enlarged prostate (benign prostatic hyperplasia or BPH).* We have successfully completed several Phase 1 and Phase 2 multi-center, double-blind, placebo-controlled clinical trials, and follow-up studies, in the U.S. for NX- 1207, our drug candidate for the treatment of enlarged prostate (benign prostatic hyperplasia or BPH), and are presently in Phase 3. We cannot predict with any certainty the outcome of any future trials nor estimate the costs of completing such trials, given the inherent uncertainties in conducting clinical trials, including as yet unknown response rates to our treatment candidate, unforeseeable safety issues, patient enrollment rates, manufacturing costs, and regulatory requirements. We anticipate starting a Phase 3 trial in the near future and subsequently filing a New Drug Application (NDA) with the FDA. Given the inherent uncertainties with any Phase 3 clinical trial, we cannot provide a more precise estimate of the costs and timing of the completion of this project. These uncertainties include the chances of success of any phase of the clinical trials, the nature and extent of FDA requirements to proceed with a Phase 3 and for filing an NDA, our ability to scale up manufacture in accordance with current good manufacturing requirements (cGMP) and in sufficient quantities for commercial use, and whether or when the FDA will ultimately grant us such approval.
- *Anti-infectives.* Our anti-bacterial agent, NXC-4720, which is being developed as a treatment of meat at the processing stage, has shown to be capable of substantially reducing the level of potentially fatal *E. coli* O157:H7 contamination on fresh beef according to laboratory studies. Other projects in this area, such as treating *E. coli* O157:H7 infection in livestock and treating bacterial infections in humans, are in preliminary stages of development with more uncertain prospects and timing and course of development. Because of the early stage of development of this project, it is impossible to outline the nature, timing or estimated costs of the efforts necessary to complete this project or the anticipated completion dates for this project. The facts and circumstances indicating the uncertainties that preclude us from making a reasonable estimate of the costs and timing necessary to complete this project include the risks inherent in any field trials of NXC-4720, the uncertainty as to the nature and extent of regulatory requirements both for safety and efficacy, and the ability to manufacture NXC-4720 in accordance with current good manufacturing requirements (cGMP) and in sufficient quantities both for large scale trials and for commercial use. In addition, we anticipate that we may need to partner with a larger Corporation in the food or agricultural sectors in order to finance and conduct field trials and to market any approved product; thus the timing of completion of the regulatory approval of such a product will not likely be within our sole control.
- *Tobacco exposure and other diagnostic tests.* We developed and validated NicAlert™, which is an FDA-cleared test for tobacco product use, and TobacAlert™, which is an over-the-counter test for second-hand smoke exposure. These are completed projects with any further research and development costs being related to

product improvement and obtaining regulatory approvals where required in order to expand the market for these products. The development of other new diagnostic tests using our patented diagnostic technologies are in early stage development. Because of the early stage of development of these projects, it is not possible to outline the nature, timing or estimated costs of the efforts necessary to complete any of them nor their anticipated completion dates. The facts and circumstances indicating the uncertainties that preclude us from making a reasonable estimate include the uncertainty about whether we will be able to successfully adapt our patented diagnostic technologies to these new diagnostic indicators, whether any new diagnostic tests we develop will pass proof-of-principle testing both in the laboratory and in clinical trials, and whether we will be able to manufacture such tests at a commercially competitive price.

- *Therapeutic products for Alzheimer's disease.* We are conducting early stage research and development work into preclinical development of novel drug candidates and original research into the role spherons play in the Alzheimer's disease process in order to pursue spheron-based therapeutics. Because of the early stage of development of this project, it is impossible to outline the nature, timing or estimated costs of the efforts necessary to complete this project, nor the anticipated completion dates for this project. The facts and circumstances indicating the uncertainties that preclude us from making a reasonable estimate include the inherent uncertainties in the pre-clinical and clinical development of therapeutic candidates. In addition, given the very high costs of development of a drug for Alzheimer's disease, we anticipate having to partner with a larger pharmaceutical corporation to conduct and finance clinical trials. The terms of such a partnership arrangement along with our related financial obligations cannot be determined at this time and the timing of completion of the approval of such a drug will likely not be within our sole control. Most pre-clinical drug candidates do not meet necessary milestones to enter clinical trials; of those which do, only a small percentage ultimately achieve regulatory approval and enter the marketplace. We also have global patent rights to the use of statins in the prevention or treatment of Alzheimer's disease. Various published epidemiological and other research studies have shown evidence that statins may help in the prevention or treatment of Alzheimer's disease; other studies have shown otherwise. Other companies and organizations are currently carrying out clinical trials into the use of statin drugs for Alzheimer's disease. The effect of the results of such trials on this program is uncertain.

- *Oncology products.* We are in the early stages of developing therapeutic products for oncological indications. Because of the early stage of development of this project, it is impossible to outline the nature, timing or estimated costs of the efforts necessary to complete this project nor its anticipated completion dates. The development of cancer therapeutics in particular is associated with high risks and many uncertainties and a drug candidate that shows efficacy can take a long period (7 years or more) to achieve regulatory approval.

Research and development expenses allocated to our major research and development programs are as follows:

	Year ended Dec 31, 2010	Year ended Dec 31, 2009	Year ended Dec 31, 2008
<b>Alzheimer's Disease: Diagnostics</b>	\$71,932	\$253,020	\$458,080
<b>Alzheimer's Disease: Therapeutics</b>	\$18,744	\$95,184	\$94,200
<b>Anti-Infectives</b>	\$5,091	\$5,963	\$0
<b>BPH (Enlarged Prostate) Therapeutics</b>	\$4,231,508	\$2,576,936	\$1,339,141
<b>Tobacco Exposure Tests:</b>			
	\$7,095	\$5,353	\$103,817
<b>NicAlert™ and TobacAlert™</b>			
<b>Oncology</b>	\$217,349	\$106,763	\$393,673
<b>Total</b>	\$4,551,719	\$3,043,219	\$2,388,911

For the earlier periods from 1995 to 1998, the Corporation did not maintain a cost accounting system that tracked research and development costs on a project-by-project basis. During the initial discovery stages, research and development is more general in nature and cannot be specifically categorized. During the periods 1995 to 2001, the general research expenses related primarily to the development of diagnostic products and therapeutic candidates for Alzheimer's disease. From 2002 to 2004, expenses related primarily to R&D in the areas of Alzheimer's disease and in BPH. Since 2005, expenses have primarily related to the development and clinical trials of NX-1207, our candidate for the treatment of BPH. The breakdown of research and development costs for these periods is as follows: 2007: \$3,468,273; 2006: \$3,171,428; 2005: \$2,292,610. The total research and development expenditures for the 1995 to 2004 period were \$18,507,409. Total research and development expenditures to date are \$37,423,569.

The Corporation expenses all research and development costs as incurred but does not currently maintain a cost accounting system to track, record and allocate staffing time on a specific project-by-project basis. We manage our ongoing research and development projects and programs in a dynamic, flexible manner. Our researchers, staff and management are typically involved in more than one of our research and development projects and the percentage of time an employee may be involved in a project varies according to the changing needs and progress of that project. As well, a significant portion of the Corporation's research and development expenses, such as laboratory supplies, travel, information systems and services and facilities costs, benefit multiple projects and are not necessarily individually tracked or allocated to a specific project when incurred. Research and development costs are allocated in reasonable and realistic proportion to the projects that benefited from those costs.

According to industry statistics, on average it takes 10 to 15 years to research, develop and bring to market a new prescription medicine in the United States. In light of the steps and complexities involved, the successful development of our product candidates is highly uncertain. Actual product timelines and costs are subject to enormous variability and are very difficult to predict. Accordingly, we cannot provide reliable estimates of the nature, timing and estimated costs of the efforts necessary to complete our programs. This is particularly the case for our programs in early stage development. The risk of failure to complete any such program is high because of uncertain feasibility and commercial viability, long lead times to program completion and potentially high costs in relation to anticipated returns. We update and change our product development programs to reflect the most recent preclinical and clinical

data and other relevant information. Many of our products under development require regulatory approval before being sold. The process of obtaining such approvals is often lengthy and uncertain and requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect our business. We cannot assure you that any such approvals required will be obtained on a timely basis, if at all.

**Trend Information**

The Corporation does not currently know of any material trends that would be material to our operations.

**Off-Balance Sheet Arrangements**

The Corporation has no existing off-balance sheet arrangements.

## **ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

### **Directors and Senior Management**

Paul Averback, M.D., D.A.B.P., 60, President and Director since September 1995 and Chairman since June of 2001, is the founder of Nymox and the inventor of much of its initial technology. Prior to founding Nymox, Dr. Averback served as President of Nymox's predecessor, DMS Pharmaceuticals Inc. He received his M.D. in 1975 and taught pathology at universities, including Cambridge University, England (1977-1980), during which time he initiated his research on Alzheimer's disease. He has practised medicine in numerous institutions as well as in private practice. Dr. Averback has published extensively in the scientific and medical literature.

Randall Lanham, Esquire, 47, has been a director since June 8, 2006. He attained his Juris Doctor from Whittier College School of Law in 1991 and a Bachelor of Science degree from the University of Delaware in 1987. Mr. Lanham has vast experience in both domestic and international corporate legal matters. Currently Mr. Lanham manages his own law office in California specializing in corporate mergers and acquisitions. In addition, Mr. Lanham has a broad base of entrepreneurial experience and currently owns and operates several small entertainment companies.

Paul F. McDonald, 85, has been a director since June 8, 2006. A graduate in law of McGill University, he has had a long and varied career as a member of the Canadian investment industry. Mr. McDonald was previously Vice-President of the Montreal Exchange, and he was principal owner and president of a stock exchange firm. His principal focus has been in the financing and development of growth companies in the high-tech and resources sectors, and he has had numerous appointments to corporate boards. He has devoted much time to committee work in the investment sector, as well as to public affairs, including a lengthy tenure as a director of the Quebec Industrial Development Corporation. Mr. McDonald currently works as a private consultant.

Professor David Morse, Ph.D., 54, has been a director since June 8, 2006. He is a world expert in the biochemistry, proteomics and genomics of cell function particularly as it relates to circadian regulation in single cell organisms. He received a Ph.D. from McGill University in 1984, completed a post-doctoral fellowship at Harvard University in 1989 and has been a Full Professor at the University of Montreal since 2001. He has published extensively in the peer-reviewed scientific literature, including papers in journals such as Science, Cell, Proceedings of the National Academy of Science, Journal of Biological Chemistry, and Nature. Dr. Morse has previously collaborated with Nymox scientists in research and development projects.

Roger Guy, M.D., 60, has been a director since June 8, 2006. He received his B.Sc., M.Sc. and M.D degrees from Memorial University of Newfoundland. He is a highly experienced medical doctor who has served as a national examiner. Dr. Guy has broad human clinical trial and business experience.

Jack Gemmell, 59, has been a Director since June, 2001 and is Nymox's General Counsel and Chief Information Officer. He graduated from the Faculty of Law at the University of Toronto in 1977 and was called to the bar in 1979. He practiced in private practice primarily in the area of litigation for over 19 years before joining Nymox in July, 1998.

Roy M. Wolvin, 56, has been Secretary-Treasurer and Chief Financial Officer since September 1995. Prior to September 1995, Mr. Wolvin was Account Manager, private business, for a Canadian chartered bank. Mr. Wolvin holds a degree in Economics from the University of Western Ontario.

Brian Doyle, B.Sc., M.B.A., 56, has been Senior Manager Global Sales and Marketing since May 2003. He received his B.Sc. in Microbiology and Immunology from McGill University, in 1979. He worked in the Experimental Surgery

department at McGill in cancer research, before completing his MBA at Concordia University, in 1983. He has wide sales, marketing and merchandising experience and spent 15 years at a technical sales representative firm, where he was National Sales Manager before joining Nymox.

## **Compensation**

### **Named Executive Officers**

The Summary Compensation Table and Outstanding Incentive Plan Awards tables below for Named Executive Officers summarize the total compensation paid during the Corporation's financial year ending on December 31, 2010 to the Named Executive Officers of the Corporation and all incentive plan awards outstanding at December 31, 2010 for the Named Executive Officers: The Named Executive Officers are the Corporation's Chief Executive Officer, Chief Financial Officer, and three most highly compensated executive officers.

During the financial year ended December 31, 2010, one executive received a grant of 25,000 options. No executive officer received any other share-based awards, or any bonuses or other non-equity incentive compensation. The Corporation does not have a share-based incentive plan, non-equity incentive plan or pension plan for its executive officers. The Corporation has not made any agreements or arrangements with any of its executive officers in connection with any termination or change of employment or change of control of the Corporation.



## Compensation Discussion and Analysis

The Human Resources and Compensation Committee of the Board of Directors oversees the compensation of executive officers of the Corporation. The members of the Human Resources and Compensation Committee for the financial year ending December 31, 2010 were Dr. Roger Guy, Paul McDonald and Randall Lanham.

The Corporation's current compensation policy for its executive officers, including the Chief Executive Officer and the Named Executive Officers, emphasizes the granting of options over base salary as a means of attracting, motivating and retaining talented individuals. Such a policy is believed to better further the Corporation's business goals by allocating more financial resources to the Corporation's ongoing product development programs. Given the current stage of the Corporation's development, the Corporation has not established and does not use formal benchmarks, performance goals, review processes or other qualitative or quantitative criteria or targets relating to the performance of the Corporation or the individual in order to determine compensation. The Corporation does not have a non-equity incentive plan or a policy of annually granting performance bonuses or salary increases to its executive officers.

The Corporation grants option-based awards to its executive officers in accordance with a stock option plan approved by the shareholders. Further details of the stock option plan are provided below. The stock option plan provides long-term incentives to the Corporation's officers and employees to advance the Corporation's drug development programs towards commercialization and to enhance shareholder value. The Corporation endeavours to provide salaries and option grants that are internally equitable and that are consistent with both job performance and ongoing progress towards corporate goals. The amount of option grants is determined in part by the amount and terms of outstanding and expiring options, the experience and expertise of each executive officer and the needs of the Corporation, among other factors. The Human Resources and Compensation Committee of the Board of Directors reviews all proposals for awards of stock options to executive officers and decides on the appropriateness of the awards. In doing so, the Committee relies solely on discussion among the independent board members on the Committee without any formal pre-determined objectives, criteria or analytic processes but with a view to attracting and retaining executive officers who can help further the Corporation's business plan.

By relying on option grants as a primary means of compensating its executive officers, the Corporation's intention is to provide a direct link between corporate performance and executive compensation while maximizing shareholder value and controlling cash expenditures.

## Directors

The Summary Compensation Table and Outstanding Incentive Plan Awards tables below for the directors of the Corporation summarize the total compensation paid during the Corporation's financial year ending on December 31, 2010 to the directors of the Corporation and all incentive plan awards outstanding at December 31, 2010 for the directors. Two current directors, Dr. Paul Averback, the President and CEO of the Corporation, and Jack Gemmell, General Counsel, are members of the senior management of the Corporation and do not receive any compensation for acting as a director. Their compensation as Named Executive Officers is summarized in the summary tables for compensation and incentive plans for Named Executive Officers below.

## Summary Compensation Table: Named Executive Officers

Name and principal position	Year	Salary (\$)	Share-based awards	Option-based awards	Non-equity incentive plan compensation (\$)		Pension value	All Other Compensation	Total Compensation
					Annual incentive	Long-term incentive			

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		(\$)	plans	plans	(\$)	(\$)	(\$)
Dr. Paul Averback CEO and President	2010	190,000					190,000
Mr. Roy Wolvin CFO	2010	97,093					97,093
Mr. Brian Doyle Global Sales Manager	2010	161,715					161,715
Mr. Jack Gemmell General Counsel, CIO	2010	116,512	25,000				116,512

Salaries are payable in Canadian dollars, but expressed above in US\$.

**Outstanding Incentive Plan Awards as of December 31, 2010: Named Executive Officers**

Name	Option-based Awards					Value of unexercised in-the-money options (\$)
	Number of securities underlying unexercised options (#)			Option exercise price (\$)	Option expiration date (mm/dd/yy)	
	Total	Unvested	Vested			
		(1)				
Dr. Paul Averback	500,000		500,000	\$3.00	10/24/13	\$2,020,000
	3,000,000	750,000	2,250,000	\$3.00	08/24/16	\$9,090,000
	5,000		5,000	\$2.62	09/09/13	\$22,100
	50,000		50,000	\$2.82	06/09/16	\$211,000
Mr. Roy Wolvin	150,000	37,500	112,500	\$3.00	08/24/16	\$454,500
	20,000		20,000	\$3.65	05/14/19	\$67,800
	25,000		25,000	\$1.93	04/23/11	\$127,750
	20,000		20,000	\$2.62	09/09/13	\$88,400
Mr. Jack Gemmell	210,000	52,500	157,500	\$3.00	08/24/16	\$636,300
	50,000		50,000	\$3.30	01/23/19	\$187,000
	25,000		25,000	\$3.40	05/03/20	\$91,000
Mr. Brian Doyle	50,000		50,000	\$3.75	04/28/13	\$164,500
	50,000	11,250	38,750	\$3.00	08/24/16	\$156,550

Option exercise prices and the values of unexercised in-the-money options are expressed in US\$. The Corporation does not have a share-based award plan.

(1) Unvested options vest quarterly over a 6 year period beginning in August 2006.

**Summary Compensation Table: Directors**

Name	Year	Fees Earned (\$)	Share-based awards (\$)	Option-based awards	Non-equity incentive plan compensation (\$)	Pension value (\$)	All other compensation (\$)	Total (\$)
Paul McDonald	2010	\$16,500		10,000				\$16,500
Randall Lanham	2010	\$16,000		10,000				\$16,000
Roger Guy, MD	2010	\$16,500		10,000				\$16,500
David Morse, Ph.D.	2010	\$14,500		10,000				\$14,500

**Outstanding Incentive Plan Awards as of December 31, 2010: Directors**

Name	Option-based Awards			
	Number of securities underlying unexercised options	Option exercise price (\$)	Option expiration date (mm/dd/yy)	Value of unexercised in-the-money options (\$)

	(#)			
	10,000	\$2.74	07/17/16	\$43,000
	10,000	\$5.95	08/23/17	\$10,900
Paul McDonald	10,000	\$3.61	07/16/18	\$34,300
	10,000	\$4.83	07/09/19	\$22,100
	10,000	\$2.90	07/16/20	\$41,400
	10,000	\$2.74	07/17/16	\$43,000
	10,000	\$5.95	08/23/17	\$10,900
Randall Lanham	10,000	\$3.61	07/16/18	\$34,300
	10,000	\$4.83	07/09/19	\$22,100
	10,000	\$2.90	07/16/20	\$41,400
	10,000	\$2.74	07/17/16	\$43,000
	10,000	\$5.95	08/23/17	\$10,900
Roger Guy, MD	10,000	\$3.61	07/16/18	\$34,300
	10,000	\$4.83	07/09/19	\$22,100
	10,000	\$2.90	07/16/20	\$41,400
	10,000	\$2.74	07/17/16	\$43,000
	10,000	\$5.95	08/23/17	\$10,900
David Morse, Ph.D.	10,000	\$3.61	07/16/18	\$34,300
	10,000	\$4.83	07/09/19	\$22,100
	10,000	\$2.90	07/16/20	\$41,400

During the same period from 2000 to 2010, the salaries of Named Executive Officers increased from \$465,805US (2000) to \$565,320US (2010), an increase of 1.9% per annum over that eleven year period, or 21.4% in total. During the same period, the Corporation's stock price has increased approximately 261%.

## Share Ownership

As of March 15, 2011, the number of common shares owned or controlled by directors and senior officers of the Corporation were as follows:

Name	Common Shares Owned and Controlled	Percentage of Common Shares Owned and Controlled
Paul Averbach, M.D.	13,115,395	40.3%
Randall Lanham	0	*
Paul McDonald	0	*
David Morse, Ph.D.	396	*
Roger Guy, MD	51,979	*
Jack Gemmell	13,725	*
Roy Wolvin	8,920	*
Brian Doyle	10,100	*

\* Denotes less than 1%.

## Options

Nymox has created a stock option plan for its employees, officers and directors, and for consultants. The board of directors of Nymox administers the stock option plan and authorizes the granting of options in accordance with the terms of the plan. Each option gives the individual granted the option the right to purchase a common share of the Corporation at a fixed price during a specified period of no more than ten years. The board may also make all or a portion of the options granted effective only as of a specific future date or dates. The option price must not be less than the market price of the common shares when the option is granted. The total number of shares under option to any one individual may not exceed fifteen percent of the total number of issued and outstanding common shares of the Corporation. The options may not be assigned, transferred or pledged, and expire within three months of the termination of employment or active office with the Corporation and six months of the death of the individual.

No more than 5,500,000 common shares may be under option at any time and a maximum of 5,500,000 common shares are available to be issued under the stock option plan as the result of the exercise of options. Options that expire or terminate without being exercised become available to be granted again. Material changes to the stock option plan such as the number of shares available to be optioned require shareholder approval. On June 21, 2007, the shareholders approved amendments to the plan that included increasing the maximum number of shares that could be issued in total under the plan from 2,500,000 to 5,500,000, and to any one individual from 5% to 15% of the total number of issued shares. Since the inception of the stock option plan in 1995, 346,400 common shares have been issued as a result of the exercise of options granted under the plan.

## Board Practices

Directors are elected at each annual meeting for a term of office until the next annual meeting. Executive officers are appointed by the board of directors and serve at the pleasure of the board. Other than Dr. Averbach, no other officer or director previously was affiliated with DMS Pharmaceuticals Inc.

Nymox does not have written contracts with any of the directors named above. We do not have any pension plans or other type of plans providing retirement or similar benefits for directors, nor any benefits upon termination of service as a director.

Nymox's Audit Committee consists of three directors appointed by the Board who are independent of management and who are generally knowledgeable