NYMOX PHARMACEUTICAL CORP
Form 20-F
March 15, 2013

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
[X] Annual Report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 For the fiscal year ended December 31, 2012
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.

33,572,442 shares as of December 31, 2012

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 [ ]

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 [X] 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 [ ] International Financial Reporting Standards [X] Other [ ]
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 [X]

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 International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") for 2012, 2011 and 2010 and in accordance with Canadian generally accepted accounting principles ("GAAP"), reconciled to U.S. GAAP, for 2009 and 2008. The financial statements have been audited by KPMG LLP, Montreal, Canada as at and for the years ended December 31, 2008, 2009, 2010, 2011 and 2012 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)

IFRS	**Dec. 31, 2012**	**Dec. 31, 2011**	**Dec. 31, 2010**
Current Assets	$ 1,739,061	$ 6,335,710	$ 13,470,096
Property & Equipment	15,118	22,160	14,730
Patents & Intellectual Property	0		0
Total Assets	1,754,179	6,375,266	13,502,222
Total Current Liabilities	3,672,759	3,429,092	5,195,503
Share Capital	69,705,389	66,062,961	62,855,147
Equity	(7,444,713)	(5,197,559)	(2,454,614)
Sales	454,987	496,215	582,383
Total Revenues (including sales)	3,072,587	3,113,815	691,450
Research & Development Expenditures (1)	8,282,762	8,974,171	4,880,126
Loss from operating activities	7,594,651	9,625,327	6,505,132
Net Loss	7,627,589	9,652,389	6,536,313
Loss per Share (basic & diluted)	$ 0.23	$ 0.30	$ 0.20
Weighted Avg. No. of Common Shares	33,176,185	32,711,431	31,940,584

(1) We earn research tax credits by making qualifying research and development expenditures. These amounts shown are net of research tax credits and grants.

(2) The Corporation adopted IFRS in 2011 with a transition date of January 1, 2010. Consequently, the selected consolidated financial data for 2009 and 2008, which was presented in conformity with Canadian GAAP, and with U.S. GAAP, was not restated in accordance with IFRS and accordingly, is not comparable with the information for 2012, 2011 and 2010.

Canadian GAAP (2)	**Dec. 31, 2009**	**Dec. 31, 2008**
Current Assets	$ 1,074,279	$ 480,505
Property & Equipment	16,152	21,525
Patents & Intellectual Property	0	220,855
Total Assets	1,090,431	749,879
Total Current Liabilities	1,742,597	1,256,885
Share Capital	57,955,147	53,850,147
Equity	(1,452,166)	(1,307,006)
Sales	415,980	426,675
Total Revenues (including sales)	415,980	428,409
Research & Development Expenditures (1)	3,043,219	2,388,911
Loss from operating activities	5,125,125	4,631,637
Net Loss	5,130,074	4,637,103
Loss per Share (basic & diluted)	$ 0.17	$ 0.16
Weighted Avg. No. of Common Shares	30,717,822	29,749,000
U.S. GAAP (2)		
Net Loss	$ 5,282,534	$ 4,590,345
Loss per Share	0.17	0.15
Shareholder’s Equity	2,102,997	2,400,617

Nymox has never paid any dividends and does not expect to do so in the foreseeable future.

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 the achievement of our milestones, such as the commencement and completion of clinical trials, 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, AlzheimAlert™, NicAlert™ and TobacAlert™. We have never made a profit. We incurred a net loss of approximately $9.7 million in 2011 and $7.6 million in 2012. As of December 31, 2012, Nymox's accumulated deficit was approximately $89.9 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 $6.5 – 9.7 million per year over the next year through our current cash position and additional financing, including drawdowns through our Common Stock Private Purchase agreement with Lorros-Greyse Investments, Ltd. ("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 AlzheimAlert™, NicAlert™ or 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, AlzheimAlert™, 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 AlzheimAlert™ 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 global 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. 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). Subsequent to the completion of the Phase 2 studies, the Corporation has reported positive results in several follow-up studies of BPH patients that participated in the Phase 2 studies. 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. On March 1, 2012 Nymox announced the initiation of a Phase 2 U.S. clinical trial to evaluate NX-1207 for the treatment of low grade localized prostate cancer. On November 28, 2012, Nymox announced completion of patient enrollment in the Corporation’s pivotal U.S. Phase 3 NX02-0017 Study of NX-1207 for BPH. 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 Merck, Johnson & Johnson, Novartis, and Baxter are working on Alzheimer's disease therapies.
- Johnson & Johnson, Roche, Merck, and Bristol-Myers Squibb are working on Alzheimer's disease therapies.
- drugs targeting the tau protein which forms tangles in brain cells of Alzheimer's disease patient. A number of pharmaceutical and biotechnology companies including TauRx Therapeutics and Bristol-Myers Squibb are working on such therapies.
- drugs designed to enhance cognition from AstraZeneca and Roche among others.

There is also ongoing research into possible methods of preventing Alzheimer's disease such as taking certain cholesterol-lowering drugs called statins, certain diabetes drugs, 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 BPH face significant competition from existing products. There are eight drugs approved for treatment of BPH: four proprietary drugs (dutasteride (Avodart®), tamsulosin (Flomax®), alfusozin (Uroxatral®), and silodosin (Rapaflo®)), a combination of two drugs (dutasteride and tamsulosin) (Jalyn™), and four generics (finasteride, terazozin, doxazozin, 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. Amyvid® (florbetapir), a radioactive diagnostic agent for Positron Emission Tomography (PET) imaging marketed by Lilly, recently received FDA approval as an aid to the evaluation of patients with signs of Alzheimer's disease. GE and Bayer are also developing similar technologies. 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 eleven 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, the Patient Protection and Affordable Care Act. Important market reforms have begun 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 Corporation depends on financing under the Common Stock Private Purchase Agreement to fund its operations. Moreover, Nymox may use its shares as currency in acquisitions. 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 33,731,492 common shares of Nymox issued and outstanding as of March 15, 2013. In addition, 5,930,500 share options are outstanding, of which 5,890,500 are currently vested. Expiry dates for Nymox options range from 1 month to 9.6 years (see note 9(b) to our consolidated financial statements). These options have been granted to employees, officers, directors and consultants of the Corporation.

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, 13th 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.

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 by third party distributors, including 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 443,000 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 3,400 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. Nymox has entered into distribution and marketing agreements with companies and organizations in the U.S. and the U.K. 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 April 2013.

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 *Hum Psychopharmacol.* 2010 25(1): 80–83, *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 2015 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 NTP, 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.

Nymox believes that its AlzheimAlert™ test can assist a physician faced with the task of diagnosing whether a patient has Alzheimer's disease. An independent peer-reviewed double blind study from 8 prestigious centers across the U.S. found the level of accuracy of the AlzheimAlert™ 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 NTP measurements in patients with suspected Alzheimer's disease," Goodman I *et al.*). This study confirmed several earlier Corporation funded trials of the AlzheimAlert™ 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.

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 AlzheimAlert™ test (*J Clin Lab Anal.* Jan 2007;21:24-33, "Competitive ELISA studies of NTP 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.

Some 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* (2007; 8:21-30), *Journal of Clinical Laboratory Analysis* (Jan 2007;21:24-33), *Expert Review of Molecular Diagnostics* (2008; 8:21-28) and *Journal of the American Medical Directors Association* (2011; 12(5):372-6).

There is a large need for a simple, non-invasive test that can aid in the diagnosis of Alzheimer's disease. According to 2012 Alzheimer's Disease Facts and Figures, U.S. Alzheimer's Association, Alzheimer's disease is the most common cause of dementia and is the sixth leading cause of death in the United States. It is estimated that as many as 5.4 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 $200 billion a year and rising. 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 AlzheimAlert™ 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 AlzheimAlert™ 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 AlzheimAlert™ test faces growing competition which could detrimentally impact on our ability to successfully market and sell our diagnostic test. Our competitors include:

- Eli Lilly and Company, which is currently marketing Amyvid® (florbetapir), a radioactive diagnostic agent for Positron Emission Tomography (PET) imaging, which is used to estimate the density of neuritic plaques in patients being evaluated for Alzheimer's disease.
- 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, 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., which currently markets a research test to detect aggregated amyloid protein in brain test and has under development related blood and CSF tests.

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. A number of companies, including GE and Bayer, 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 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.

In July 2012, Nymox reported positive results from a new study of long-term treatment outcomes for men who had received a single injection of NX-1207 2.5 mg for treatment for their BPH. The study analysis found that a statistically significant greater number of men who had received NX-1207 2.5 mg reported positive treatment outcomes as compared to men who had received a placebo. The study involved the latest available blinded follow-up study data (an average of 57 months post-injection) from the completed clinical trials for these treatment groups. A positive treatment outcome was seen if the patient was not using other BPH medications and no surgical treatment (including MIST) for BPH was reported at any time during the post-injection follow-up period. The combined new statistical analysis of blinded study data showed NX-1207 2.5 mg to have a lasting benefit in terms of positive treatment outcomes that was significantly superior to placebo. Previous follow-up studies have shown long-term benefit from a single NX-1207 treatment in excess of 5 years in some cases.

Completed Phase 2 studies have shown that a single administration of NX-1207 resulted in symptomatic improvements which reached statistical significance compared to double-blinded placebo and study controls. Patient-reported improvements in the

standardized BPH symptom score were on average 8 to 10 points at 90 days as compared to the approximately 3 to 5 points reported on average for currently approved BPH drugs. The drug is administered by a urologist in an office setting in a brief procedure that does not require anesthesia, sedation, or catheterization and involves little or no pain or discomfort. NX-1207 treatment has not been found to have the sexual, blood pressure, or other side effects associated with the use of the approved drugs for the treatment of BPH. Follow-up studies have shown clinical efficacy effects lasting up to 7½ years after a single treatment.

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 enrolment of 1,000 patients.

In July 2012, Nymox announced the completion of enrollment for the Phase 3 repeat injection Study NX02-0020. The NX02-0020 study started in July 2011 and involved men who had previously participated in one of the earlier Nymox NX-1207 studies for BPH. On January 22, 2013, Nymox announced the completion of the six month primary endpoint evaluating safety for the NX02-0020 study and reported that the safety assessment was positive with no reported significant adverse events related to the drug and none of the reported sexual, cardiovascular, or other side effects that are associated with approved BPH medications.

On November 28, 2012, Nymox announced completion of patient enrollment in the Corporation’s pivotal U.S. Phase 3 NX02-0017 Study of NX-1207 for BPH.

Our treatments under development for enlarged prostate (benign prostatic hyperplasia or BPH) face significant competition from existing products. There are nine drugs approved for treatment of BPH: five proprietary drugs (dutasteride (Avodart®), tamsulosin (Flomax®), alfusozin (Uroxatral®), and silodosin (Rapaflo®)) a combination of two drugs (tadalafil (Cialis®), dutasteride and tamsulosin) (Jalyn™), and four generics (finasteride, terazozin, doxazozin, 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 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.

On March 1, 2012, Nymox announced the initiation of a Phase 2 U.S. clinical trial to evaluate the Corporation's NX-1207 drug for the treatment of low grade localized prostate cancer in accordance with an Investigational New Drug (IND) application filed with the FDA and specific direction and guidance provided by the FDA in Pre-IND meetings. Preclinical studies of NX-1207 have shown activity against prostate cancer cells at higher dosage levels of NX-1207 than the dosage used in the current Phase 3 BPH clinical trials. The clinical trial (NX03-0040) is currently enrolling men in a two dose 6 week Phase 2 study designed to test both low and high doses of NX-1207 for their effect on low grade localized prostate cancer in 150 subjects.

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 pro