

NYMOX PHARMACEUTICAL CORP
Form 20-F
March 31, 2016

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, 2015
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)

Bahamas

(Jurisdiction of incorporation or organization)

Bay & Deveaux Streets
Nassau, The Bahamas
(Address of principal executive offices)

Contact person: Erik Danielsen
Tel. 800-936-9669, e-mail: edanielsen@nymox.com, fax: 514-332-2227
(name, telephone, e-mail and/or facsimile number and address of company contact person)

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

Title of each class

Name of each exchange on which registered

Common Stock

The NASDAQ Stock Market LLC (NASDAQ Capital Market)

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

None

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

None

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

42,988,419 shares as of December 31, 2015

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

Yes [] No [X]

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

Yes [] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes [X] No []

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive 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).

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Yes No

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

Large accelerated filer

Accelerated filer

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

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

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

Not Applicable

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable

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

The following table sets forth selected consolidated financial data for Nymox for the periods indicated, derived from financial statements prepared in accordance with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board (“IASB”) for 2015, 2014, 2013, 2012 and 2011. The financial statements have been audited by KPMG LLP, Montreal, Canada as of and for the years ended December 31, 2011, 2012, 2013, 2014 and audited by THAYERONEAL, Sugar Land, Texas, United States as of and for the year ended December 31, 2015 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)

Fiscal Year Ended December 31,	2015	2014	2013	2012	2011
Current Assets	\$ 691,436	\$ 1,395,770	\$ 936,468	\$ 1,739,061	\$ 6,335,710
Property & Equipment	\$ 3,399	\$ 9,400	\$ 12,521	\$ 15,118	\$ 22,160
Total Assets	\$ 712,231	\$ 1,422,566	\$ 966,385	\$ 1,754,179	\$ 6,375,266
Total Current Liabilities	\$ 2,250,568	\$ 4,484,678	\$ 4,116,222	\$ 3,672,759	\$ 3,429,092
Convertible notes	\$ 814,672	\$ 718,831	\$ 0	\$ 0	\$ 0
Share Capital	\$ 84,954,211	\$ 81,227,058	\$ 76,046,549	\$ 69,705,389	\$ 66,062,961
Total Equity	\$ (2,753,009)	\$ (4,180,943)	\$ (6,058,370)	\$ (7,444,713)	\$ (5,197,559)
Sales	\$ 252,732	\$ 331,909	\$ 741,410	\$ 454,987	\$ 496,215
Total Revenues (including sales)	\$ 2,761,265	\$ 2,949,509	\$ 3,359,010	\$ 3,072,587	\$ 3,113,815
Research & Development Expenditures (1)	\$ 8,649,510	\$ 4,496,730	\$ 5,719,872	\$ 8,282,762	\$ 8,974,171
Loss from operating activities	\$ 17,660,304	\$ 4,724,705	\$ 4,884,957	\$ 7,594,651	\$ 9,625,327
Net Loss	\$ 17,893,863	\$ 4,594,093	\$ 4,908,603	\$ 7,627,589	\$ 9,652,389
Loss per Share (basic & diluted)	\$ 0.48	\$ 0.13	\$ 0.14	\$ 0.23	\$ 0.30
Weighted Avg. No. of Common Shares	37,402,598	35,253,879	34,147,666	33,176,185	32,711,431

(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 Fexapotide Triflutate (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 Fexapotide Triflutate (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 already collected clinical trial results on a stand-alone basis and/or in combination with any future clinical trial results 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. 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 expects to continue its efforts to work on the development program.

Setbacks in our clinical trials or in our efforts to seek regulatory approval for NX-1207 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 Fexapotide Triflutate (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. 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.

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. On July 27, 2015 Nymox announced that the Company's U.S. long-term extension prospective double-blind Phase 3 BPH studies NX02-0017 and NX02-0018 of fexapotide trifluate (NX-1207) for BPH have successfully met the pre-specified primary endpoint of long-term symptomatic statistically significant benefit superior to placebo. The Company announced that Fexapotide showed an excellent safety profile with no evidence of drug-related short-term or long-term toxicity nor any significant related molecular side effects in the 2 studies. As a result of the clinical benefits observed in the long-term extension trial, the Company intends to meet with regulatory authorities in various jurisdictions around the world and in due course to proceed to file for approval where possible.

A Setback in Any of Our Clinical Trials or Efforts to Obtain Regulatory Clearance for Our Products 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”). Recordati did not complete any clinical trials for the NX-1207 in 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, NicAlert™ and TobacAlert™. We have never made a profit. We incurred a net loss of approximately \$4.6 million in 2014 and \$17.9 million in 2015. As of December 31, 2015, Nymox's accumulated deficit was approximately \$118.0 million and we have negative cash flows from operations. As of December 31, 2015, we had negative working capital of \$1,559,132.

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 \$374,463 and a working capital deficiency of \$1,559,132 as of December 31, 2015. Cash flows used in operations during 2015 were \$3,752,842.

Management believes that current cash balances as at December 31, 2015 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 additional capital through private placements of its Common Stock and or other financing mechanisms over the next year.

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.

We Have Identified Material Weaknesses in Our Internal Control Over Financial Reporting. Although We Expect to Make Every Effort to Address these Material Weaknesses, We May Find that We are Unable to Remediate these Deficiencies 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 years ended December 31, 2015 and 2014, we and our independent registered public accounting firm identified material weaknesses in the design and operation of our internal control over financial reporting. These material weaknesses relate to (1) 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 and (ii) the lack of a sufficient complement of accounting personnel in 2015 to ensure that complex, non-routine accounting matters were properly addressed, which resulted in the restatement of the interim financial statements for the second quarter of 2015 to correct a material error in stock-based compensation expense. 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 weaknesses in the immediate future with oversight from our Audit Committee of the Board of Directors. If we fail to effectively remediate the material weaknesses 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 weaknesses, 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 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. On July 27, 2015 Nymox announced that the Company's U.S. long-term extension prospective double-blind Phase 3 BPH studies NX02-0017 and NX02-0018 of fexapotide trifluate (NX-1207) for BPH have successfully met the pre-specified primary endpoint of long-term symptomatic statistically significant benefit superior to placebo. The Company announced that Fexapotide showed an excellent safety profile with no evidence of drug-related short-term or long-term toxicity nor any significant related molecular side effects in the 2 studies. As a result of the clinical benefits observed in the long-term extension trial, the Company intends to meet with regulatory authorities in various jurisdictions around the world and in due course to proceed to file for approval where possible. Nevertheless, 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

Our treatments under development for enlarged prostate BPH face significant competition from existing products. There are at least 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. 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 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.

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.

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 2016 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.

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 as well as direct private placements of its Common Stock to qualified investors 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 43,810,869 common shares of Nymox issued and outstanding as of March 30, 2016. 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, 6,519,500 share options are outstanding, of which 6,509,500 are currently vested. Expiry dates for Nymox options range from 1.5 years to 10.7 years (see note 12 to our consolidated financial statements). These options have been granted to employees, officers, directors and consultants of the Corporation.

If We Fail to Maintain 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. The Company was notified on May 18, 2015 that it had successfully met the requirements for continued listing on the NASDAQ Stock market. However, 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, our ability to raise additional capital could be impeded and thus 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 Bahamian, U.S. and Canadian offices. Most of our expenses are derived in U.S. dollars. As a result, we are exposed to the risk of losses due to fluctuations primarily 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. In 2015, the Corporation changed domicile to The Bahamas. 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

Bay & Deveaux Sts., Nassau, The Bahamas
Phone: (800) 936-9669 Fax: (514) 332-2227

Nymox's registered agent in the United States is:

CT Corporation System

111 Eighth Avenue, 13th Floor
New York, NY, 10011

Nymox's two subsidiaries are located at:

Nymox Corporation

777 Terrace Avenue
Hasbrouck Heights, NJ, USA 07604

Serex, Inc.

777 Terrace Avenue
Hasbrouck Heights, NJ, USA 07604

Nymox Pharmaceutical Corporation is a biopharmaceutical 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 would 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. Over 94% of the shareholders agreed to move the Corporation Domicile from Canada 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. 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

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.

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 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 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 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.

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. 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. 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. At the time, the Corporation announced that it was in the process of performing further data analysis and assessments of the two studies. The Company further announced that it expects to continue its efforts to work on the development program.

On July 27, 2015 Nymox announced initial clinical results from its ongoing analysis and assessment of its Phase 3 development program in BPH. The Company announced that the U.S. long-term extension prospective double-blind Phase 3 BPH studies NX02-0017 and NX02-0018 of fexapotide trifluate (NX-1207) for BPH had successfully met the pre-specified primary endpoint of long-term symptomatic statistically significant benefit superior to placebo. Fexapotide showed an excellent safety profile with no evidence of drug-related short-term or long-term toxicity nor any significant related molecular side effects in the 2 studies. As a result of the clinical benefits observed in the long-term extension trial, the Company announced that it intends to meet with regulatory authorities in various jurisdictions around the world and in due course explore the possibility to proceed to file for approval where possible.

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®), alfuzozin (Uroxatral®), silodosin (Rapaflo®), and tadalafil (Cialis®)) a combination of two drugs (dutasteride and tamsulosin) (Jalyn™), and four generics (finasteride, terazozin, 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 enrolling a total of 147 patients at 28 clinical centers across the U.S. to evaluate the Corporation's NX-1207 drug for the treatment of low grade localized prostate cancer. The trial was initiated 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. Initial positive results from this trial were 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.

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.

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.

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. 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 of approximately 3,070 square feet of leased space. A new lease was signed in August 2015 and expires in August 2016. 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 in Quebec and New Jersey are adequate for its current needs and that additional space, if required, would be available on commercially reasonable terms.

Governmental Regulation

All our products – approved and under development - are subject to extensive government regulation in the United States and in international markets. Any changes in any national or regional legislation could have an impact on our future ability to offer or

market any pharmaceutical and/or diagnostic product and thus have a negative effect on our ability to obtain reimbursement from any health insurance programs and providers.

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 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 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 continued 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.

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 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. Our patents have varying expiration dates going out 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 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.

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.

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.

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.

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 2015, 2014 and 2013 include recognition of revenue related to the upfront payment of U.S. \$13.1 million received from Recordati in December 2010.

Revenues:	Canada	United States	Europe & Other
2015	\$ 8,125	\$ 221,926	\$ 2,531,214
2014	\$ 6,845	\$ 290,061	\$ 2,652,603
2013	\$ 5,104	\$ 365,277	\$ 2,988,629

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, Fexapotide Triflutate (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 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.

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