

NYMOX PHARMACEUTICAL CORP  
Form 20-F  
March 31, 2015

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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, 2014  
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: Andre Monette  
Tel. 800-936-9669, e-mail: amonette@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

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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.

35,872,445 shares as of December 31, 2014

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

Yes ☐ No ☒

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 ☒

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website; if any, every interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232-405 of this chapter) during the preceding twelve months (or for such shorter period 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 ☐

International Financial Reporting Standards ☒

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 ☒

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;
- access financing under the Common Stock Private Purchase Agreement;
- successfully defend pending and/or unforeseeable future litigation;
- 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;
- overcome recent negative results from its clinical trials;
- 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 2014, 2013, 2012, 2011 and 2010. The financial statements have been audited by KPMG LLP, Montreal, Canada as at and for the years ended December 31, 2010, 2011, 2012, 2013, and 2014 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)**

<b>IFRS</b>	<b>Dec. 31, 2014</b>	<b>Dec. 31, 2013</b>	<b>Dec. 31, 2012</b>	<b>Dec. 31, 2011</b>	<b>Dec. 31, 2010</b>
Current Assets	\$ 1,395,770	\$ 936,468	\$ 1,739,061	\$ 6,335,710	\$ 13,470,090
Property & Equipment	9,400	12,521	15,118	22,160	14,730
Total Assets	1,422,566	966,385	1,754,179	6,375,266	13,502,220
Total Current Liabilities	4,484,678	4,116,222	3,672,759	3,429,092	5,195,500
Convertible notes	718,831	0	0	0	0
Share Capital	81,227,058	76,046,549	69,705,389	66,062,961	62,855,140
Total Equity	(4,180,943)	(6,058,370)	(7,444,713)	(5,197,559)	(2,454,614)
Sales	331,909	741,410	454,987	496,215	582,380
Total Revenues (including sales)	2,949,509	3,359,010	3,072,587	3,113,815	691,450
Research & Development Expenditures (1)	4,496,730	5,719,872	8,282,762	8,974,171	4,880,120
Loss from operating activities	4,724,705	4,884,957	7,594,651	9,625,327	6,505,130
Net Loss	4,594,093	4,908,603	7,627,589	9,652,389	6,536,310
Loss per Share (basic & diluted)	\$ 0.13	\$ 0.14	\$ 0.23	\$ 0.30	\$ 0.20
Weighted Avg. No. of Common Shares	35,253,879	34,147,666	33,176,185	32,711,431	31,940,580

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

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. On November 2, 2014, following the completion of data verification and auditing procedures, top-line results of the Phase 3 NX02-0017 and NX02-0018 U.S. clinical trials of NX-1207 for BPH at 12 months post-treatment were not statistically significant compared to placebo. The Corporation is in the process of further data analysis and assessments of the two studies, and expects to continue its efforts to work on the development program.

Setbacks in our clinical trials or failure to obtain regulatory approval could cause the price of our shares to decline and adversely affect our business, operations, product development programs and financial condition. See “A Setback in Any of Our Clinical Trials Would Likely Cause a Drop in the Price of Our Shares”.

### **Our Clinical Trials for Certain Of Our Therapeutic Products May Be Delayed, Making it Impossible to Achieve Anticipated Development or Commercialization Timelines And Our Development of NX-1207 for BPH Has Been Delayed Due To Negative Results In Phase III Clinical Trials.**

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, 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.

On November 2, 2014, following the completion of data verification and auditing procedures and the unblinding and top line analysis of efficacy of the studies, Nymox announced that the NX02-0017 and NX02-0018 Phase 3 clinical trials had failed to meet their primary endpoints. Top-line results of the Phase 3 NX02-0017 and NX02-0018 U.S. clinical trials of NX-1207 for BPH at 12 months post-treatment were not statistically significant compared to placebo. The Corporation is in the process of further data analysis and assessments of the two studies, and expects to continue its efforts to work on the development program.

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**

On November 2, 2014, following the completion of data verification and auditing procedures and the unblinding and top line analysis of efficacy of the studies, Nymox announced that the NX02-0017 and NX02-0018 Phase 3 clinical trials had failed to meet their primary endpoints. On November 3, 2014 the Corporation's stock fell approximately 82%, from \$5.14 to \$0.93.

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 further 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”). After the top-line statistical failure of Nymox’s U.S. Phase 3 studies NX02-0017 and NX02-0018 at 12 months post-treatment, Recordati has terminated development and commercialization activities of NX-1207 in the licensed territories.

#### **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, for instance, such as the completion of our Phase

3 development of NX-1207 for BPH, which has been delayed due to certain negative results, 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, and 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™, NicAlert™ and TobacAlert™. We have never made a profit. We incurred a net loss of approximately \$4.9 million in 2013 and \$4.6 million in 2014. As of December 31, 2014, Nymox's accumulated deficit was approximately \$100.0 million and we have negative cash flows from operations. As at December 31, 2014, we had negative working capital (excluding deferred revenue) of \$580,375.

We cannot say when, if ever, Nymox will become profitable or operate with positive cash flows and/or working capital. 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 Will Require Additional Funding to Continue as a Going Concern**

The Corporation will require additional funds to pursue its operations as a going concern for the fiscal year ending December 31, 2015 and beyond, some of the funds of which would be used to conduct further research and development, schedule clinical testing, obtain regulatory approvals and the commercialization of its product candidates. The Corporation had available cash of approximately \$632,272 and a working capital deficiency (excluding deferred revenue) of \$580,375 as of December 31, 2014. Cash flows used in operations during 2014 were \$5,515,479.

Management believes that current cash balances as at December 31, 2014 and anticipated funds from product sales are not sufficient to fund substantially all of its planned business operations and research and development programs over the next year. The Corporation intends to access financing through the existing Common Stock Private Purchase Agreement and/or other sources of capital in order to fund these operations and activities over the next year.

If the purchaser does not purchase the Corporation's common shares as provided for under the Common Stock Private Purchase Agreement, the Corporation will have to seek other sources of financing in order to be able to pay its obligations as they become due, which could have an impact on its ability to continue as a going concern. There can be no assurance that any additional funding will be available at terms that are acceptable to the Corporation to enable the Corporation to continue to pursue its operations. Considering recent developments and the need for additional financing, there exists a material uncertainty that casts substantial doubt about the Corporation's ability to continue as a going concern. Our consolidated financial statements do not reflect adjustments that would be necessary if the going concern assumption was not appropriate. If the going concern assumption is not appropriate, then adjustments may be necessary to the carrying value and classification of assets and liabilities and reported results of operations and such adjustments could be material.

We have incurred operating losses throughout our history. Management believes that such operating losses will continue for at least the next few years as a result of expenditures relating to research and development of our potential therapeutic products.

**Our Ability to Draw on the Common Stock Private Purchase Agreement, Which Expires in November 2015, is Dependent on Adhering to General Covenants**

Under the Common Stock Private Purchase Agreement, the Corporation must adhere to 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 Common Stock Private Purchase Agreement, with respect to the business and operations of the Corporation. In the past, the Corporation has been successful in obtaining the required financing pursuant to the Agreement. As of the date of the financial statements, the Corporation has not received any communication from the counterparty in the Agreement that it will not honor the Corporation's future draw-down notices under the Agreement or that it intends to terminate the Agreement. As at the date hereof, the Common Stock Private Purchase Agreement, set to expire in November 2015, has not been renewed. In prior years the Corporation typically has renewed the Common Stock Private Purchase Agreement approximately one year prior to its scheduled expiry date. If we are unable to renew the agreement in a timely fashion or at all or unable to comply with the covenants set forth in the agreement, the Corporation will have to seek other sources of financing in order to continue to operate as a going concern. There can be no assurance that any additional funding will be available on acceptable terms or at all. The inability to raise additional capital would have a material adverse effect on the business and operations.

**We Have Identified a Material Weakness in Our Internal Control Over Financial Reporting. Although We Expect to Make Every Effort to Address this Material Weakness, We May Find that We are Unable to Remediate this Deficiency in Our Control Environment, Which Could Reduce the Reliability of Our Financial Reporting, Harm Investor Confidence in Our Company and Affect the Value of Our Common Stock.**

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2014, we and our independent registered public accounting firm identified a material weakness in the design and operation of our internal control over financial reporting. The material weakness relates to incompatible duties related to certain processes, primarily impacting the expenditures/disbursements processes and related information technology general controls, and sufficient compensating controls did not exist. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is reasonable possibility that a material misstatement of a company's annual financial statements will not be prevented or detected on a timely basis. We intend to address the material weakness in the immediate future with oversight from our Audit Committee of the Board of Directors to remediate the material weakness. If we fail to effectively remediate the material weakness in our control environment we may be unable to accurately report our financial results, or report them within the timeframes required by the SEC. Even if we are able to report our financial statements accurately and in a timely manner, if we do not make all necessary improvements to address the material weakness, continued disclosure of a material weakness will be required in future filings with the SEC and the accuracy of our financial statements may be called into question, both of which would likely cause our reputation to be harmed and our stock price to decline.

**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 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, 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.

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. Top-line results of the Phase 3 NX02-0017 and NX02-0018 U.S. clinical trials of NX-1207 for BPH at 12 months post-treatment were not statistically significant compared to placebo. The Corporation is in the process of further data analysis and

assessments of the two studies, and expects to continue its efforts to work on the development program. The Corporation previously successfully completed four Phase 1 and Phase 2 clinical trials of NX-1207 for BPH as well as over ten additional follow-up studies. 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 in clinical trials include:

- vaccines and other active immunotherapies for Alzheimer's disease (GlaxoSmithKline, Novartis);
- inhibitors of the production of beta-amyloid, one of the abnormal proteins associated with Alzheimer's disease. (Merck);
- antibodies that bind to beta-amyloid (Eli Lilly, Eisai, Genentech, Roche);



- drugs targeting the tau protein which forms tangles in brain cells of Alzheimer's disease patient. (TauRx Therapeutics, Bristol-Myers Squibb);
- drugs designed to enhance cognition (Merck, AbbVie, EnVivo Pharmaceuticals, Lundbeck; and
- diabetes drugs, including insulin and medications for treating Type 2 diabetes (Takeda).

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 (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 nine drugs approved for treatment of BPH: five proprietary drugs (dutasteride (Avodart®), tamsulosin (Flomax®), alfuzosin (Uroxatral®), silodosin (Rapaflo®), and tadalafil (Cialis®)), 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. In 2013, the FDA approved the Urolift™ system, a permanent surgical implant designed to pull back prostate tissue to improve urination in men with BPH.

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 FDA has approved two radioactive diagnostic agents for Positron Emission Tomography ("PET") imaging as an aid to the evaluation of patients with signs of Alzheimer's disease: Amyvid® (florbetapir), marketed by Lilly, and Vizamyl® (flutemetamol), marketed by GE Healthcare. Other companies 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 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-four patents issued or allowed relating to its technology. Our subsidiary, Serex, Inc. has nine 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 and beyond. 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.

**We Have Become Involved in Securities Class Action Litigation that is Expected to Divert Management's Attention and Could Harm our Business.**

On November 24, 2014, a shareholder of the Corporation, filed a proposed class action suit in the United States District Court, District of New Jersey, against the Corporation and the President and the Chief Executive Officer of the Corporation. The motion was heard on January 26, 2015, and was the first procedural step before any class action could be instituted. The plaintiff seeks certification of a class action on behalf of all persons, wherever they reside, who acquired the Corporation's common stock between January 31, 2011 and November 2, 2014. The plaintiff alleges that certain of the Corporation's disclosures failed to disclose material adverse facts that raised serious questions as to the ability to achieve significant results for NX-1207 in Phase 3 trials in light of difficulty of enrolling candidates, obtaining objective and measured results, and the placebo effect. The Corporation believes that the allegations made against it in these actions are meritless and will vigorously defend the matter, although no assurance can be given with respect to the ultimate outcome of such proceedings. No provision has been recognized in our financial statements for this matter. Litigation, such as this shareholder class action, often is expensive and diverts management's attention and resources, which could adversely affect our business.

**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 has historically primarily depended on financing under the Common Stock Private Purchase Agreement to fund its operations. The Corporation issued convertible notes in the amount of \$1,070,000 on December 16, 2014, convertible into 2,007,504 common shares of the Corporation at a conversion price of \$0.533 per share that, if converted, will dilute our common stock. 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 36,755,503 common shares of Nymox issued and outstanding as of March 31, 2015. A total of 548,529 warrants are outstanding, with exercise prices range from \$0.54 to \$2.00 and expiry dates range from January 2017 to December 2017. In addition, 5,104,500 share options are outstanding, of which 5,042,000 are currently vested. Expiry dates for Nymox options range from 1.5 years to 10.7 years (see note 12(b) to our consolidated financial statements). These options have been granted to employees, officers, directors and consultants of the Corporation.

**If We Fail to Regain Compliance With the Requirements for Continued Listing on The NASDAQ Stock Market, Our Common Shares Could be Delisted from Trading on the NASDAQ Stock Market, Which Would Adversely Affect the Liquidity of Our Common Shares and Our Ability to Raise Additional Capital.**

Our common shares are currently listed for quotation on the NASDAQ Stock Market. We are required to meet specified financial requirements in order to maintain our listing on the NASDAQ Stock Market. On December 16, 2014, the Corporation was notified by the Nasdaq Listing Qualifications department that the Corporation's Nasdaq Capital Market requirements were currently deficient for the preceding 30 consecutive business days. However, the Listing Rules provide the Corporation a compliance period of 180 calendar days in which to regain compliance. In order to do so, the Corporation must maintain a minimum market value of \$35 million for a minimum of ten consecutive business days and the closing bid price of the Corporation's common share must be at least \$1 for a minimum of ten consecutive business days. Failure to meet the listing requirements may lead to delisting from the

Nasdaq Capital Market in which case the Corporation will consider an alternate trading platform for its common shares. Any potential delisting of our common shares from the NASDAQ Stock Market would make it more difficult for our shareholders to sell our shares in the public market and would likely result in decreased liquidity, limited availability of market quotations for common shares, limited availability of news and analyst coverage regarding our company, a decreased ability to issue additional securities and increased volatility in the price of our common shares. Further, if we were no longer listed on the NASDAQ Stock Market or any other U.S. exchange then we would be in violation of a covenant in the Common Share Purchase Agreement and the purchaser under that agreement would not be required to purchase our common shares, which would impede our ability to raise capital and have a material adverse effect on our business and operations.

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

Nymox incurs certain expenses, principally relating to salaries and operating expenses at its Canadian 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 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 company focused on developing its drug candidate, NX-1207, for the treatment of BPH and the treatment of low-grade localized prostate cancer. The Corporation currently markets NicAlert™ and TobacAlert™, tests that use urine or saliva to detect use of tobacco products. The Corporation also has an extensive patent portfolio covering its marketed products, its investigational drug as well as other therapeutic and diagnostic 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. On March 24, 2015, the Corporation announced that it will hold a special shareholders meeting on April 15, 2015 in Montreal for a motion to transfer the Corporation's head office from Montreal (Quebec) to the Bahamas.

**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 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](http://www.tobacalert.com). Nymox has entered into distribution and marketing agreements with companies and organizations in the U.S. 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 Siemens Medical Solutions. 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 GFC 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 June 2015.

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, F. 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. Other published studies include A. Lee et al. "The Accuracy of Urinary Cotinine Immunoassay Test Strip as an Add-on Test to Self-Reported Smoking Before Major Elective Surgery," *Nicotine Tob Res.* 2013;15:1690-5 and N Montalto, W Wells, "Validation of Self-Reported Smoking Status Using Saliva Cotinine: A Rapid Semiquantitative Dipstick Method," *Cancer Epidemiol Biomarkers Prev.* 2007; 16:1858-62.

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% (*J Am Med Dir Assoc* 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). Similar results were reported by South Korean researchers: Y.C. youn *et al.* "Urine Neural Thread Protein Measurements in Alzheimer Disease" *J Am*

*Med Dir Assoc* 2011;12:372-6. 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 AlzhemAlert™ 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 2013 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 5.2 million people have Alzheimer's disease in the United States alone. By 2050 this number is projected to increase to an estimated 13.8 million Americans. The annual national health care, long-term care and hospice costs for the care of 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 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:

- Eli Lilly and Company, which is currently marketing Amyvid® (florbetapir), a radioactive diagnostic agent for PET imaging, which is used to estimate the density of neuritic plaques in patients being evaluated for Alzheimer's disease.
- GE Healthcare, which recently received FDA approval for Vizamyl® (flutemetamol), another PET imaging agent.
- 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.

- Fujirebio Europe NV, formerly 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 are actively working to develop imaging technologies for the diagnosis of Alzheimer's disease. 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 successfully completed a multi-center, double-blind, placebo-controlled Phase 2 trial in September 2006. Top-line results of the Phase 3 NX02-0017 and NX02-0018 U.S. clinical trials of NX-1207 for BPH at 12 months post-treatment were not statistically significant compared to placebo. The Corporation is in the process of further data analysis and assessments of the two studies, and expects to continue its efforts to work on the development program. 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.

We believe, 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. Top-line results of the Phase 3 NX02-0017 and NX02-0018 U.S. clinical trials of NX-1207 for BPH at 12 months post-treatment were not statistically significant compared to placebo. The Corporation is in the process of further data analysis and assessments of the two studies, and expects to continue its efforts to work on the development program.

On December 16, 2010, the Corporation signed a license and collaboration agreement with Recordati Ireland Ltd. (“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 (“Licensed Territories”). After the top-line statistical failure of Nymox’s U.S. Phase 3 studies NX02-0017 and NX02-0018 at 12 months post-treatment, Recordati has terminated development and commercialization activities of NX-1207 in the licensed territories.

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.

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®), alfuzosin (Uroxatral®), silodosin (Rapaflo®), and tadalafil (Cialis®)) 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. In 2013, the FDA approved the Urolift™ system, a permanent surgical implant designed to pull back prostate tissue to improve urination in men with BPH.

#### ***NX-1207 for Prostate Cancer***

We are also developing NX-1207 as a focal treatment for certain types of cancer. In March 2012, we initiated 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. A Phase 2 study of NX-1207 for low grade localized prostate cancer was started in 2012 with positive results reported in 2014. The Corporation is in the process of working towards definitive studies for this indication.

#### **Preclinical Studies of NX-1207 for Hepatocellular Carcinoma**

Preclinical studies of NX-1207 also showed 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. The Corporation intends to advance NX-1207 into human clinical trials for the treatment of HCC.

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. Laboratory 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. NXC-4720, which is targeted 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. 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. New vaccines against bacterial infections are also 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 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 including research on NTP and its role in the extensive brain cell loss associated with AD and another program 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.

At present, there is no cure for Alzheimer's disease. There are five drugs approved by the FDA, tacrine (brand-name Cognex®), donepezil HCI (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.

The Alzheimer's Association's *2013 Alzheimer's Disease Facts and Figures* estimates that the annual healthcare, long term and hospice costs for people with Alzheimer's disease are over \$200 billion and the annual economic value of unpaid care for people with Alzheimer's disease is \$215 billion.

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 Plan to Address *Alzheimer's Disease: 2013 Update* (U.S. Department of Health and Human Services), the number of people with AD will increase significantly if current population trends continue unless the disease can be effectively treated or prevented. As people live longer, they become more at risk of developing Alzheimer's disease. The U.S. Census Bureau projects that the number of people in the U.S. aged 65 will double to about 72 million people by 2035 with the 85-and-older group being the fastest growing segment of the U.S. population by then.

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.

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 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 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 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 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 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.

### ***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 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 Pharmaceutical Corporation lease office and research facilities in St. Laurent, Quebec, Canada that comprise 11,210 square feet of leased space. The lease agreement expires on August 31, 2015. Nymox Corporation and Serex, Inc. facilities in Hasbrouck Heights, New Jersey comprise 4,799 square feet of leased space. That lease agreement expires October 31, 2016. Nymox Pharmaceutical Corporation and its two US subsidiaries Nymox Corporation and

Serex, Inc. own equipment used in 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 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 BPH and for low grade localized prostate cancer. 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 March 2010, the United States enacted sweeping 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. 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 has an extensive patent portfolio covering its marketed products, its investigational drug as well as other therapeutic and diagnostic indications in the U.S. and other countries around the world. Nymox has twenty-four 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 current issued patents is June 2014 and the rest range from 2014 through 2028.

Nymox's subsidiary, Serex, has nine 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 2014 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 December 2014.

The Corporation has three issued U.S. patents covering NX-1207 that relate to the composition of the compound, its formulation and its methods of use. The earliest expiry date for these U.S. patents is in 2022. Under current U.S. laws, if NX-1207 is approved for marketing by the FDA, the product may be eligible for a patent term extension of up to five years, depending on the duration of the regulatory testing and review phases prior to FDA approval, as well as up

to five years of data exclusivity protection. The Corporation has issued patents and pending patent applications relating to NX-1207 in other countries, including EU member states (Great Britain, Germany, France, Italy, The Netherlands, Sweden and Spain), Israel, Russia, China, Japan, South Korea, India, Indonesia, Australia, New Zealand, South Africa, Canada, Mexico and Brazil. The Corporation does not license any material patents related to NX-1207 from any third parties.

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 AlzheimerAlert™ 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 PET imaging, which is used to estimate the density of neuritic plaques in patients being evaluated for Alzheimer's disease.
- GE Healthcare, which recently received FDA approval for Vizamyl® (flutemetamol), another PET imaging agent.
- Athena Diagnostics, Inc., a division of Quest Diagnostics, 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.

- Fujirebio Europe NV, formerly 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 are actively working to develop imaging technologies for the diagnosis of Alzheimer's disease. 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 GFC Diagnostics Ltd. in the United Kingdom, and from 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 BPH face significant competition from existing products. There are eight drugs approved for treatment of BPH: five proprietary drugs (tadalafil (Cialis®), 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. In 2013, the FDA approved the Urolift™ system, a permanent surgical implant designed to pull back prostate tissue to improve urination in men with BPH.

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

At present, we do most of our marketing ourselves. To increase our marketing, distribution and sales, 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**

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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. The revenue in 2014, 2013 and 2012 include recognition of revenue related to the upfront payment of €10 million (U.S. \$13.1 million) received from Recordati in December 2010.

Revenues:	Canada	United States	Europe & Other
2014	\$ 6,845	\$ 290,061	\$ 2,652,603
2013	\$ 5,104	\$ 365,277	\$ 2,988,629
2012	\$ 17,780	\$ 353,397	\$ 2,701,410

#### ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

#### ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

##### General

Nymox Pharmaceutical Corporation is a biopharmaceutical company focused on developing its drug candidate, NX-1207, for the treatment of BPH and the treatment of low-grade localized prostate cancer. The Corporation also has an extensive patent portfolio covering its marketed products, its investigational drug as well as other therapeutic and diagnostic indications.

We 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 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 have under development our novel proprietary drug candidate, NX-1207, for the treatment of BPH and we are also developing NX-1207 for the treatment of low-grade localized prostate cancer.

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.

As announced in November 2014, top-line results of the Phase 3 NX02-0017 and NX02-0018 U.S. clinical trials of NX-1207 for BPH at 12 months post-treatment were not statistically significant compared to placebo. The Corporation is in the process of further data analysis and assessments of the two studies, and expects to continue its efforts to work on the development program. After the top-line statistical failure of Nymox's U.S. Phase 3 studies NX02-0017 and NX02-0018 at 12 months post-treatment, Recordati has terminated development and commercialization activities of NX-1207 in the licensed territories. A Phase 2 study of NX-1207 for low grade localized prostate cancer was started in 2012 with positive results reported in 2014. The Corporation is in the process

of working towards definitive studies for this indication.

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 substantial operating losses since our inception due in large part to expenditures for our research and development activities. As at December 31, 2014, we had an accumulated deficit of \$100.0 million, and our total liabilities exceeded our total assets. Our current level of annual expenditures exceeds the anticipated revenues from sales of goods and may not be covered by additional sources of funds. Management believes that such operating losses will continue for at least the next few years as a result of expenditures relating to research and development of our potential therapeutic products.

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

### **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. In addition, Nymox received an upfront payment of \$13,088,000 through a license and collaboration agreement with Recordati in 2010. 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. In December 2014, the Corporation issued secured convertible notes through a private placement for aggregate gross proceeds of \$1,070,000 which bear interest at 6% per annum.

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, 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 \$1,000,000 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. As at the date hereof, the Common Stock Private Purchase Agreement, set to expire in November 2015, has not been renewed. In prior years the Corporation typically has renewed the Common Stock Private Purchase Agreement approximately one year prior to its scheduled expiry date.

Under the agreement dated November 1, 2012; we received a total of \$6,000,000 during 2013.

In November, 2013, we signed a new Common Stock Private Purchase Agreement, whereby Lorros-Greyse was committed to purchase up to \$15 million of Nymox's common shares over the twenty-four month period beginning in November 2013, subject to the same terms and conditions as before. Under this agreement, which became effective December 3, 2013, we received a total of \$5,450,000 for the following shares under this Common Stock Private Purchase Agreement:

- December 18, 2013, 48,544 common shares were issued at a price of \$6.18 per share.
- January 14, 2014, 69,686 common shares were issued at a price of \$5.74 per share.
- February 4, 2014, 61,533 common shares were issued at a price of \$5.69 per share.
- February 28, 2014, 62,297 common shares were issued at a price of \$5.62 per share.
- March 25, 2014, 65,408 common shares were issued at a price of \$5.35 per share.
- April 11, 2014, 28,468 common shares were issued at a price of \$5.27 per share.
- April 25, 2014, 29,487 common shares were issued at a price of \$5.09 per share.
- May 7, 2014, 63,573 common shares were issued at a price of \$4.72 per share.
- May 16, 2014, 59,595 common shares were issued at a price of \$5.03 per share.
- May 28, 2014, 29,132 common shares were issued at a price of \$5.15 per share.
- June 10, 2014, 31,062 common shares were issued at a price of \$4.83 per share.
- June 23, 2014, 31,302 common shares were issued at a price of \$4.79 per share.
- July 3, 2014, 21,501 common shares were issued at a price of \$4.65 per share.
- July 8, 2014, 52,312 common shares were issued at a price of \$4.78 per share.
- July 24, 2014, 31,672 common shares were issued at a price of \$4.74 per share.
- August 5, 2014, 31,179 common shares were issued at a price of \$4.81 per share.
- August 8, 2014, 60,926 common shares were issued at a price of \$4.92 per share.
- August 27, 2014, 60,048 common shares were issued at a price of \$5.00 per share.

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- September 9, 2014, 61,703 common shares were issued at a price of \$4.86 per share.
- September 15, 2014, 31,049 common shares were issued at a price of \$4.83 per share.
- September 30, 2014, 37,406 common shares were issued at a price of \$4.01 per share.
- October 9, 2014, 33,791 common shares were issued at a price of \$4.44 per share.
- October 24, 2014, 50,040 common shares were issued at a price of \$5.00 per share.
- November 12, 2014, 138,889 common shares were issued at a price of \$0.72 per share.

Twenty-four drawings were made under the November 2013 Common Stock Private Purchase Agreement, for total proceeds of \$5,450,000.

As of March 31, 2015, Nymox had \$9.55 million of financing available under the November 2013 Common Stock Private Purchase Agreement, subject to adhering to the general covenants included therein.

On December 16, 2014, the Corporation issued secured convertible notes through a private placement for aggregate gross proceeds of \$1,070,000 which bear interest at 6% per annum, payable quarterly with a maximum term of three years. The Corporation will also pay an administrative fee of 2% per annum on the outstanding principal amount, calculated quarterly and

paid at the same time that the interest are paid on these notes. The notes are convertible by the holder at any time into common shares of the Corporation at a conversion price of \$0.533 per share.

As part of its business plan, the Corporation anticipates the need to raise capital to pursue its planned business operations and research and development programs over the next year. The Corporation intends to access financing through the existing Common Stock Private Purchase Agreement and/or other sources of capital in order to fund these operations and activities over the next year.

If the Purchaser does not purchase the Corporation's common shares as provided for under the existing Common Stock Private Purchase Agreement, or if the agreement is not renewed, the Corporation will have to seek other sources of financing in order to be able to pay its obligations as they become due, which could have an impact on its ability to continue as a going concern.

The Corporation's ability to raise capital through the Agreement and other sources of financing will be impacted by the market price and trading volumes of its common shares. The results of the NX02-0017 and NX02-0018 clinical trials may adversely affect the Corporation's ability to raise capital on a timely basis, requiring the Corporation to reduce its cash requirements by eliminating or deferring spending on research, development and corporate activities. In addition, other sources of financing may not be available or may be available only at a price or on terms that are not favorable to the Corporation.

Also, the Corporation has received total proceeds of approximately \$1.09 million from the exercise of 383,400 options since 1995. In 2014, no option were exercised (2013 – 1,000; 2012 – 8,000). An additional 100,514 shares have also been issued relating to options under "cashless exercises" since 1995.

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, 137,723 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 21,351 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. The remaining 19,713 warrants expired on July 31, 2005.

In total, Nymox has raised over \$81.6 million through the issuance of common stock or securities exercisable for shares of common stock, since its incorporation in May 1995.

We have contractual obligations under long-term lease commitments for our premises in Canada of \$20,571 per month until August 2015 and in the United States of \$9,007 per month until October 2016 and contractual obligations under the 6% secured convertible notes. Corporation's contractual obligations are summarized in the Management's Discussion and Analysis below.

## 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, 2014, 2013 and 2012. This MD&A should be read together with the audited Consolidated Financial Statements and the related notes. This MD&A is dated March 31, 2015. All amounts in this report are in U.S. dollars, unless otherwise noted.

Except as otherwise indicated, all financial information contained in this MD&A and in the Consolidated Financial Statements has been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). The Consolidated Financial Statements and this MD&A were reviewed by the Corporation's Audit 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 focused on developing its drug candidate, NX-1207, for the treatment of BPH and the treatment of low-grade localized prostate cancer. Since 1989, the Corporation's activities and resources have been directed primarily on developing certain pharmaceutical technologies. Since 2002, Nymox has been developing its novel proprietary drug candidate, NX-1207, for the treatment of benign prostatic hyperplasia ("BPH"). 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 for BPH in Europe including Russia and the CIS, the Middle East, the Maghreb area of North Africa and South Africa. After the top-line statistical failure of Nymox's U.S. Phase 3 studies NX02-0017 and NX02-0018 at 12 months post-treatment, Recordati has terminated development and commercialization efforts for NX-1207 in the licensed territories. NX-1207 showed positive results for the treatment of BPH in Phase 1 and 2 clinical trials in the U.S. and in follow-up studies of available subjects from the completed clinical trials. In 2009, Nymox started two pivotal double blind placebo controlled Phase 3 trials for NX-1207, NX02-0017 and NX02-0018, that were conducted at investigational sites across the U.S. with a total enrollment of approximately 1,000 patients. Nymox also initiated subsequent open-label U.S. re-injection Phase 3 safety studies, NX02-0020 and NX02-0022. The NX02-0017 study completed patient enrollment and participation in December 2013 and the NX02-0018 study in May 2014. Top-line results of the Phase 3 NX02-0017 and NX02-0018 U.S. clinical trials of NX-1207 for BPH at 12 months post-treatment were not statistically significant compared to placebo. The Corporation is in the process of further data analysis and assessments of the two studies, and expects to continue its efforts to work on the development program. Nymox is also developing NX-1207 for the treatment of low-grade localized prostate cancer. A Phase 2 study of NX-1207 for low grade localized prostate cancer was started in 2012 with positive results reported in 2014. The Corporation is in the process of working towards definitive studies for this indication. The Corporation also has an extensive patent portfolio covering its marketed products, its investigational drug as well as other therapeutic and diagnostic indications. Nymox developed the AlzheimerAlert™ test, which is certified with a CE Mark in Europe. 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 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.

The Corporation is subject to a number of risks, including the successful development and marketing of its technologies and its ability to finance its research and development programs and operations through the sale of its



common shares. Since 2003, the Corporation has relied on the Common Stock Private Purchase Agreement (the 'Agreement') (referred to in note 12 (a) to the Consolidated Financial Statements), private placements and other types of financings collaboration agreements, and revenues from product sales to fund its operations and research programs. 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 debt or capital in the near term and/or achieve sales and other revenue-generating activities. Management has taken steps to reduce expenditures going forward in the short term by staff reductions, deferral of management salaries, and operational changes.

The top-line failure of the two Phase 3 studies of NX-1207 for BPH materially affects the Corporation's current ability to fund its operations, meet its cash flow requirements, realize its assets and discharge its obligations. Under the Common Stock Private Purchase Agreement, the Corporation must adhere to 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. In the past, the Corporation has been successful in obtaining the required financing pursuant to the Agreement. As of the date of the financial statements, the Corporation has not received any communication from the counterparty in the Agreement that it will not honor the Corporation's future draw-

down notices under the Agreement or that it intends to terminate the Agreement. On November 12, 2014, the Corporation completed a drawdown of \$100,000 pursuant to this Agreement.

Management believes that current cash balances as at December 31, 2014 and anticipated funds from product sales are not sufficient to fund substantially all of its planned business operations and research and development programs over the next year. The Corporation intends to access financing through the existing Common Stock Private Purchase Agreement and/or other sources of capital in order to fund these operations and activities over the next year.

If the purchaser does not purchase the Corporation's common shares as provided for under the Agreement, the Corporation will have to seek other sources of financing in order to be able to pay its obligations as they become due, which could have an impact on its ability to continue as a going concern. Considering recent developments and the need for additional financing, there exists a material uncertainty that casts substantial doubt about the Corporation's ability to continue as a going concern. These financial statements do not reflect adjustments that would be necessary if the going concern assumption was not appropriate. If the going concern assumption is not appropriate, then adjustments may be necessary to the carrying value and classification of assets and liabilities and reported results of operations and such adjustments could be material.

We have incurred operating losses throughout our history. Management believes that such operating losses will continue for at least the next few years as a result of expenditures relating to research and development of our potential therapeutic products.

## **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 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 Certain Of Our Therapeutic Products May Be Delayed, Making it Impossible to Achieve Anticipated Development or Commercialization Timelines And Our Development of NX-1207 Has Been Delayed Due to Negative Results In Phase III Clinical Trials
- 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 Will Require Additional Funding to Continue as a Going Concern
- Our Ability to Draw on the Common Stock Private Purchase Agreement, Which Expires in November 2015, is Dependent on Adhering to General Covenants
- We Have Identified a Material Weakness in our Internal Control over Financial Reporting. Although We Expect to Make Every Effort to Address this Material Weakness, We May Find that We are Unable to Remediate this Deficiency in our Control Environment, Which Could Reduce the Reliability of Our Financial Reporting, Harm Investor Confidence in our Company and Affect the Value of our Common Stock.
- 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 Have Become Involved in Securities Class Action Litigation That is Expected to Divert Management's Attention and Could Harm our Business
- The Issuance of New Shares May Dilute Nymox's Stock
- If We Fail to Regain Compliance With the Requirements for Continued Listing on The NASDAQ Stock Market, Our Common Shares Could be Delisted from Trading on the NASDAQ Stock Market, Which Would Adversely Affect the Liquidity of Our Common Shares and Our Ability to Raise Additional Capital

- We Face Potential Losses Due to Foreign Currency Exchange Risks
- We Have Never Paid a Dividend and are Unlikely to do so in the Foreseeable Future

### **Critical Accounting Policies**

The Consolidated Financial Statements of the Corporation have been prepared under International Financial Reporting Standards as issued by the International Accounting Standards Board. The Corporation's functional and presentation 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.

#### The going concern basis of presentation

The Consolidated Financial Statements have been prepared under the going concern assumption. Refer to 'Corporate Profile' and note 1 to the consolidated financial statements for a detailed discussion of this matter.

#### Revenue Recognition

The Corporation has generally derived its revenue from product sales and collaboration agreements. Revenue from product sales is recognized when the product has been delivered and 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 collectability 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 collectability is reasonably assured.

Revenue recognition is subject to critical judgments, particularly in the collaboration agreement described above. Management uses judgment in estimating the service period over which revenue is recognized for upfront payments received.

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. There is estimation uncertainty with respect to selecting inputs to the Black-Scholes pricing model used to determine the fair value of the stock options. 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.

Contingent liabilities

Subsequent to the press release dated November 2, 2014 referred to in the 'Corporate Profile' section, a plaintiff is seeking certification of a class action suit against the Corporation and an officer of the Corporation. Refer to note 13 to the Consolidated Financial Statements. Assessing the recognition of contingent liabilities requires judgement in evaluating whether it is probable that economic benefits will be required to settle the matters subject to litigation.

Compound financial instruments

Compound financial instruments issued by the Corporation comprise convertible notes that can be converted to share capital at the option of the holder, and the number of shares to be issued does not vary with changes in their fair value.

The liability component of a compound financial instrument is recognized initially at the fair value of a similar liability that does not have an equity conversion option. The model used to measure the fair value of the liability component comprises estimation uncertainty in determining the interest rate applicable to a similar liability that does not have an equity conversion option. The equity component is recognized initially at the difference between the fair value of the compound financial instrument as a whole and the fair value of the liability component. Any directly attributable transaction costs are allocated to the liability and equity components in proportion to their initial carrying amounts.

Subsequent to initial recognition, the liability component of a compound financial instrument is measured at amortized cost using the effective interest method. The equity component of a compound financial instrument is not remeasured subsequent to initial recognition.

**Results of Operations**

<b>Selected Annual Information</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>
Total revenues	\$2,949,509	\$3,359,010	\$3,072,587
Net loss	\$(4,594,093)	\$(4,908,603)	\$(7,627,589)
Loss per share (basic & diluted)	\$(0.13)	\$(0.14)	\$(0.23)
Total assets	\$1,422,566	\$966,385	\$1,754,179
Non-current financial liabilities	\$1,118,831	\$400,000	\$400,000

<b>Quarterly Results</b>	<b>Q4 – 2014</b>	<b>Q3 – 2014</b>	<b>Q2 – 2014</b>	<b>Q1 – 2014</b>
Total revenues	\$729,136	\$735,529	\$752,280	\$732,564
Net loss	\$(492,799)	\$(688,206)	\$(820,272)	\$(2,592,816)
Loss per share (basic & diluted)	\$(0.02)	\$(0.02)	\$(0.02)	\$(0.07)
	<b>Q4 – 2013</b>	<b>Q3 – 2013</b>	<b>Q2 – 2013</b>	<b>Q1 – 2013</b>
Total revenues	\$937,490	\$743,288	\$839,586	\$838,646
Net loss	\$(1,316,921)	\$(1,020,387)	\$(1,477,389)	\$(1,093,906)
Loss per share (basic & diluted)	\$(0.04)	\$(0.03)	\$(0.04)	\$(0.03)

The revenues in 2014, 2013 and 2012 include the recognition of revenue related to the upfront payment of €10 million (US\$13.1 million) received from Recordati in December 2010. The net loss during the first quarter of 2014 includes a stock compensation charge in the amount of \$1,420,185 which explains the increase in net losses for that quarter

compared to other quarters presented.

Results of Operations – 2014 compared to 2013

Net losses were \$492,799, or \$0.02 per share, for the quarter, and \$4,594,093, or \$0.13 per share, for the year ended December 31, 2014, compared to \$1,316,921, or \$0.04 per share, for the quarter, and \$4,908,603, or \$0.14 per share, for the year ended December 31, 2013. Net loss includes stock compensation charges of \$1,579,914 in 2014 and \$307,326 in 2013. The decrease in net loss for the twelve months ended December 31, 2014 compared to the same period in 2013 is primarily due to decreases of \$1,223,142 in net research and development expenditures, and \$95,439 in marketing expenses, net of increases of \$1,061,315 in general and administrative expenses, \$85,874 in finance costs and a non-recurring gain on settlement of agreement of \$189,575 in 2014. The decrease in net losses for the quarter ended December 31, 2014 compared to same period in 2013 is mainly due to a decrease of \$942,219 in research and development, an increase of \$72,358 in finance costs and a non-recurring gain on settlement of agreement of \$189,575 in 2014, net of a decrease of \$54,458 in research tax credits. The weighted average number of common shares outstanding for the year ended December 31, 2014 was 35,253,879 compared to 34,147,666 for the same period in 2013.

## Revenues

For the quarter and year ended December 31, 2014, amounts of \$654,400 and \$2,617,600 respectively, were recognized as revenue relating to the upfront payment received from Recordati in December 2010. At December 31, 2014, the deferred revenue related to this transaction recorded in the statement of financial position amounted to \$2,508,533 (2013 -\$5,126,133). Refer to 'Subsequent Events'.

Revenues from sales of goods amounted to \$74,736 for the quarter and \$331,909 for the year ended December 31, 2014, compared with \$283,090 for the quarter and \$741,410 for the year ended December 31, 2013. The decrease for the year ended December 31, 2014 compared to the same period in 2013 is primarily due to the non-recurrence in 2014 of the sale of goods of \$333,249 for the year ended December 31, 2013 under our licensing agreement with Recordati. The development of therapeutic candidates and of 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.

## Research and Development

Research and development expenditures were \$738,989 for the quarter and \$4,761,557 for the year ended December 31, 2014, compared with \$1,681,208 for the quarter and \$6,274,903 for the year ended December 31, 2013. Research and development expenditures include costs incurred mainly for advancing Nymox's BPH and prostate cancer product candidate NX-1207 through clinical trials. Research and development expenditures also include stock compensation charges of \$1,119 for the quarter and \$631,217 for the year ended December 31, 2014 and \$2,611 for the quarter and \$12,679 for the year ended December 31, 2013. On November 2, 2014, the Corporation announced that the two Phase 3 U.S. studies of NX-1207 for the treatment of BPH, NX02-0017 and NX02-0018, failed to meet their primary efficacy endpoints. The decrease in expenses for the quarter ended December 31, 2014 is mainly attributable to a reduction of \$672,924 in clinical trial expenditures and a decrease of \$140,517 in salaries and payroll related expenses. For the year ended December 31, 2014, a decrease of \$1,696,384 in clinical trial expenditures, a decrease of \$165,543 in professional fees and a decrease of \$184,431 in other expenditures combined with an increase of \$618,538 in stock compensation charges and a decrease of \$85,527 in salaries and payroll related expenses explained the reduction of expenses compared to the same period in 2013. In 2014, research tax credits amounted to \$264,827 compared to \$555,031 in 2013. The decrease of \$290,204 in 2014 is mainly attributable by the receipt, in 2013, of amounts totaling \$194,695 which were realized but related to prior years, as well as less activities due to the fact that the U.S. BPH 12 month trials were completed in November 2014 and a reduction, in June 2014, of the research tax credit rate from 37.5% to 30.0%. The Corporation expects that research and development expenditures will decrease as a result of the Corporation's U.S. BPH trial activity reduction, pending the evaluation of the data. Because of the early stage of development and the uncertainty related to 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 as further described in the section entitled "Risk Factors". 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 were \$63,963 for the quarter and \$186,616 for the year ended December 31, 2014 compared with \$44,356 for the quarter and \$282,055 for the year ended December 31, 2013. Marketing expenses for the quarter were relatively stable. The decrease in expenses for the year ended December 2014 is attributable to stock compensation charges recorded in the second quarter of 2013 which amounted to \$123,700 compared to nil for the same period in 2014. 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 were \$614,075 for the quarter and \$2,817,201 for the year ended December 31, 2014, compared with \$401,038 for the quarter and \$1,755,886 for the year ended December 31, 2013. General and administrative expenditures also include stock compensation charges of \$948,697 for the year ended December 31, 2014 and \$170,947 in the comparative period in 2013. The increase of \$1,061,315 in expenses for the year ended December 31, 2014 is primarily

attributable to an increase of \$777,750 in stock compensation charges, an increase of \$73,247 in salaries and payroll related expenses, other charges of \$121,000 related to operational changes, an increase of \$61,839 in professional fees and a decrease of \$68,818 in investor relations compared to the same period in 2013. The increase of \$213,037 for the quarter ended December 31, 2014 is mainly attributable to an increase of \$98,143 in professional fees, other charges of \$121,000 related to operational changes offset by a decrease of \$62,984 in investor relations compared to 2013. The Corporation expects that general and administrative expenditures will increase if and when product development leads to expanded operations.

#### Finance Costs - Foreign Exchange

Finance costs were \$79,343 for the quarter and \$ 112,922 for the year ended December 31, 2014, compared with \$3,141 and \$27,048 for the year ended December 31, 2013. The increase of \$85,874 for the year ended December 31, 2014 is primarily due to financial costs of \$71,009 incurred in connection with a bridge loan that was repaid before year-end and \$26,148 in accretion of liabilities incurred in connection with the departure of the former Chief Financial Officer. The increase of \$72,358 for the quarter ended December 31, 2014 is mainly attributable to the finance costs of \$71,009 incurred in connection with a bridge loan that was repaid before year-end.

The Corporation incurs expenses in the local currency of the countries in which it operates, which include the United States and Canada. Approximately 56% of 2014 expenses (2013 - 59%; 2012 - 57%) were in U.S. dollars. Foreign exchange fluctuations had no meaningful impact on the Corporation's results in 2014, 2013 or 2012.

#### Gain on settlement

This gain relates to the settlement agreement for the departure of the former Chief Financial Officer. Refer to note 8 to the Consolidated Financial Statements.

#### Inflation

The Corporation does not believe that inflation has had a significant impact on its results of operations.

#### Results of Operations – 2013 compared to 2012

Net losses were \$1,316,921, or \$0.04 per share, for the quarter, and \$4,908,603, or \$0.14 per share, for the year ended December 31, 2013, compared to \$2,813,922, or \$0.08 per share, for the quarter, and \$7,627,589, or \$0.23 per share, for the year ended December 31, 2012. Net losses include stock compensation charges of \$307,326 in 2013 and \$1,962,085 in 2012. The decrease in net losses for the quarter and the year ended December 31, 2013 compared to the same periods in 2012 is primarily attributable to lower stock compensation. The balance of the decrease for the year ended December 31, 2013 compared to the year ended December 31, 2012 is related to reductions in many areas of expenditures mainly due to a reduction in clinical trial expenditures as patient participation in the NX-1207 studies reach or near completion. Patient participation in NX02-0020 was completed in 2012 and in NX02-0017 in 2013. The weighted average number of common shares outstanding for the year ended December 31, 2013 was 34,147,666 compared to 33,176,185 for the same period in 2012.

#### Revenues

Revenues from sales of goods amounted to \$283,090 for the quarter and \$741,410 for the year ended December 31, 2013, compared with \$135,150 for the quarter and \$454,987 for the year ended December 31, 2012. The increase for the quarter and the year ended December 31, 2013 compared to the same periods in 2012 is due to new revenue relating to the sale of goods under our licensing agreement.

For the three months and year ended December 31, 2013, amounts of \$654,400 and \$2,617,600 respectively were recognized as revenue relating to the upfront payment received from Recordati in December 2010, compared to \$654,400 and \$2,617,600 respectively for the three months and year ended December 31, 2012. At December 31, 2013, the deferred revenue related to this transaction recorded in the statement of financial position amounted to \$5,126,133 (2012 -\$7,743,733).

#### Research and Development

Research and development expenditures were \$1,681,208 for the quarter and \$6,274,903 for the year ended December 31, 2013, compared with \$3,218,858 for the quarter and \$8,572,528 for the year ended December 31, 2012. 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. Research and development expenditures also include stock compensation charges of \$2,611 for the quarter and \$12,679 for the year ended December 31, 2013 and \$1,653,428 for the quarter and \$1,686,310 for the year ended December 31, 2012. The decrease in expenses for the quarter and for the year ended December 31, 2013 compared to the same periods in 2012 is primarily attributable to lower stock compensation. The

balance of the decrease for the year ended December 31, 2013 compared to the year ended December 31, 2012 is due to a reduction in clinical trial expenditures as patient participation in the NX-1207 studies reach or near completion. Patient participation in NX02-0020 was completed in 2012 and in NX02-0017 in 2013. In 2013, research tax credits amounted to \$555,031 compared to \$289,766 in 2012. The increase in 2013 reflects the receipt of amounts totaling \$194,695 which were reserved as provisions in prior years. No provisions were reserved on research tax credits in 2013, which explains the balance of the increase.

### Marketing Expenses

Marketing expenditures were \$44,356 for the quarter and \$282,055 for the year ended December 31, 2013, in comparison to expenditures of \$36,756 for the quarter and \$158,431 for the year ended December 31, 2012. The increase in expenses for the year is attributable to stock compensation expenses recorded in 2013 which amounted to \$123,700 compared to \$389 in 2012.

### General and Administrative Expenses

General and administrative expenses were \$401,038 for the quarter and \$1,755,886 for the year ended December 31, 2013, compared with \$356,341 for the quarter and \$1,972,120 for the year ended December 31, 2012. General and administrative expenditures also include stock compensation charges of \$170,947 for the year ended December 31, 2013 and \$275,386 in 2012. The increase for the quarter is due to higher expenditures on shareholder relations compared to the same quarter in 2012. The decrease in expenses for the year ended December 31, 2013 is primarily attributable to a reduction in stock compensation expenses and professional fees in 2013 compared to 2012.

### **Contractual Obligations**

Nymox has no contractual obligations of significance other than its accounts payable, accrued liabilities and the following:

<b>Contractual Obligations</b>	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>4-5 years</b>
Rent for laboratory and office space	\$362,730	\$272,658	\$90,072	\$0
Insurance premium installments	\$61,406	\$61,406	\$0	\$0
Operating leases	\$28,102	\$16,262	\$11,840	\$0
Convertible notes	\$1,070,000	\$0	\$1,070,000	\$0
Interest and fees on convertible notes	\$249,667	\$85,600	\$164,067	\$0
Total Contractual Obligations other than accounts payable and accrued liabilities	\$1,771,905	\$435,926	\$1,335,979	\$0

The redeemable preferred shares for the Corporation's subsidiary Serex, Inc. in the amount of \$400,000 have no specific terms of repayment.

### **Off-Balance Sheet Arrangements**

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 statement of financial position except for operating leases and insurance premium installments.

### **Contingent liabilities**

On November 24, 2014, a shareholder of the Corporation, filed a proposed class action suit in the United States District Court, District of New Jersey, against the Corporation and the President and CEO of the Corporation. The motion was heard on January 26, 2015, and was the first procedural step before any class action could be instituted. The plaintiff seeks certification of a class action on behalf of all persons, wherever they reside, who acquired the Corporation's common stock between January 31, 2011 and November 2, 2014. The plaintiff alleges that certain of the Corporation's disclosures failed to disclose material adverse facts that raised serious questions as to the ability to achieve significant results for NX-1207 in Phase 3 trials in light of difficulty of enrolling candidates, obtaining objective and measured results, and the placebo effect. On March 10, 2015, we were served with a class-action lawsuit. The Corporation believes that the allegations made against it in these actions are meritless and will vigorously defend the matter, although no assurance can be given with respect to the ultimate outcome of such proceedings. No provision has been recognized in these financial statements for this matter.

In November 2011, two former directors of the Corporation, who ceased to be directors in 2006, served the Corporation with a Motion to Institute Proceedings filed with the Quebec Superior Court seeking an order that they are entitled to exercise options to purchase a total of 125,000 shares of the Corporation at a price of US\$4.33 or, in the alternative, damages for lost profit. On February 18, 2014, the claim by one of the former directors against Nymox was dismissed. On December 3, 2014, the Corporation and the other director signed an agreement and settled the claim out of court.

## Transactions with Related Parties

The Corporation had no transactions with related parties in 2014, 2013 and 2012 other than those disclosed for key management personnel to note 21 of the Consolidated Financial Statements.

## Financial Position

### Liquidity and Capital Resources

As of December 31, 2014, cash and receivables including tax credits totalled \$1,307,501 compared with \$876,489 at December 31, 2013. A decrease of \$168,680 in accounts receivable is primarily due to the non-recurrence in 2014 of the sales of goods of \$144,623 during the fourth quarter of 2013, under our licensing agreement with Recordati. An increase of \$254,324 in tax credits receivable represents the amount earned for the year ended December 31, 2014. The increase of \$336,749 in cash is due to the difference in the drawing amounts received under our Common Stock Private Purchase Agreement as well as funds received from the issuance of convertible notes and private placement, and the timing differences in payments of our expenditures. In November 2013, the Corporation signed a Common Stock Private Purchase Agreement, whereby Lorros-Greyse Investments, Ltd. (the "Purchaser") was committed to purchase up to \$15 million of the Corporation's common shares over a twenty-four month period. The agreement became effective December 3, 2013. As at December 31, 2014, twenty-four drawings were made under the Common Stock Private Purchase Agreement, for total proceeds of \$5,450,000. On December 18, 2013, 48,544 common shares were issued at a price of \$6.18 per share. On January 14, 2014, 69,686 common shares were issued at a price of \$5.74 per share. On February 4, 2014, 61,533 common shares were issued at a price of \$5.69 per share. On February 28, 2014, 62,297 common shares were issued at a price of \$5.62 per share. On March 25, 2014, 65,408 common shares were issued at a price of \$5.35 per share. On April 11, 2014, 28,468 common shares were issued at a price of \$5.27 per share. On April 25, 2014, 29,487 common shares were issued at a price of \$5.09 per share. On May 7, 2014, 63,573 common shares were issued at a price of \$4.72 per share. On May 16, 2014, 59,595 common shares were issued at a price of \$5.03 per share. On May 28, 2014, 29,132 common shares were issued at a price of \$5.15 per share. On June 10, 2014, 31,062 common shares were issued at a price of \$4.83 per share. On June 23, 2014, 31,302 common shares were issued at a price of \$4.79 per share. On July 3, 2014, 21,501 common shares were issued at a price of \$4.65 per share. On July 8, 2014, 52,312 common shares were issued at a price of \$4.78 per share. On July 24, 2014, 31,672 common shares were issued at a price of \$4.74 per share. On August 5, 2014, 31,179 common shares were issued at a price of \$4.81 per share. On August 8, 2014, 60,926 common shares were issued at a price of \$4.92 per share. On August 27, 2014, 60,048 common shares were issued at a price of \$5.00 per share. On September 9, 2014, 61,703 common shares were issued at a price of \$4.86 per share. On September 15, 2014, 31,049 common shares were issued at a price of \$4.83 per share. On September 30, 2014, 37,406 common shares were issued at a price of \$4.01 per share. On October 9, 2014, 33,791 common shares were issued at a price of \$4.44 per share. On October 24, 2014, 50,040 common shares were issued at a price of \$5.00 per share. On November 12, 2014, 138,889 common shares were issued at a price of \$0.72 per share. Since November 12, 2014, the Corporation has not executed any new drawing amounts under the Common Stock Private Purchase Agreement. At March 31, 2015, the Corporation can require the Purchaser to purchase up to \$9,550,000 of common shares over the remaining term of the Agreement subject to the conditions therein. As at the date of this MD&A, the Common Stock Private Purchase Agreement, set to expire in November 2015, has not been renewed. In prior years the Corporation typically has renewed the Common Stock Private Purchase Agreement approximately one year prior to its scheduled expiry date.

The Corporation believes its current cash balance as at December 31, 2014 and anticipated funds from product sales are not sufficient to fund substantially all of its planned business operations and research and development programs over the next year. The Corporation intends to access financing through the existing Common Stock Private Purchase Agreement and/or other sources of capital in order to fund these operations and activities over the next year. The Corporation cannot assure you that it will be able to secure additional financing on favorable terms or at all.

The top-line failure of the two Phase 3 studies of NX-1207 for BPH, announced by the Corporation on November 2, 2014, materially affects the Corporation's current ability to fund its operations, meet its cash flow requirements, realize its assets and discharge its obligations. The Corporation's ability to raise capital through the Common Stock Private Purchase Agreement is subject to the Corporation complying with general covenants in the Agreement 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. On November 2, 2014, the Corporation announced that the Corporation's Phase 3 trials of its investigational drug product, NX-1207, for the treatment of benign prostatic hyperplasia (BPH), NX02-0017 and NX02-0018, had failed to meet their primary endpoints. On November 3, 2014, the Corporation's stock price fell from its previous close of \$5.14 to a closing price of \$0.93 equaling, an 82% decline. As of March 31, 2015, the Corporation has not received any communications from the Purchaser that it will not honor the Corporation's future drawdown notices under the agreement or that it intends to terminate the agreement. On November 12, 2014, the Corporation completed a drawdown of \$100,000 pursuant to the agreement. The Corporation has not executed any new drawing amounts since that date.

If the Purchaser does not purchase the Corporation's common shares as provided for under the agreement, or if the agreement is not renewed, the Corporation will have to seek other sources of financing in order to be able to pay its obligations as they become due, which could have an impact on its ability to continue as a going concern.

The Corporation's ability to raise capital through the Agreement and other sources of financing will be impacted by the market price and trading volumes of its common shares. The results of the NX02-0017 and NX02-0018 clinical trials may adversely affect the Corporation's ability to raise capital on a timely basis, requiring the Corporation to reduce its cash requirements by eliminating or deferring spending on research, development and corporate activities. In addition, other sources of financing may not be available or may be available only at a price or on terms that are not favorable to the Corporation.

In addition to financing operations through the issuance of equity, the Corporation may also secure additional funding through the issuance of debt, licensing or partnering products in development, increasing revenue from our products, or realizing on intellectual property and other assets. There can be no assurances that the Corporation will be successful in realizing on any such potential opportunities for additional funding at a price or on terms that are favorable to the Corporation.

On December 16, 2014, the Corporation issued secured convertible notes through a private placement for aggregate gross proceeds of \$1,070,000 which bear interest at 6% per annum, payable quarterly with a maximum term of 3 years. The Corporation will also pay an administrative fee of 2% per annum on the outstanding principal amount, calculated quarterly and paid at the same time that the interest are paid on these notes. The notes are convertible by the holder at any time into common shares of the Corporation at a conversion price of \$0.533 per share.

On January 23, 2015, the Corporation completed a \$200,000 private placement financing. A total of 383,058 units were issued at an average price of \$0.52 per share and on March 12, 2015, the Corporation completed a \$200,000 private placement financing. A total of 500,000 units were issued at an average price of \$0.40 per share. Each Unit is comprised of one common share and one-half of one common share purchase warrant (each whole warrant, a "Warrant"). Each Warrant entitles the holder to acquire one common share of the Corporation at a price per share equal to U.S. \$2.00 for a period 24 months following the subscription date.

Other than the financing discussed above, the Corporation does not have arranged sources of financing.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. As at December 31, 2014, we had an accumulated deficit of \$100,039,579, and we have negative cash flows from operations. Excluding the non-cash deferred revenue amount, the Corporation's working capital deficiency is \$580,375 at December 31, 2014. Our current level of annual expenditures exceeds the anticipated revenues from sales of goods and may not be covered by additional sources of funds.

In response to the top-line twelve month failure of the two Phase 3 trials of NX-1207 for BPH, Management has taken steps to reduce expenditures going forward in the short term by staff reductions for the U.S. BPH development program for NX-1207, deferral of management salaries, and other operational changes. Management is exploring other options, including the securing of additional sources of financing. While management believes the use of the going concern assumption is appropriate, there is no assurance the above actions will be successful. The Consolidated Financial Statements for the year ended December 31, 2014, do not include any adjustments or disclosures that may be necessary should the Corporation not be able to continue as a going concern. If the going concern assumption is not appropriate for the Consolidated Financial Statements for the year ended December 31, 2014, then adjustments may be necessary to the carrying value and classification of assets and liabilities and reported results of operations and such adjustments could be material.



## 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 makes every attempt to manage its liquidity to minimize shareholder dilution when possible.

The Corporation defines capital as total equity. To fund its activities, the Corporation has followed an approach that relies almost exclusively on the issuance of common shares and, 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 an investment company that has been replaced annually by a new agreement with the same purchaser (see note 12 (a) - Common Stock Private Purchase Agreement of the Consolidated Financial Statements). The Corporation intends to access financing under this agreement when appropriate to fund its research and development activities. Since 2003 through to December 2014, Lorros-Greyse has always complied with the drawdowns made pursuant to the agreement. 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. As at the date of the MD&A, the Common Stock Private Purchase Agreement, set to expire in November 2015, has not been renewed.

On December 16, 2014, the Corporation issued secured convertible notes through a private placement for aggregate gross proceeds of \$1,070,000 which bear interest at 6% per annum, payable quarterly with a maximum term of 3 years (see note 9 of the Consolidated Financial Statements). On January 23, 2015 and on March 12, 2015, the Corporation completed two \$200,000 private placement financing for a total of \$400,000 (see note 23(a) of the Consolidated Financial Statements).

As part of its business plan, the Corporation anticipates the need to raise financing to pursue its planned business operations and research and development programs over the next year. The Corporation intends to access financing through the existing Common Stock Private Purchase Agreement and/or other sources of capital in order to fund these operations and activities over the next year.

If the Purchaser does not purchase the Corporation's common shares as provided for under the existing Common Stock Private Purchase Agreement, or if the agreement is not renewed, the Corporation will have to seek other sources of financing in order to be able to pay its obligations as they become due, which could have an impact on its ability to continue as a going concern.

The Corporation's ability to raise capital through the Agreement and other sources of financing will be impacted by the market price and trading volumes of its common shares. The results of the NX02-0017 and NX02-0018 clinical trials may adversely affect the Corporation's ability to raise capital on a timely basis, requiring the Corporation to reduce its cash requirements by eliminating or deferring spending on research, development and corporate activities. In addition, other sources of financing may not be available or may be available only at a price or on terms that are not favorable to the Corporation.

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, research 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.

Other than the financing discussed above, the Corporation does not have arranged sources of financing.

The Corporation is not subject to any capital requirements imposed by external parties other than the Nasdaq Capital Market requirements related to the Listing Rules. On December 16, 2014, the Corporation was notified, by the Nasdaq Listing Qualifications department, that the Corporation's Nasdaq Capital Market requirements were currently deficient for the preceding 30 consecutive business days.

However, the Listing Rules provide the Corporation a compliance period of 180 calendar days in which to regain compliance. In order to regain compliance, the Corporation must maintain a minimum market value of \$35 million for a minimum of ten consecutive business days and the closing bid price of the Corporation's common share must be at least \$1 for a minimum of ten consecutive business days. Failure to meet the listing requirements may lead to delisting from the Nasdaq Capital Market in which case the Corporation will consider an alternate trading platform for its common shares.

### **Financial risk management**

This section provides disclosures relating to the nature and extent of the Corporation's exposure to risks arising from financial instruments, including foreign currency risk, credit risk, interest rate risk and liquidity risk, and to how the Corporation manages those risks.

#### Foreign currency risk

The Corporation uses the US dollar as its measurement currency because a substantial portion of revenues, expenses, assets and liabilities of its Canadian and US operations are denominated in US dollars. The Corporation's equity financing facility is also in US dollars. Foreign currency risk is limited to the portion of the Corporation's business transactions denominated in currencies other than the US dollar. The Canadian operation has transactions denominated in Canadian dollars, principally relating to salaries and rent. Additional variability arises from the translation of monetary assets and liabilities denominated in currencies other than the US dollar at each statement of financial position date. Fluctuations in the currency used for the payment of the Corporation's expenses denominated in currencies other than the US dollar (primarily Canadian dollars) could cause unanticipated fluctuations in the Corporation's operating results, but would not impair or enhance its ability to pay its Canadian dollar denominated obligations. The Corporation's objective in managing its foreign currency risk is to minimize its net exposures to foreign currency cash flows by transacting with parties in US dollars to the maximum extent possible. The Corporation does not engage in the use of derivative financial instruments to manage its currency exposures.

Approximately 56% of expenses that occurred during the year ended December 31, 2014 (2013 - 59%; 2012 - 57%) were denominated in US dollars. Foreign exchange fluctuations had no meaningful impact on the Corporation's results in 2014, 2013 or 2012.

The following table provides significant items exposed to foreign exchange:

CA\$	December 31, 2014	December 31, 2013
Cash	\$5,840	\$128,117
Trade accounts receivable and other receivables	\$55,239	\$41,477
Trade accounts payable and accrued liabilities	\$(595,411)	\$(272,011)
	\$(534,332)	\$(102,417)

The following exchange rates were applied for the years ended December 31, 2014, 2013 and 2012:

	Average rate (twelve months)	Reporting date rate
US\$ - CA\$ - December 31, 2014	1.1047	1.1601
US\$ - CA\$ - December 31, 2013	1.0299	1.0636
US\$ - CA\$ - December 31, 2012	0.9996	0.9949

Based on the Corporation's foreign currency exposures noted above, varying the above foreign exchange rates to reflect a 5% strengthening of the US dollar against the Canadian dollar would have decreased the net loss for the year ended December 31, 2014 by less than \$31,000, assuming that all other variables remained constant.

An assumed 5% weakening of the US dollar against the Canadian dollar would have had an equal but opposite effect on the amount shown above, on the basis that all other variables remained constant.

#### Credit risk

Credit risk results from the possibility that a loss may occur from the failure of another party to perform according to the terms of the contract. Financial instruments that potentially subject the Corporation to concentrations of credit risk consist primarily of cash and trade accounts receivable. Cash is maintained with high-credit quality financial institutions. For trade accounts receivable, the Corporation performs periodic credit evaluations and typically does not require collateral. Allowances are maintained for potential credit losses consistent with the credit risk, historical trends, general economic conditions and other information.

The Corporation has a limited number of customers. Included in the consolidated statement of financial position are trade accounts receivable of \$12,959 (December 31, 2013 - \$181,639), all of which were aged under 45 days. Two customers (December 31, 2013 - three customers) accounted for 86.8% (December 31, 2013 - 95.6%) of the trade receivables balance at December 31, 2014, all of whom have a good payment record with the Corporation. No bad debt expense on trade accounts receivable was recorded for the year ended December 31, 2014, nor for the year ended December 31, 2013.

At December 31, 2014, the Corporation's maximum credit exposure corresponded to the carrying amount of cash, trade accounts receivable and other receivables.

#### Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. Cash bears interest at a variable rate. Trade accounts receivable, other receivables,

trade accounts payable and accrued liabilities bear no interest. The convertible notes bear interest at 6% per annum. In addition, the Corporation pays an administrative fee of 2% per annum under the terms of the convertible notes. An account payable of \$20,201 (CA\$23,435) bears interest at 12.99%. The Corporation has no other interest-bearing financial instruments.

Based on the value of variable interest-bearing cash during the year ended December 31, 2014, an assumed 0.5% increase or 0.5% decrease in interest rates during such period would have had no significant effect on the net loss.

#### Liquidity risk

Liquidity risk is the risk that the Corporation will not be able to meet its financial obligations as they fall due. The Corporation manages liquidity risk through the management of its capital structure, as outlined in Capital Disclosures above. The Corporation does not have an operating credit facility and has historically financed its activities primarily through an equity financing agreement with an investment company and the issuance of convertible notes, as described in Liquidity and Capital Resources above.

The following are the contractual maturities of financial liabilities:

<b>Trade accounts payable and accrued liabilities:</b>	<b>Carrying Amount</b>	<b>Less than 1 year</b>	<b>1 year to 5 years</b>
December 31, 2014	\$1,976,145	\$1,976,145	—
December 31, 2013	\$1,498,622	\$1,498,622	—
<b>Convertible notes <sup>(1)</sup> :</b>			
December 31, 2014	\$718,831	—	\$1,070,000
December 31, 2013	—	—	—
(1) Before financing costs			

The redeemable preferred shares for the Corporation's subsidiary Serex, Inc. in the amount of \$400,000 have no specific terms of repayment.

If purchases of the Corporation's common shares as provided for under the Common Share Purchase Agreement are not made in a timely fashion or at all, the Corporation will have to seek other sources of financing in order to be able to pay its obligations as they become due, which could have an impact on its liquidity.

The Corporation's ability to raise capital through the Common Share Purchase Agreement and other sources of financing will be impacted by the market price and trading volumes of its common shares. The results of the NX02-0017 and NX02-0018 clinical trials may adversely affect the Corporation's ability to raise capital on a timely basis, requiring the Corporation to reduce its cash requirements by eliminating or deferring spending on research, development and corporate activities. In addition, other sources of financing may not be available or may be available only at a price or on terms that are not favorable to the Corporation.

In addition to financing operations through the issuance of equity, the Corporation may also secure additional funding through the issuance of debt, licensing or partnering products in development, increasing revenue from our products, or realizing on intellectual property and other assets. There can be no assurances that the Corporation will be successful in realizing on any such potential opportunities for additional funding at a price or on terms that are favorable to the Corporation.

### **Outstanding Share Data**

As at March 31, 2015, there were 36,755,503 common shares of Nymox issued and outstanding, as well as, 5,104,500 share options are outstanding, of which 5,042,000 are currently vested. There are 548,529 warrants outstanding. In addition, the convertible notes are convertible into 2,007,504 common shares.

### **Subsequent Events**

In December 2014, the Corporation received aggregate proceeds of \$200,000 under a private placement financing that was completed in January 2015. A total of 383,058 Units were issued at an average price of \$0.52 per share. Each Unit is comprised of one common share and one-half of one common share purchase warrant (each whole warrant, a "Warrant"). Each Warrant entitles the holder to acquire one common share of the Corporation at a price per share equal to U.S. \$2.00 for a period 24 months following the subscription date.

After the top-line statistical failure of Nymox's U.S. Phase 3 studies NX02-0017 and NX02-0018 at 12 months post-treatment, Recordati has terminated development and commercialization efforts for NX-1207 in the licensed territories. Consequently, in the first quarter of 2015, the Corporation will recognize, as revenue, the amount of

\$2,508,533 which represents the remaining deferred revenue as of December 31, 2014.

In February 2015, the Corporation received aggregate proceeds of \$200,000 under a private placement financing that was completed in March 2015. A total of 500,000 Units were issued at an average price of \$0.40 per share. Each Unit is comprised of one common share and one-half of one common share purchase warrant (each whole warrant, a "Warrant"). Each Warrant entitles the holder to acquire one common share of the Corporation at a price per share equal to U.S. \$2.00 for a period 24 months following the subscription date.

#### **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 audit committee. Based on an evaluation of the Corporation's disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934 and National Instrument 52-109), the Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures were not effective as of December 31, 2014

because of the material weakness in our internal control over financial reporting that is described below in “Management’s Annual Report on Internal Control Over Financial Reporting.”

However, giving full consideration to the material weakness, the Corporation’s management has concluded that the Consolidated Financial Statements as of and for the year ended December 31, 2014 present fairly, in all material respects, the Corporation’s financial position, results of operations and cash flows for the periods disclosed in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

KPMG LLP has issued its report dated March 26, 2015, which expressed an unqualified opinion on those Consolidated Financial Statements

### **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. Internal control is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect 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, 2014, based on the framework set forth in *Internal Control-Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Corporation’s annual financial statements will not be prevented or detected on a timely basis. Based on its evaluation under this framework, the Chief Executive Officer and the Chief Financial Officer concluded that our internal control over financial reporting (as defined in Rules 13a-15(f) of the Securities Exchange Act and National Instrument 52-109) was not effective as of December 31, 2014 due to the material weakness described below.

Following the announcement made on November 2, 2014 concerning the results of the two U.S. Phase 3 clinical trials, Management took steps to reduce expenditures going forward, including operational staff reductions. As a result, the Corporation did not employ a sufficient complement of finance and accounting personnel at December 31, 2014 to ensure that there was proper segregation of incompatible duties related to certain processes, primarily impacting the expenditures/disbursements processes and information technology general controls (“ITGC”), and sufficient compensating controls did not exist in these areas. Specifically, because of the limited number of qualified personnel, review controls of expenditures and disbursements were not effective to ensure that expenditures and disbursements were properly authorized and recorded in the financial information system, and certain ITGCs that potentially impact two applications used for expenditures and disbursements were not effective to monitor activities of individuals with access to modify data.



While the control deficiency identified did not result in any misstatements, a reasonable possibility exists that a material misstatement to the annual consolidated financial statements will not be prevented or detected on a timely basis.

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.

Attestation report of independent registered public accounting firm

KPMG LLP, an independent registered public accounting firm, which audited and reported on our financial statements, has issued an adverse opinion on the effectiveness of our internal control over financial reporting as at December 31, 2014, which is included herein.

Remediation Plan for Material Weakness in Internal Control over Financial Reporting

Management believes that a lack of segregation of duties is typical of companies with limited personnel and resources. Nonetheless, in response to the material weakness identified above, the Corporation, in the immediate future, intends to develop a plan with oversight from the Audit Committee of the Board of Directors to remediate the material weakness. The Corporation does not currently intend to hire additional finance personnel or engage external experts until the size and operations warrant such additional resources.

The remediation efforts expected to be implemented include the following:

- i) Evaluate staffing levels and responsibilities to enhance appropriate segregation of duties where possible amongst our personnel.
- ii) Establishing a more comprehensive review and approval process for authorizing user access to financial information systems and monitoring user access to ensure that all information technology controls designed to restrict access to applications and data are operating in a manner that provides the Corporation with assurance that such access is properly restricted to the appropriate personnel.

Changes in Internal Controls Over Financial Reporting

Other than the material weakness described above, there have been no changes since December 31, 2013 in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Changes in accounting policies:**

**New accounting standards and interpretations:**

Adopted during the period:

On January 1, 2014, the Corporation adopted IFRIC 21, Levies. IFRIC 21 provides guidance on accounting for levies in accordance with IAS 37, Provisions, Contingent Liabilities and Contingent Assets. The interpretation defines a levy as an outflow of resources from an entity imposed by a government in accordance with legislation, other than income taxes within the scope of IAS 12, Income Taxes, and confirms that an entity recognizes a liability for a levy only when the triggering event specified in the legislation occurs. The adoption of IFRIC 21 did not have an impact on the Corporation's consolidated financial statements.

Issued but not yet adopted:

A number of new standards, interpretations and amendments to existing standards were issued by the IASB or International Financial Reporting Standards Interpretations Committee ("IFRS IC"). They are mandatory but not yet effective for the period ended December 31, 2014, and have not been applied in preparing these consolidated financial statements. Many of these are not applicable or are inconsequential to the Corporation and have been excluded from the discussion below.

The following standards and interpretations have been issued by the IASB and the IFRS IC and the Corporation is currently assessing their impact on the financial statements:

- (a) IFRS 9, Financial Instruments:

IFRS 9 - *Financial Instruments* (“IFRS 9”) ultimately replaces IAS 39 – Financial Instruments: Recognition and Measurement (“IAS 39”). The replacement of IAS 39 is a three-phase project with the objective of improving and simplifying the reporting for financial instruments.

IFRS 9 (2009) introduces new requirements for the classification and measurement of financial assets. Under IFRS 9 (2009), financial assets are classified and measured based on the business model in which they are held and the characteristics of their contractual cash flows.

IFRS 9 (2010) introduces additional changes relating to financial liabilities.

IFRS 9 (2013) includes a new general hedge accounting standard which will align hedge accounting more closely with risk management. Special transitional requirements have been set for the application of the new general hedging model. The Corporation currently does not hedge and therefore does not anticipate this phase will have an impact on the Corporation.

This standard is effective for annual periods beginning on or after January 1, 2018 with earlier adoption permitted. The Corporation has not yet assessed the impact of the adoption of this standard on its consolidated financial statements.

(b) IFRS 15, Revenue from Contracts with Customers:

In May 2014, the IASB issued IFRS 15, Revenue from Contracts with Customers, which establishes principles for reporting the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. It provides a single model in order to depict the transfer of promised goods or services to customers.

IFRS 15 supersedes the following standards: IAS 11, Construction Contracts, IAS 18, Revenue, IFRIC 13, Customer Loyalty Programmes, IFRIC 15, Agreements for the Construction of Real Estate, IFRIC 18, Transfers of Assets from Customers, and SIC-31, Revenue - Barter Transactions Involving Advertising Service.

The core principle of IFRS 15 is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services.

IFRS 15 also includes a cohesive set of disclosure requirements that would result in an entity providing comprehensive information about the nature, amount, timing and uncertainty of revenue and cash flows arising from the entity's contracts with customers.

This standard is effective for annual periods beginning on or after January 1, 2017 with earlier adoption permitted. The Corporation has not yet assessed the impact of the adoption of this standard on its consolidated financial statements.

### 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, 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.

Factors that could cause actual results or plans to differ materially from those projected in forward-looking statements made by, or on behalf of, the Corporation, many of which are beyond our control, include the Corporation's ability to:

- identify and capitalize on possible collaboration, strategic partnering or divestiture opportunities;
- obtain suitable financing to support its operations and clinical trials;
- access financing under the Common Stock Private Purchase Agreement;
- successfully defend pending and/or unforeseeable future litigation;
- 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;
- overcome recent negative results from its clinical trials;

- 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.

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 primarily focused on our drug candidate, NX-1207, for the treatment of BPH and the treatment of low-grade localized prostate cancer. Corporation's areas are the followings:

- *Therapeutic products for enlarged prostate (benign prostatic hyperplasia or BPH) and prostate cancer.* 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 BPH, and are presently in Phase 3. Top-line results of the Phase 3 NX02-0017 and NX02-0018 U.S. clinical trials of NX-1207 for BPH at 12 months post-treatment were not statistically significant compared to placebo. The Corporation is in the process of further data analysis and assessments of the two studies, and expects to continue its efforts to work on the development program. In March 2012, Nymox started a Phase 2 U.S. clinical trial to evaluate the company's NX-1207 drug for the treatment of low grade localized prostate cancer with positive results reported in 2014. 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. 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 cGMP and in sufficient quantities for commercial use, and whether or when the FDA will ultimately grant us such approval.
- *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 Alzheimer's disease.* We have conducted 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.

- *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 is 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 neither 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.
- *Anti-infectives.* Our anti-bacterial agent, NXC-4720, which is targeted 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 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.

Research and development expenses, excluding stock-based compensation and depreciation expenses, allocated to our major research and development programs are as follows:

	<b>Year ended Dec 31, 2014</b>	<b>Year ended Dec 31, 2013</b>	<b>Year ended Dec 31, 2012</b>
<b>Alzheimer's Disease: Diagnostics</b>	\$39,311	\$33,667	\$41,688
<b>Alzheimer's Disease: Therapeutics</b>	\$13,966	\$4,686	\$8,562
<b>Anti-Infectives</b>	\$7,103	\$4,692	\$9,787
<b>BPH (Enlarged Prostate) and Prostate Cancer Therapeutics</b>	\$3,783,158	\$5,650,931	\$6,511,143
<b>Tobacco Exposure Tests: NicAlert™ and TobacAlert™</b>	\$15,326	\$4,113	\$14,859
<b>Total</b>	\$3,858,864	\$5,698,089	\$6,586,039

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: 2011: \$6,602,148; 2010: \$4,551,719; 2009: \$3,043,219; 2008: \$2,388,911; 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, excluding stock-based compensation and depreciation expenses, are \$60,180,611.

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. 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 trends that would be material to our operations other than those disclosed in Items 4 and 5.

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## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

### Directors and Senior Management

Paul Averback, M.D., D.A.B.P., 64, 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, 51, 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, 89, 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., 58, 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., 64, 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. He resigned from the Board of Directors on December 15, 2014.

Jack Gemmell, 63, 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. He ceased being an Executive Officer of the Corporation on November 20, 2014. He resigned from the Board of Directors on November 25, 2014.

Andre Monette, 57, is our new Secretary-Treasurer and Chief Financial Officer since January 24, 2014. He received his B.B.A. from the "Ecole des Hautes Etudes Commerciales" of Montreal in 1979. He is a Chartered Professional Accountant and a Chartered Financial Analyst. Prior to January 2014, he provided consulting services in financial reporting. He has served for 17 years as an executive in the securities industry.

Brian Doyle, B.Sc., M.B.A., 60, 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. He ceased being an Executive Officer of the Corporation on November 21, 2014.

Roy M. Wolvin, 60, has been Secretary-Treasurer and Chief Financial Officer from September 1995 to January 22, 2014. 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. He ceased being an Executive Officer of the Corporation on January 22, 2014.

## **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 ended on December 31, 2014 to the Named Executive Officers of the Corporation and all incentive plan awards outstanding at December 31, 2014 for the Named Executive Officers. The Named Executive Officers are the Corporation's Chief Executive Officer, Chief Financial Officer, and two most highly compensated executive officers.

During the financial year ended December 31, 2014, the Chief Executive Officer received an option grant totaling 500,000 options and the Chief Financial Officer received an option grant totaling 100,000 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, 2014 were Dr. Roger Guy, Paul McDonald, Dr. David Morse and Randall Lanham, Esq.. Dr. Roger Guy resigned on December 15, 2014.

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 ended on December 31, 2014 to the directors of the Corporation and all incentive plan awards outstanding at December 31, 2014 for the directors. One current director, Dr. Paul Averbach, the President and CEO of the Corporation, is member of the senior management of the Corporation and does not receive any compensation for acting as a director. His compensation as Named Executive Officer 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	Non-equity incentive plan compensation		Pension value	All Other Compensation	Total Compensation (\$)
				Option-based awards (#)	Annual incentive plans			
Dr. Paul Averbach CEO and President	2014	\$290,000* <sup>6</sup>		500,000				\$290,000
André Monette CFO	2014	\$128,071* <sup>7</sup>		100,000				\$128,071
Roy Wolvin CFO <sup>1</sup>	2014	\$10,564*					\$185,068 <sup>5</sup>	\$195,632
Brian Doyle Global Sales Manager <sup>2</sup>	2014	\$128,333*					\$65,696 <sup>4</sup>	\$194,029
Jack Gemmell General Counsel, CIO <sup>3</sup>	2014	\$162,122*						\$162,122

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

<sup>1</sup> Mr. Wolvin ceased being an Executive Officer on January 22, 2014.

<sup>2</sup> Brian Doyle ceased being an Executive Officer on November 21, 2014.

<sup>3</sup> Jack Gemmell ceased being an Executive Officer on November 20, 2014.

<sup>4</sup> Includes commissions and severance payment paid in Canadian dollars, but expressed above in US\$.

<sup>5</sup> Amounts paid under option settlement agreement in Canadian dollars, but expressed above in US\$.

<sup>6</sup> \$48,333 expected to be paid in 2015

<sup>7</sup> \$10,775 paid in 2015

**Outstanding Incentive Plan Awards as of December 31, 2014: Named Executive Officers**

## Option-based Awards

Name	Number of securities underlying unexercised options			Option exercise price	Option expiration date (mm/dd/yy)	Value of unexercised in-the-money options
	Total	Unvested	Vested			
Dr. Paul Averback	3,000,000		3,000,000	\$3.00	08/24/16	\$0
	500,000		500,000	\$7.08	01/24/21	\$0
	500,000		500,000	\$6.51	10/15/22	\$0
	500,000		500,000	\$5.88	01/09/24	\$0
André Monette	100,000		62,500	\$6.47	01/23/24	\$0
	210,000		210,000	\$3.00	08/24/16	\$0
Jack Gemmell <sup>2,3</sup>	50,000		50,000	\$3.30	01/23/19	\$0
	25,000		25,000	\$3.40	05/03/20	\$0
	170,000		170,000	\$7.08	01/24/21	\$0
	30,000		30,000	\$3.00	08/24/16	\$0
Brian Doyle <sup>1,3</sup>	100,000		100,000	\$7.08	01/24/21	\$0
	50,000		50,000	\$4.76	04/29/23	\$0

<sup>1</sup>Brian Doyle ceased being an Executive Officer on November 21, 2014.

<sup>2</sup>Jack Gemmell ceased being an Executive Officer on November 20 2014.

<sup>3</sup>The options may be exercised until the expiration of the option or the date that is 90 days following the termination date, whichever occurs first.

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.

**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	2014	\$29,000		10,000				\$29,000
Randall Lanham, Esq.	2014	\$15,500		10,000				\$15,500
Roger Guy, MD <sup>1</sup>	2014	\$15,500		10,000				\$15,500
David Morse, Ph.D.	2014	\$13,500		10,000				\$13,500

<sup>1</sup>Dr. Roger Guy resigned on December 15, 2014.

**Outstanding Incentive Plan Awards as of December 31, 2014: Directors**

Name	Number of securities underlying unexercised options	Option-based Awards		Value of unexercised in-the-money options
		Option exercise price	Option expiration date (mm/dd/yy)	
Paul McDonald	10,000	\$5.95	08/23/17	\$0
	10,000	\$3.61	07/16/18	\$0
	10,000	\$4.83	07/09/19	\$0
	10,000	\$9.10	07/16/21	\$0
	10,000	\$6.88	07/16/22	\$0
	10,000	\$5.83	07/16/23	\$0
	10,000	\$5.15	08/14/24	\$0
	10,000	\$2.74	07/17/16	\$0
	10,000	\$5.95	08/23/17	\$0
	10,000	\$3.61	07/16/18	\$0
Randall Lanham, Esq.	10,000	\$4.83	07/09/19	\$0
	10,000	\$2.90	07/16/20	\$0
	10,000	\$9.10	07/16/21	\$0
	10,000	\$6.88	07/16/22	\$0
	10,000	\$5.83	07/16/23	\$0
	10,000	\$5.15	08/14/24	\$0
	10,000	\$2.74	07/17/16	\$0
	10,000	\$5.95	08/23/17	\$0
	10,000	\$3.61	07/16/18	\$0
	10,000	\$4.83	07/09/19	\$0
Roger Guy, MD <sup>1</sup>	10,000	\$2.90	07/16/20	\$0
	10,000	\$9.10	07/16/21	\$0
	10,000	\$6.88	07/16/22	\$0
	10,000	\$5.83	07/16/23	\$0
	10,000	\$5.15	08/14/24	\$0
	10,000	\$2.74	07/17/16	\$0
	10,000	\$5.95	08/23/17	\$0
	10,000	\$3.61	07/16/18	\$0
	10,000	\$4.83	07/09/19	\$0
	10,000	\$2.90	07/16/20	\$0
David Morse, Ph.D.	10,000	\$9.10	07/16/21	\$0
	10,000	\$6.88	07/16/22	\$0
	10,000	\$5.83	07/16/23	\$0
	10,000	\$5.15	08/14/24	\$0



<sup>1</sup>Dr. Roger Guy resigned on December 15, 2014. The options may be exercised until the expiration of the option or the date that is 90 days following the termination date, whichever occurs first.

During the period from 2000 to 2014, the salaries of Named Executive Officers increased from \$465,805US (2000) to \$746,828US (2014), an increase of 3.4% per annum over that fifteen year period, or 58.3% in total. During the same period, the Corporation's stock price has decreased approximately 79%.

### Share Ownership

As of March 31, 2015, the number of common shares owned or controlled by directors and senior officers of the Corporation were as follows:

<b>Name</b>	<b>Common Shares Owned and Controlled</b>	<b>Percentage of Common Shares Owned and Controlled</b>
Paul Averbach, M.D.	10,931,448	29.7%
Paul Averbach, M.D., Trustee	607,031 <sup>1</sup>	1.7%
Paul McDonald	0	*
David Morse, Ph.D.	396	