NYMOX PHARMACEUTICAL CORP
Form 20-F
March 30, 2018

United States

Securities and Exchange Commission

Washington, D.C. 20549

Form 20–F

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

or

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

For the fiscal year ended **December 31, 2017**

or

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

or

o 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.

56,378,306 shares as of December 31, 2017

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

Yes o 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 o 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 o

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

Yes x No o

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 o Accelerated filer x Non-accelerated filer o

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

U.S. GAAP o	International Financial Reporting Standards x as issued by the International Accounting Standards Board.	Other o

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 o Item 18 o

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 o No x

In this annual report, the terms “Nymox”, “The Corporation”, “The Company”, “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 simi 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;

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") the financial statements have been audited by Thayer O'Neal Company, LLC of Houston, Texas in the United States as of and for the year ended December 31, 2017, 2016 and 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,	**2017**	**2016**	**2015**	**2014**	**2013**
Total Assets	$ 979,137	$ 2,057,253	$ 712,231	$ 1,422,566	$ 966,385
Share Capital	$ 108,196,243	$ 92,125,364	$ 84,954,211	$ 81,227,058	$ 76,046,549

Total Equity	$ (1,251,350)	$ (641,420)	$ (2,753,009)	$ (4,180,943)	$ (6,058,370)
Sales	$ 223,719	$ 283,611	$ 252,732	$ 331,909	$ 741,410
Total Revenues (including sales)	$ 223,719	$ 283,611	$ 2,761,265	$ 2,949,509	$ 3,359,010
Loss from operating activities	$ 13,235,302	$ 12,869,398	$ 17,660,304	$ 4,724,705	$ 4,884,957
Net Loss	$ 13,428,878	$ 13,109,608	$ 17,893,863	$ 4,594,093	$ 4,908,603
Loss per Share (basic & diluted)	$ 0.26	$ 0.28	$ 0.48	$ 0.13	$ 0.14
Weighted Avg. No. of Common Shares	52,647,913	46,155,018	37,402,598	35,253,879	34,147,666

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.

Part I

ITEM 3. KEY INFORMATION

Selected Financial Data

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.

Part I

ITEM 3. KEY INFORMATION

Selected Financial Data

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 triflutate (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 favorable 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.

Part I

ITEM 3. KEY INFORMATION

Selected Financial Data

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 $13.1 million in 2016 and $13.4 million in 2017. As of December 31, 2017, Nymox's accumulated deficit was approximately $144.5 million and we have negative cash flows from operations. As of December 31, 2017, we had negative working capital of $1,269,342.

We cannot say when, if ever, Nymox will become profitable or operate with positive cash flows from operations. 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.

Part I

ITEM 3. KEY INFORMATION

Selected Financial Data

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, 2017 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 $851,251 and a negative working capital of $1,269,342 as of December 31, 2017. Cash flows used in operations during 2017 were $6,205,114.

Management believes that current cash balances as at December 31, 2017 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 Face Challenges in Developing, Manufacturing and Improving Our Products

We are still developing many of our products and have not yet brought them to market. We cannot make any assurances that we will be able to develop our products and to market them successfully. Developing and improving our diagnostic products is 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.

Part I

ITEM 3. KEY INFORMATION

Selected Financial Data

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;

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 triflutate (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 has to met with regulatory authorities in various jurisdictions around the world and has filed for regulatory approval in Europe and intends to file with the FDA later this year. Nevertheless, we cannot predict with any certainty the outcome of this program, what further steps may be required or whether regulatory authorities will ultimately grant us such approval.

Part I

ITEM 3. KEY INFORMATION

Selected Financial Data

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®), alfusozin, (Uroxatral®), silodosin (Rapaflo®), and tadalofil (Cialis®)), a combination of two drugs (dutasteride and tamsulosin) (Jalyn™), and four generics (finasteride, terazozin, doxazozin, and prazosin). There are a number of thermal treatments on the market designed to shrink the enlarged prostate by heating its tissue with a device inserted through the urethra (the passage leading from the bladder through the penis through which men urinate). The devices on the market use microwave energy (Prostatron®, Targis Therapy® or TherMatrx®), low level radiowaves (TUNA System®), lasers (Indigo LaserOptic Treatment System® or Laserscope GreenLight PVP™), direct heat, energy or hot water to heat or burn away prostate tissue. A variety of surgical procedures exist to surgically reduce or remove the prostate or to widen the urethra. These include procedures to cut away prostate tissue such as TURP (transurethral resection of the prostate) and using a resectoscope with an electrical loop inserted through the penis to cut the prostate tissue. A small device used to widen the constricted urethra called a prostatic stent can also be inserted. 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.

Part I

ITEM 3. KEY INFORMATION

Selected Financial Data

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.

Part I

ITEM 3. KEY INFORMATION

Selected Financial Data

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, has converted into 2,007,504 common shares of the Corporation by the year end of December 31, 2017 at a conversion price of $0.533 per share that has diluted 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 57,207,538 common shares of Nymox issued and outstanding as of March 26, 2018. In addition, 5,710,000 share options are outstanding, of which 5,710,000 are currently vested. Expiry dates for Nymox options range from 7.4 years to 9.0 years (see note 11 to our consolidated financial statements). These options have been granted to employees, officers, directors and consultants of the Corporation.

Part I

ITEM 3. KEY INFORMATION

Selected Financial Data

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. 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.

12

Part I

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.

We have funded our operations and projects primarily by selling shares of Nymox's common stock. On December 1, 1996, 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. In total through December 31, 2017, Nymox has raised over $108 million through the issuance of common stock or securities exercisable for shares of common stock since its incorporation in May 1995.

Organizational Structure

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

Business Overview

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.

Part I

ITEM 4. INFORMATION ON THE CORPORATION

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.

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.

Part I

ITEM 4. INFORMATION ON THE CORPORATION

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.

Part I

ITEM 4. INFORMATION ON THE CORPORATION

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 is 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 triflutate (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®), alfusozin (Uroxatral®), silodosin (Rapaflo®), and tadalafil (Cialis®)) a combination of two drugs (dutasteride and tamsulosin) (Jalyn™), and four generics (finasteride, terazozin, doxazozin, and prazosin). There are a number of thermal treatments on the market designed to shrink the enlarged prostate by heating its tissue with a device inserted through the urethra (the passage leading from the bladder through the penis through which men urinate). The devices on the market use microwave energy (Prostatron®, Targis Therapy® or TherMatrx®), low level radiowaves (TUNA System®), lasers (Indigo LaserOptic Treatment System® or Laserscope GreenLight PVP™), direct heat 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.

Part I

ITEM 4. INFORMATION ON THE CORPORATION

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.

Historical Expenditures for Research and Development Activities

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:2014: 3,858,864; 2013: $5,698,089; 2012: $6,586,039; 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 $71.153,973.

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.

Part I

ITEM 4. INFORMATION ON THE CORPORATION

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.

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.

Part I

ITEM 4. INFORMATION ON THE CORPORATION

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.

Part I

ITEM 4. INFORMATION ON THE CORPORATION

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. 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.

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 cover much of our current product development and technologies.

Nymox's subsidiary, Serex, has patents issued or allowed in the United States and a corresponding patents worldwide. These patents and patent applications cover such areas as Serex's proprietary diagnostic technologies and methodologies

The Corporation has issued U.S. patents and other countries 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 is eligible for a patent term extension of up to five years or more depending on the jurisdiction. The Corporation does not license any material patents related to NX-1207 from any third parties.

Part I

ITEM 4. INFORMATION ON THE CORPORATION

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 agreemebottom:0pt; font-family:Times New Roman; font-size:10pt">we have deposited with the applicable trustee all required payments of the principal, any premium or make-whole amount, interest and, to the extent permitted by law, interest on overdue installment of interest, plus applicable fees, expenses, disbursements and advances of the applicable trustee; and

all events of default, other than the non-payment of accelerated principal, or a specified portion thereof, and any premium or make-whole amount, have been cured or waived.

Table of Contents

The indentures require each trustee to give notice to the holders of debt securities within the later of 90 days after an event of default and 30 days after the event of default is actually known to a responsible officer of such trustee, unless such default has been cured or waived. However, the trustee may withhold notice if specified persons of such trustee consider such withholding to be in the interest of the holders of debt securities.

The indentures provide that holders of debt securities of any series may not institute any proceedings, judicial or otherwise, with respect to such indenture or for any remedy under the indenture, unless the trustee fails to act for a period of 90 days after the trustee has received a written request to institute proceedings in respect of an event of default from the holders of 25% or more in principal amount of the outstanding debt securities of such series, as well as an offer of indemnity reasonably satisfactory to the trustee. However, this provision will not prevent any holder of debt securities from instituting suit for the enforcement of payment of the principal of, and any premium or make-whole amount, and interest on, such debt securities at the respective due dates thereof.

The indentures provide that, subject to provisions in each indenture relating to its duties in the case of a default, a trustee has no obligation to exercise any of its rights or powers at the request or direction of any holders of any series of debt securities then outstanding under the indenture, unless the holders have offered to the trustee reasonable security or indemnity. The holders of at least a majority in principal amount of the outstanding debt securities of any series or of all debt securities then outstanding under an indenture shall have the right to direct the time, method and place of conducting any proceeding for any remedy available to the applicable trustee, or of exercising any trust or power conferred upon such trustee. However, a trustee may refuse to follow any direction which:

is in conflict with any law or the applicable indenture;

may involve the trustee in personal liability; or

may be unduly prejudicial to the holders of debt securities of the series not joining the proceeding.

Within 120 days after the close of each fiscal year, we will be required to deliver to each trustee a certificate, signed by one of our several specified officers, stating whether or not that officer has knowledge of any default under the applicable indenture. If the officer has knowledge of any default, the notice must specify the nature and status of the default.

Modification of the Indentures

The indentures provide that modifications and amendments may be made only with the consent of the affected holders of a majority in principal amount of all outstanding debt securities issued under that indenture:

We and our respective trustee may make modifications and amendments of an indenture without the consent of any holder of debt securities for any of the following purposes:

to evidence the succession of another person to us as obligor under such indenture;

to provide for uncertificated debt securities in addition to or in place of certificated debt securities;

to add to our covenants for the benefit of the holders of all or any series of debt securities or to surrender any right or power conferred upon us in such indenture;

to add events of default for the benefit of the holders of all or any series of debt securities;

to add to, delete from, or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication, and delivery of debt securities;

to make any change that does not adversely affect the rights of any securityholder in any material respect;

to establish the form or terms of debt securities of any series;

Table of Contents

to provide for the acceptance of appointment by a successor trustee or facilitate the administration of the trusts under an indenture by more than one trustee; or

to cure any ambiguity, defect or inconsistency in an indenture, provided that such action shall not adversely affect the interests of holders of debt securities of any series issued under such indenture.

Voting

The indentures provide that in determining whether the holders of the requisite principal amount of outstanding debt securities of a series have given any request, demand, authorization, direction, notice, consent or waiver under the indentures or whether a quorum is present at a meeting of holders of debt securities, the principal amount of an original issue discount security that shall be deemed to be outstanding shall be the amount of the principal thereof that would be due and payable as of the date of such determination upon declaration of acceleration of the maturity thereof.

Subordination

Unless otherwise provided in the applicable prospectus supplement, subordinated debt securities will be subject to the following subordination provisions.

Upon any distribution to our creditors in a liquidation, dissolution or reorganization, the payment of the principal of and interest on any subordinated debt securities will be subordinated to the extent provided in the applicable indenture in right of payment to the prior payment in full of all senior debt. However, our obligation to make payments of the principal of and interest on such subordinated debt securities otherwise will not be affected. No payment of principal or interest will be permitted to be made on subordinated debt securities at any time if a default on senior debt exists that permits the holders of such senior debt to accelerate its maturity and the default is the subject of judicial proceedings or we receive notice of the default. After all senior debt is paid in full and until the subordinated debt securities are paid in full, holders of subordinated debt securities will be subrogated to the rights of holders of senior debt to the extent that distributions otherwise payable to holders of subordinated debt securities have been applied to the payment of senior debt. The subordinated indenture will not restrict the amount of senior debt or other indebtedness of ours. As a result of these subordination provisions, in the event of a distribution of assets upon insolvency, holders of subordinated debt securities may recover less, ratably, than our general creditors.

No restrictions will be included in any indenture relating to subordinated debt securities upon the creation of additional senior debt.

If this prospectus is being delivered in connection with the offering of a series of subordinated debt securities, the accompanying prospectus supplement or the information incorporated in this prospectus by reference will set forth the approximate amount of senior debt outstanding as of the end of our most recent fiscal quarter.

Discharge, Defeasance and Covenant Defeasance

Unless otherwise provided in the applicable prospectus supplement, the indentures allow us to discharge our obligations to holders of any series of debt securities issued under any indenture when:

either (i) all securities of such series have already been delivered to the applicable trustee for cancellation; or (ii) all securities of such series have not already been delivered to the applicable trustee for cancellation but (a) have become due and payable, (b) will become due and payable within one year, or (c) if redeemable at our option, are to be redeemed within one year, and we have irrevocably deposited with the applicable trustee, in trust, funds in such currency or currencies, currency unit or units or composite currency or currencies in which such debt securities are payable, an amount sufficient to pay the entire indebtedness on such debt securities

Table of Contents

in respect of principal and any premium or make-whole amount, and interest to the date of such deposit if such debt securities have become due and payable or, if they have not, to the stated maturity or redemption date;

we have paid or caused to be paid all other sums payable; and

an officers certificate and an opinion of counsel stating the conditions to discharging the debt securities have been satisfied has been delivered to the trustee.

Unless otherwise provided in the applicable prospectus supplement, the indentures provide that, upon our irrevocable deposit with the applicable trustee, in trust, of an amount, in such currency or currencies, currency unit or units or composite currency or currencies in which such debt securities are payable at stated maturity, or government obligations, or both, applicable to such debt securities, which through the scheduled payment of principal and interest in accordance with their terms will provide money in an amount sufficient to pay the principal of, and any premium or make-whole amount, and interest on, such debt securities, and any mandatory sinking fund or analogous payments thereon, on the scheduled due dates therefor, the issuing company shall be released from its obligations with respect to such debt securities under the applicable indenture or, if provided in the applicable prospectus supplement, its obligations with respect to any other covenant, and any omission to comply with such obligations shall not constitute an event of default with respect to such debt securities.

Notwithstanding the above, we may not elect to defease and be discharged from the obligation to pay any additional amounts upon the occurrence of particular events of tax, assessment or governmental charge with respect to payments on such debt securities and the obligations to register the transfer or exchange of such debt securities, to replace temporary or mutilated, destroyed, lost or stolen debt securities, to maintain an office or agency in respect of such debt securities, or to hold monies for payment in trust.

The applicable prospectus supplement may further describe the provisions, if any, permitting such defeasance or covenant defeasance, including any modifications to the provisions described above, with respect to the debt securities of or within a particular series.

Conversion Rights

The terms and conditions, if any, upon which the debt securities are convertible into common stock or other securities of ours will be set forth in the applicable prospectus supplement. The terms will include whether the debt securities are convertible into shares of common stock or other securities of ours, the conversion price, or manner of calculation thereof, the conversion period, provisions as to whether conversion will be at the issuing company s option or the option of the holders, the events requiring an adjustment of the conversion price and provisions affecting conversion in the event of the redemption of the debt securities and any restrictions on conversion.

No Recourse

No recourse shall be had under any obligation, covenant or agreement of ours in the senior indenture or any supplemental indenture, or in any of the debt securities or because of the creation of any indebtedness represented thereby, against any of our incorporators, stockholders, officers or directors, past, present or future, or of any predecessor or successor entity thereof under any law, statute or constitutional provision or by the enforcement of any assessment or by any legal or equitable proceeding or otherwise. Each holder, by accepting the debt securities, waives and releases all such liability.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

Table of Contents

DESCRIPTION OF WARRANTS

We may issue warrants to purchase debt securities, common stock, or preferred stock. We may offer warrants separately or together with one or more additional warrants, debt securities, common stock, or preferred stock, or any combination of those securities in the form of units, as described in the applicable prospectus supplement. If we issue warrants as part of a unit, the accompanying prospectus supplement will specify whether those warrants may be separated from the other securities in the unit prior to the expiration date of the warrants. The applicable prospectus supplement will also describe the following terms of any warrants:

- the specific designation and aggregate number of, and the offering price at which we will issue, the warrants;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;
- whether the warrants are to be sold separately or with other securities as parts of units;
- whether the warrants will be issued in definitive or global form or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;
- any applicable material U.S. federal income tax consequences;
- the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;
- the proposed listing, if any, of the warrants or any securities purchasable upon exercise of the warrants on any securities exchange;
- the designation and terms of any equity securities purchasable upon exercise of the warrants;
- the designation, aggregate principal amount, currency and terms of any debt securities that may be purchased upon exercise of the warrants;

if applicable, the designation and terms of the debt securities, common stock, or preferred stock with which the warrants are issued and, the number of warrants issued with each security;

if applicable, the date from and after which any warrants issued as part of a unit and the related debt securities, common stock, or preferred stock will be separately transferable;

the number of shares of common stock or preferred stock purchasable upon exercise of a warrant and the price at which those shares may be purchased;

if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;

information with respect to book-entry procedures, if any;

the antidilution provisions of, and other provisions for changes to or adjustment in the exercise price of, the warrants, if any;

any redemption or call provisions; and

any additional terms of the warrants, including terms, procedures and limitations relating to the exchange or exercise of the warrants.

Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part.

Table of Contents

DESCRIPTION OF UNITS

The following description, together with the additional information that we include in any applicable prospectus supplements and in any related free writing prospectuses, summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the terms described below.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of unit agreement that describes the terms of the series of units we are offering, and any supplemental agreements, before the issuance of the related series of units. The following summaries of material terms and provisions of the units are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the particular series of units that we may offer under this prospectus, as well as any related free writing prospectuses and the complete unit agreement and any supplemental agreements that contain the terms of the units.

General

We may issue units comprised of shares of common stock, preferred stock, debt securities, warrants and units in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We will describe in the applicable prospectus supplement the terms of the series of units, including:

- designation and terms of the units, including whether and under what circumstances the securities comprising the units may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described below; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The provisions described in this section, as well as those described under Description of Capital Stock, Description of Debt Securities and Description of Warrants, will apply to each unit and to the common stock, preferred stock, debt securities and warrants included in each unit, respectively.

Issuance in Series

We may issue units in such amounts and in such numerous distinct series as we determine.

Enforceability of Rights by Holders of Units

Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

Title

We, the unit agent and any of its agents, may treat the registered holder of any unit certificate as an absolute owner of the units evidenced by that certificate for any purpose and as the person entitled to exercise the rights attaching to the units so requested, despite any notice to the contrary.

Table of Contents

FORMS OF SECURITIES

Each debt security, warrant and unit will be represented either by a certificate issued in definitive form to a particular investor or by one or more global securities representing the entire issuance of securities. Unless otherwise provided in the applicable prospectus supplement, certificated securities in definitive form and global securities will be issued in registered form. Definitive securities name you or your nominee as the owner of the security, and in order to transfer or exchange these securities or to receive payments other than interest or other interim payments, you or your nominee must physically deliver the securities to the trustee, registrar, paying agent or other agent, as applicable. Global securities name a depositary or its nominee as the owner of the debt securities, warrants or units represented by these global securities. The depositary maintains a computerized system that will reflect each investor s beneficial ownership of the securities through an account maintained by the investor with its broker/dealer, bank, trust company or other representative, as we explain more fully below.

Registered Global Securities

We may issue the registered debt securities, warrants and units in the form of one or more fully registered global securities that will be deposited with a depositary or its nominee identified in the applicable prospectus supplement and registered in the name of that depositary or nominee. In those cases, one or more registered global securities will be issued in a denomination or aggregate denominations equal to the portion of the aggregate principal or face amount of the securities to be represented by registered global securities. Unless and until it is exchanged in whole for securities in definitive registered form, a registered global security may not be transferred except as a whole by and among the depositary for the registered global security, the nominees of the depositary or any successors of the depositary or those nominees.

If not described below, any specific terms of the depositary arrangement with respect to any securities to be represented by a registered global security will be described in the prospectus supplement relating to those securities. We anticipate that the following provisions will apply to all depositary arrangements.

Ownership of beneficial interests in a registered global security will be limited to persons, called participants, that have accounts with the depositary or persons that may hold interests through participants. Upon the issuance of a registered global security, the depositary will credit, on its book-entry registration and transfer system, the participants accounts with the respective principal or face amounts of the securities beneficially owned by the participants. Any dealers, underwriters or agents participating in the distribution of the securities will designate the accounts to be credited. Ownership of beneficial interests in a registered global security will be shown on, and the transfer of ownership interests will be effected only through, records maintained by the depositary, with respect to interests of participants, and on the records of participants, with respect to interests of persons holding through participants. The laws of some states may require that some purchasers of securities take physical delivery of these securities in definitive form. These laws may impair your ability to own, transfer or pledge beneficial interests in registered global securities.

So long as the depositary, or its nominee, is the registered owner of a registered global security, that depositary or its nominee, as the case may be, will be considered the sole owner or holder of the securities represented by the registered global security for all purposes under the applicable indenture, warrant agreement or unit agreement. Except as described below, owners of beneficial interests in a registered global security will not be entitled to have the securities represented by the registered global security registered in their names, will not receive or be entitled to receive physical delivery of the securities in definitive form and will not be considered the owners or holders of the securities under the applicable indenture, warrant agreement or unit agreement. Accordingly, each person owning a beneficial interest in a registered global security must rely on the procedures of the depositary for that registered global security

and, if that person is not a participant, on the procedures of the participant through which the person owns its interest, to exercise any rights of a holder under the applicable indenture, warrant agreement or unit agreement. We understand that under existing industry practices, if we request any action of holders or if an owner of a beneficial interest in a registered global security

Table of Contents

desires to give or take any action that a holder is entitled to give or take under the applicable indenture, warrant agreement or unit agreement, the depositary for the registered global security would authorize the participants holding the relevant beneficial interests to give or take that action, and the participants would authorize beneficial owners owning through them to give or take that action or would otherwise act upon the instructions of beneficial owners holding through them.

Principal, premium, if any, and interest payments on debt securities, and any payments to holders with respect to warrants, or units, represented by a registered global security registered in the name of a depositary or its nominee will be made to the depositary or its nominee, as the case may be, as the registered owner of the registered global security. None of us, the trustees, the warrant agents, the unit agents or any other agent of ours, agent of the trustees or agent of the warrant agents or unit agents will have any responsibility or liability for any aspect of the records relating to payments made on account of beneficial ownership interests in the registered global security or for maintaining, supervising or reviewing any records relating to those beneficial ownership interests.

We expect that the depositary for any of the securities represented by a registered global security, upon receipt of any payment to holders of principal, premium, interest or other distribution of underlying securities or other property on that registered global security, will immediately credit participants accounts in amounts proportionate to their respective beneficial interests in that registered global security as shown on the records of the depositary. We also expect that payments by participants to owners of beneficial interests in a registered global security held through participants will be governed by standing customer instructions and customary practices, as is now the case with the securities held for the accounts of customers or registered in street name, and will be the responsibility of those participants.

If the depositary for any of the securities represented by a registered global security is at any time unwilling or unable to continue as depositary or ceases to be a clearing agency registered under the Exchange Act, and a successor depositary registered as a clearing agency under the Exchange Act is not appointed by us within 90 days, we will issue securities in definitive form in exchange for the registered global security that had been held by the depositary. Any securities issued in definitive form in exchange for a registered global security will be registered in the name or names that the depositary gives to the relevant trustee, warrant agent, unit agent or other relevant agent of ours or theirs. It is expected that the depositary s instructions will be based upon directions received by the depositary from participants with respect to ownership of beneficial interests in the registered global security that had been held by the depositary.

Table of Contents

USE OF PROCEEDS

Except as described in any prospectus supplement or in any related free writing prospectus that we may authorize to be provided to you, the net proceeds received by us from our sale of the securities described in this prospectus will be added to our general funds and will be used for our general corporate purposes. From time to time, we may engage in additional public or private financings of a character and amount which we may deem appropriate.

Table of Contents

PLAN OF DISTRIBUTION

We may sell securities through any one or more of the following methods from time to time:

- to or through underwriters, brokers or dealers;
- through agents;
- directly to one or more other purchasers in negotiated sales or competitively bid transactions;
- through a block trade in which the broker or dealer engaged to handle the block trade will attempt to sell the securities as agent, but may position and resell a portion of the block as principal to facilitate the transaction; or
- through a combination of any of the above methods of sale.

We may directly solicit offers to purchase securities, or agents may be designated to solicit such offers. We will, in the prospectus supplement relating to such offering, name any agent that could be viewed as an underwriter under the Securities Act and describe any commissions that we must pay. Any such agent will be acting on a best efforts basis for the period of its appointment or, if indicated in the applicable prospectus supplement, on a firm commitment basis. This prospectus may be used in connection with any offering of our securities through any of these methods or other methods described in the applicable prospectus supplement.

The distribution of the securities may be effected from time to time in one or more transactions:

- at a fixed price, or prices, which may be changed from time to time;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Each prospectus supplement will describe the method of distribution of the securities and any applicable restrictions.

The prospectus supplement with respect to the securities of a particular series will describe the terms of the offering of the securities, including the following:

the name of the agent or any underwriters;

the public offering or purchase price;

any discounts and commissions to be allowed or paid to the agent or underwriters;

all other items constituting underwriting compensation;

any discounts and commissions to be allowed or paid to dealers; and

any exchanges on which the securities will be listed.

If any underwriters or agents are utilized in the sale of the securities in respect of which this prospectus is delivered, we will enter into an underwriting agreement or other agreement with them at the time of sale to them, and we will set forth in the prospectus supplement relating to such offering the names of the underwriters or agents and the terms of the related agreement with them.

If a dealer is utilized in the sale of the securities in respect of which the prospectus is delivered, we will sell such securities to the dealer, as principal. The dealer may then resell such securities to the public at varying prices to be determined by such dealer at the time of resale.

If we offer securities in a subscription rights offering to our existing security holders, we may enter into a standby underwriting agreement with dealers, acting as standby underwriters. We may pay the standby underwriters a commitment fee for the securities they commit to purchase on a standby basis. If we do not enter into a standby underwriting arrangement, we may retain a dealer-manager to manage a subscription rights offering for us.

Table of Contents

Agents, underwriters, dealers and other persons may be entitled under agreements which they may enter into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

If so indicated in the applicable prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by certain institutions to purchase securities from us pursuant to delayed delivery contracts providing for payment and delivery on the date stated in the prospectus supplement. Each contract will be for an amount not less than, and the aggregate amount of securities sold pursuant to such contracts shall not be less nor more than, the respective amounts stated in the prospectus supplement. Institutions with whom the contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and other institutions, but shall in all cases be subject to our approval. Delayed delivery contracts will not be subject to any conditions except that:

- the purchase by an institution of the securities covered under that contract shall not at the time of delivery be prohibited under the laws of the jurisdiction to which that institution is subject; and

- if the securities are also being sold to underwriters acting as principals for their own account, the underwriters shall have purchased such securities not sold for delayed delivery. The underwriters and other persons acting as our agents will not have any responsibility in respect of the validity or performance of delayed delivery contracts.

Certain agents, underwriters and dealers, and their associates and affiliates may be customers of, have borrowing relationships with, engage in other transactions with, or perform services, including investment banking services, for us or one or more of our respective affiliates in the ordinary course of business.

In order to facilitate the offering of the securities, any underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the securities or any other securities the prices of which may be used to determine payments on such securities. Specifically, any underwriters may overallot in connection with the offering, creating a short position for their own accounts. In addition, to cover overallotments or to stabilize the price of the securities or of any such other securities, the underwriters may bid for, and purchase, the securities or any such other securities in the open market. Finally, in any offering of the securities through a syndicate of underwriters, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the securities in the offering if the syndicate repurchases previously distributed securities in transactions to cover syndicate short positions, in stabilization transactions or otherwise. Any of these activities may stabilize or maintain the market price of the securities above independent market levels. Any such underwriters are not required to engage in these activities and may end any of these activities at any time.

Under Rule 15c6-1 of the Exchange Act, trades in the secondary market generally are required to settle in two business days, unless the parties to any such trade expressly agree otherwise. The applicable prospectus supplement may provide that the original issue date for your securities may be more than two scheduled business days after the trade date for your securities. Accordingly, in such a case, if you wish to trade securities on any date prior to the second business day before the original issue date for your securities, you will be required, by virtue of the fact that your securities initially are expected to settle in more than two scheduled business days after the trade date for your securities, to make alternative settlement arrangements to prevent a failed settlement.

The securities may be new issues of securities and may have no established trading market. The securities may or may not be listed on a national securities exchange. We can make no assurance as to the liquidity of or the existence of trading markets for any of the securities.

In compliance with the guidelines of the Financial Industry Regulatory Authority, or FINRA, the aggregate maximum discount, commission or agency fees or other items constituting underwriting compensation to be received by any FINRA member or independent broker-dealer will not exceed 8% of the proceeds from any offering pursuant to this prospectus and any applicable prospectus supplement.

Table of Contents

LEGAL MATTERS

The validity of the securities being offered by this prospectus will be passed upon by Goodwin Procter LLP, Boston, Massachusetts.

Table of Contents

EXPERTS

The consolidated financial statements of Repligen Corporation appearing in Repligen Corporation s Annual Report (Form 10-K) for the year ended December 31, 2018, and the effectiveness of Repligen Corporation s internal control over financial reporting as of December 31, 2018 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their reports thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firm as experts in accounting and auditing.

Table of Contents

REPLIGEN CORPORATION

Common Stock

Preferred Stock

Debt Securities

Warrants

Units

PROSPECTUS

April 29, 2019

Table of Contents

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses, other than underwriting discounts and commissions, in connection with the issuance and distribution of the securities registered hereby. The registrant is deferring payment of the registration fee in reliance on Rule 456(b) and Rule 457(r) under the Securities Act. All the amounts shown are estimates.

	Amount to be Paid
SEC registration fee	$ (1)
Nasdaq listing fee	(2)
Accounting fees and expenses	(2)
Legal fees and expenses	(2)
Trustee and Transfer Agent fees and expenses	(2)
Printing fees	(2)
Miscellaneous	(2)
Total	$ (2)

(1) Omitted because the registration fee is being deferred pursuant to Rule 456(b) and Rule 457(r) under the Securities Act.
(2) These fees and expenses depend on the securities offered and the number of issuances, and accordingly cannot be estimated at this time and will be reflected in the applicable prospectus supplement.

Item 15. Indemnification of Directors and Officers.

Section 145(a) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer,

employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or other adjudicating court shall deem proper.

Table of Contents

Section 145(g) of the Delaware General Corporation Law provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify the person against such liability under Section 145 of the Delaware General Corporation Law.

Article SEVENTH of our certificate of incorporation (the Charter) provides that we shall, to the fullest extent permitted by Section 145 of the Delaware General Corporation Law, indemnify any persons that we shall have the power to indemnify under that section, against any expenses, liabilities or other matters referred to in that section. Further, Article SEVENTH of our Charter provides that the indemnification provided for therein shall not be deemed exclusive of any other rights to which those seeking indemnification may be entitled under any by-law, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in their official capacities and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

Article EIGHTH of our Charter provides that no director of our company shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (1) for any breach of the director s duty of loyalty to us or our stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) in respect of unlawful dividend payments or stock redemptions or repurchases, or (4) for any transaction from which the director derived an improper personal benefit. In addition, our Charter provides that if the Delaware General Corporation Law is amended to authorize the further elimination or limitation of the liability of directors, then the liability of a director of our company shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended. The Charter further provides that any repeal or modification of such article will not adversely affect any right or protection of a director existing at the time of such repeal or modification. The Charter also provides that the provisions of Article EIGHTH shall not eliminate the liability of a director for any act or omission occurring prior to the effective date of our Charter containing the provisions of Article EIGHTH.

Article V of our second amended and restated by-laws (the By-Laws), provides that to the full extent permitted by the Delaware General Corporation Law as the same may be amended from time to time, and our Charter, we shall indemnify each person whom we may indemnify pursuant thereto. Furthermore, Article V of the By-Laws authorizes us to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent, or is or was serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any capacity or arising out of such person s status as such, whether or not we would have the power to indemnify such person against such liability under the provisions of the Delaware General Corporation Law.

We also maintain a general liability insurance policy which covers certain liabilities of directors and officers of our company arising out of claims based on acts or omissions in their capacities as directors or officers.

Table of Contents

Item 16. Exhibits.

Exhibit No.	Description of Document
1.1*	Form of Underwriting Agreement.
3.1	Restated Certificate of Incorporation dated June 30, 1992, as amended September 17, 1999 and May 16, 2014 (filed as Exhibit 3.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference).
3.2	Second Amended and Restated By-laws (filed as Exhibit 3.1 to the Company s Current Report on Form 8-K filed on May 23, 2017 and incorporated herein by reference).
4.1	Specimen Common Stock Certificate (filed as Exhibit 4.1 to the Company s Annual Report on Form 10-K for the year ended March 31, 2002 and incorporated herein by reference).
4.2*	Specimen Preferred Stock Certificate and Certificate of Designations of Preferred Stock.
4.3	Form of Senior Indenture (including Form of Senior Note).
4.4	Form of Subordinated Indenture (including Form of Subordinated Note).
4.5*	Form of Warrant Agreement.
4.6*	Form of Unit Agreement.
5.1	Opinion of Goodwin Procter LLP.
23.1	Consent of Ernst & Young LLP.
23.2	Consent of Goodwin Procter LLP (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).
25.1*	Form of T-1 Statement of Eligibility of Trustee for Indenture under the Trust Indenture Act of 1939.

* To be filed, if necessary, subsequent to the effectiveness of this registration statement by incorporation by reference pursuant to a Current Report on Form 8-K in connection with an offering of securities.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission, or the Commission, pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Table of Contents

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser

and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Table of Contents

(6) That, for purposes of determining any liability under the Securities Act, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(7) To supplement the prospectus, after the expiration of the subscription period, to set forth the results of the subscription offer, the transactions by the underwriters during the subscription period, the amount of unsubscribed securities to be purchased by the underwriters, and the terms of any subsequent reoffering thereof. If any public offering by the underwriters is to be made on terms differing from those set forth on the cover page of the prospectus, a post-effective amendment will be filed to set forth the terms of such offering.

(8) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by a registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, that the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(9) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under Section 305(b)(2) of the Trust Indenture Act.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Waltham, Commonwealth of Massachusetts, on this 29th day of April, 2019.

Repligen Corporation

By: /s/ Tony J. Hunt
Tony J. Hunt
President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby severally constitutes and appoints Tony J. Hunt and Jon K. Snodgres, and each of them singly, as such person s true and lawful attorneys in fact and agents, with full power of substitution and resubstitution, for such person and in such person s name, place, and stead, in any and all capacities, to sign any and all amendments (including post effective amendments or any abbreviated or subsequent registration statement and any amendments thereto filed pursuant to Rule 462(b) and any supplement to any prospectus included in this registration statement or any such amendment or any abbreviated or subsequent registration statement filed pursuant to Rule 462(b)), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys in fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys in fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ Tony J. Hunt	*President, Chief Executive Officer, and Director*	April 29, 2019
Tony J. Hunt	*(Principal Executive Officer)*	
/s/ Jon K. Snodgres	*Chief Financial Officer*	April 29, 2019
Jon K. Snodgres	*(Principal Financial and Accounting Officer)*	
/s/ Karen A. Dawes	*Director, Chairperson of the Board*	April 29, 2019
Karen A. Dawes		
/s/ Nicolas M. Barthelemy	Director	April 29, 2019

Nicolas M. Barthelemy		
/s/ Glenn L. Cooper, M.D.	Director	April 29, 2019
Glenn L. Cooper, M.D.		
/s/ John G. Cox	Director	April 29, 2019
John G. Cox		
/s/ Thomas F. Ryan, Jr.	Director	April 29, 2019
Thomas F. Ryan, Jr.		
/s/ Glenn P. Muir	Director	April 29, 2019
Glenn P. Muir		