NYMOX PHARMACEUTICAL CORP
Form 20-F
June 30, 2006

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, 2005
or

[_] Transition Report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to

Commission File Number: 001-12033

NYMOX PHARMACEUTICAL CORPORATION
(Exact name of registrant as specified in its charter)

Canada
(Jurisdiction of incorporation or organization)

9900 Cavendish Blvd., Suite 306
St. Laurent, Quebec, Canada, H4M 2V2
(Address of principal executive offices)

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
None	Not Applicable

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

Common Stock

Securities registered or to be registered 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.

26,728,781 shares as of December 31, 2005

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

Yes [X] No [ ]

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 [X] Item 18 [ ]

In this annual report, the term Nymox refers to both Nymox Pharmaceutical Corporation and its subsidiaries, Nymox Corporation and Serex Inc., and, where applicable, a predecessor private corporation, DMS Pharmaceuticals Inc. Unless otherwise indicated all dollar amounts are in United States Dollars.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

identify and capitalize on possible collaboration, strategic partnering or divestiture opportunities,

obtain suitable financing to support its operations and clinical trials,

manage its growth and the commercialization of its products,

achieve operating efficiencies as it progresses from a development-stage to a later-stage biotechnology company,

successfully compete in its markets,

realize the results it anticipates from the clinical trials of its products,

succeed in finding and retaining joint venture and collaboration partners to assist it in the successful marketing, distribution and commercialization of its products,

achieve regulatory clearances for its products,

obtain on commercially reasonable terms adequate product liability insurance for its commercialized products,

adequately protect its proprietary information and technology from competitors and avoid infringement of proprietary information and technology of its competitors,

assure that its products, if successfully developed and commercialized following regulatory approval, are not rendered obsolete by products or technologies of competitors and

not encounter problems with third parties, including key personnel, upon whom it is dependent.

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

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not Applicable

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable

ITEM 3. KEY INFORMATION

Selected Financial Data

The following table sets forth selected consolidated financial data for Nymox for the periods indicated, derived from financial statements prepared in accordance with generally accepted accounting principles (GAAP). We prepare our basic financial statements in accordance with Canadian GAAP and include, as a note to the statements, a reconciliation of material differences to United States GAAP. The financial statements have been audited by KPMG LLP, Montreal, Canada as at and for the years ended December 31, 2001, 2002, 2003, 2004 and 2005. The data set forth below should be read in conjunction with the Company 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 (1))

	Dec. 31, 2005	Dec. 31, 2004	Dec. 31, 2003	Dec. 31, 2002	Dec. 31, 2001
CANADIAN GAAP					
Current Assets	$ 291,454	$ 699,074	$ 747,672	$ 862,366	$ 644,522
Property & Equipment	11,463	25,348	133,161	185,293	217,083
Patents & Intellectual Property	3,310,129	3,271,599	3,034,529	3,223,498	3,154,441
Total Assets	3,719,039	4,066,021	4,022,862	4,358,657	4,192,241
Total Liabilities	2,506,902	2,053,634	1,724,164	1,471,727	747,493
Share Capital	39,488,350	36,553,350	32,503,600	28,407,600	25,376,557
Shareholder's Equity	412,137	1,212,387	1,478,698	2,086,930	2,644,748
Total Revenues	426,282	321,948	200,132	361,748	380,609
Sales	424,506	321,895	199,217	356,162	362,691
Research & Development Expenditures(2)	1,828,516	1,851,881	2,477,032	1,689,430	1,479,602
Net Loss	3,584,528	3,745,625	4,354,288	3,412,609	3,049,504
Loss per Share (basic & diluted)	$ 0.14	$ 0.15	$ 0.18	$ 0.15	$ 0.14
Weighted Avg. No. of Common Shares	26,080,470	24,924,674	23,669,852	22,651,639	21,873,966
U.S. GAAP(3)					
Net Loss	$ 3,609,448	$ 3,770,545	$ 4,395,428	$ 3,453,749	$ 3,095,133
Loss per Share	0.14	0.15	0.19	0.15	0.14
Shareholder's Equity	$ 402,028	$ 1,202,278	$ 1,468,589	$ 1,947,696	$ 2,496,104

(1) Effective January 1, 2000, the Corporation adopted the United States dollar as its measurement currency as a result of the increasing proportion of operating, financing and investing transactions in the Canadian operations that are denominated in U.S. dollars. Reference is made to note 2(g) of the consolidated financial statements.

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

(3) Reference is made to Note 12 of Nymox s audited financial statements as at and for the year ended December 31, 2005 for a reconciliation of differences between Canadian and U.S. GAAP.

Risk Factors

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

Our clinical trials for our therapeutic products in development, such as NX-1207, may not be successful and we may not receive the required regulatory approvals necessary to commercialize these products.

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

Our clinical trials for our therapeutic products, such as NX-1027, may be delayed, making it impossible to achieve anticipated development or commercialization timelines.

Delays in the initiation, conduct or completion of clinical trials are not uncommon. If one or more of our clinical trials is delayed, we may not 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 company s business, operations, product development programs and financial condition.

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

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

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

design of the protocol;
the size of the patient population;
eligibility criteria for the study in question;

perceived risks and benefits of the drug under study;
availability of competing therapies;
efforts to facilitate timely enrollment in clinical trials;
patient referral practices of physicians; and
availability of clinical trial sites.

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

A setback in any of our clinical trials would likely cause a drop in the price of our shares.

We have successfully completed the first two Phase 1 and Phase 1-2 U.S. clinical trials for NX-1207, our drug candidate for the treatment of enlarged prostate (benign prostatic hyperplasia or BPH), and are in the midst of a pivotal Phase 2 clinical trial. Setbacks in any phase of the clinical development of our product candidates could have a negative impact on our business, operations, product development programs and financial condition, could jeopardize FDA or other regulatory approval and would likely cause a drop in the price of our shares.

We may not be able to make adequate arrangements with third parties for the commercialization of our product candidates, such as NX-1207.

In order to commercialize our product candidates successfully, we intend, on a product-by-product basis, either to make arrangements with third parties to perform some or all of these services or to develop our own sales, marketing and distribution capabilities. We currently have limited marketing capabilities and limited experience in developing, training or managing a marketing or sales force. We currently rely upon distributors for the sales of our existing products. The cost of establishing and maintaining our own 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.

We may not achieve our projected development goals in the time frames we announce and expect.

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

Even if we obtain regulatory approvals for our product candidates, we will be subject to stringent ongoing government regulation.

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

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

changes in the suppliers of raw materials are subject to further regulatory review and approval.

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

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

We first began operations in 1995 and are only in the early stages of commercial marketing of our diagnostic products, AlzheimAlert , NicAlert and TobacAlert . We have never made a profit. We incurred a net loss of $4.0 million in 2000, $3.0 million in 2001, $3.4 million in 2002, $4.3 million in 2003, $3.7 million in 2004 and $3.6 in 2005. As of December 31, 2005, Nymox s accumulated deficit was $39.7 million.

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

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

Nymox has funded its operations primarily by selling shares of its common stock. Since late 1998, a small portion of the funds came from sales. However, sales have not been, and may not be in the foreseeable future, sufficient to meet our anticipated financial requirements.

We will continue to need to raise substantial amounts of capital for our business activities including our research and development programs, the conduct of clinical trials needed to obtain regulatory approvals and the marketing and sales of our products. We anticipate being able to fund our current total annual budgeted expenditures of approximately $3 4 million per year over the next year through our current cash position and additional financing, including draw downs through our common stock private purchase agreement with Lorros-Greyse Investments, Inc. Clinical trials will substantially increase cash requirements. We anticipate being able to meet these requirements as they arise. We plan to raise capital either through a new round of financing and/or through partnering with a major pharmaceutical company. Additional financing may not be available when needed, or, if available, may not be available on acceptable terms. If adequate funds on acceptable terms are not available, we may have to curtail or eliminate expenditures for research and development, testing, clinical trials, promotion and marketing for some or all of our products.

We Face Challenges in Developing, Manufacturing and Improving Our Products

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

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

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

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

Our Products and Services May Not Receive Necessary Regulatory Approvals.

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

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

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

We currently market AlzheimAlert as a clinical reference laboratory service provided by our government inspected clinical reference laboratory in New Jersey. Physicians send us urine samples from their patients to our laboratory where the AlzheimAlert test is performed and the results reported back to the physicians. A clinical laboratory test like AlzheimAlert does not require approval from the United States Food and Drug Administration (FDA). Our laboratory is regulated by the Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) and is subject to inspection and certification. In addition, individual states like New York and Florida have their own requirements for reference laboratories like ours that offer diagnostic services. In addition, the FDA has its own regulations governing in vitro diagnostic products, including some of the reagents used in clinical reference laboratories. Any changes in CMS or state law requirements or in the FDA regulations could have a detrimental impact on our ability to offer or market any reference laboratory services and/or on our ability to obtain reimbursement from the Medicare and Medicaid programs and providers.

We have developed a diagnostic kit based on AlzheimAlert for sale to third parties. We will require prior approval from the FDA before we can market, distribute or sell this product in the United States. In July, 2005, an FDA advisory panel voted 5-2 against approval of the kit, citing the need for further studies, such as long term follow-up and autopsy confirmation. The Company continues to pursue kit approval and is still in the process of working with the FDA to try to meet all the requirements. We cannot predict with any certainty when or if such approval will be forthcoming and it is possible that the FDA may require more clinical testing or further documentation before approval. If approved, the diagnostic kit would then be subject to postmarketing record and reporting obligations and manufacturing requirements.

Similar requirements exist in many other countries. Obtaining these approvals and complying with the subsequent regulatory requirements can be both time-consuming and expensive. In November 2004, Nymox satisfactorily completed the testing and registration required by European regulatory, environmental and quality standards in order to obtain a CE Mark for the AlzheimAlert kit. The CE Mark makes the AlzheimAlert kit eligible for sale in the European Union and will allow European clinical and hospital laboratories to perform the AlzheimAlert test in their own facilities in Europe.

We currently sell NicAlert and TobacAlert as tests for tobacco product use and exposure and for research use. In October, 2002, we received 510(k) clearance from the U.S. Food and Drug Administration for our NicAlert product for medical uses.

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. We have not submitted any drugs for final FDA approval. In 2003, we successfully completed the first two Phase 1 and Phase 1-2 U.S. clinical trials for NX-1207, our investigational new drug treatment for benign prostatic hyperplasia (BPH). We are in the midst of a pivotal Phase 2 clinical trial. We cannot predict with any certainty the outcome of this trial, what further steps may be required in order to apply for final FDA approval for this drug or whether the FDA will ultimately grant us such approval.

Similar requirements exist in many other countries.

We Face Significant and Growing Competition

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

vaccines for Alzheimer's disease;

enzyme-blocking therapies intended to block the production of the protein found in the senile plaques characteristic of Alzheimer s disease. A number of pharmaceutical and biotechnology companies including Amgen, Elan and Bristol-Myers Squibb are working on such therapies.

drugs aimed at reducing, blocking or clearing the aggregation or accumulation of the protein found in senile plaques. A number of pharmaceutical and biotechnology companies including Neurochem, Praecis Pharmaceuticals and Prana Biotechnology are working on such therapies.

memory enhancing compounds from Cortex Pharmaceuticals, Memory Pharmaceuticals, Helicon Therapeutics and Sention, among others.

drugs aimed at inhibiting an enzyme that breaks down an important neurotransmitter involved in memory and cognition. A number of pharmaceutical and biotechnology companies including Axonyx are working on such therapies.

implantation of a shunt (COGNIShunt) developed by its maker, Eunoe Inc., and designed to drain cerebrospinal fluid from the patient s skull into his or her abdominal cavity.

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

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

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

We May Not Be Able to Successfully Market Our Products

To increase our marketing, distribution and sales capabilities both in the United States and around the world, we will need to enter into licensing arrangements, contract sales agreements and co-marketing deals. We cannot assure you that we will be able to enter into agreements with other companies on terms acceptable to us, that any licensing arrangement will generate any revenue for the company 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 over 200 patents and patent applications in countries around the world, including the United States, Europe, Japan, Canada, Australia, New Zealand and South Korea. In the United States alone, Nymox has seventeen patents issued or allowed and fourteen patent applications pending relating to its technology. Its subsidiary, Serex, Inc. has ten patents issued and allowed. Through licensing agreements with the Massachusetts General Hospital, Nymox separately licensed global patent rights relating to neural thread proteins and to novel cancer markers that have potential application both for the treatment and diagnosis of specific cancers. These licensed patent rights include six issued United States patents and numerous patents and patent applications in other countries around the world.

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

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

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

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. Such 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 AlzheimAlert product. These changes can seriously impact the potential for growth for the market for AlzheimAlert , either favorably when the decision is to offer broad coverage for our test at a reasonable price or negatively when the decision is to deny coverage altogether. Changes in the healthcare delivery system have resulted in major consolidation among reference laboratories 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.

The Issuance of New Shares May Dilute Nymox s Stock

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 27,710,464 common shares of Nymox issued and outstanding as of June 26, 2006. All of these shares are eligible for sale under Rule 144 or are otherwise freely tradable. In addition, 1,711,500 share options are outstanding, of which 1,701,500 are currently vested. Expiry dates for Nymox options range from 2 months to 10 years (see note 7(e) to our consolidated financial statements). These options have been granted to employees, officers, directors and consultants of the company. Moreover, Nymox may use its shares as currency in acquisitions.

We Face Potential Losses Due to Foreign Currency Exchange Risks

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

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

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

ITEM 4. INFORMATION ON THE COMPANY

History of the Company

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

Nymox s principal executive offices are located at:

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

Fax: (514) 332-2227

Nymox s registered agent in the United States is:

CT Corporation System
208 South Lasalle St.
Chicago, IL 60604

Nymox s two subsidiaries are located at:

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

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

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

Acquisition of a Majority Interest in Serex, Inc.

On March 2, 2000, we closed our acquisition of a controlling interest in Serex, Inc., a privately held diagnostic company based in New Jersey. We have subsequently acquired more shares of the common stock of Serex, Inc. from other shareholders and now own approximately 99% of its common stock.

Serex s NicAlert and TobacAlert strips can reliably detect one of the metabolic products of nicotine in human urine, in order to determine whether a person, such as a teenager or insurance applicant, is using or has been exposed to a tobacco product. NicAlert and TobacAlert are currently being distributed by Nymox, CVS/pharmacy®, Drugstore.com and Jant Pharmacal Corporation.

Serex developed and patented its particle valence technology, a unique, highly sensitive, new method to detect very small amounts of biochemical indicators in body fluids such as blood, urine and saliva. This technology can be adapted to detect a wide range of biochemical indicators for diseases, conditions and drug use.

Serex also assisted in the development of our AlzheimAlert test.

Products

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

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

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

NicAlert has received clearance from the U.S. Food and Drug Administration (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 NicAlert with a CE Mark making it eligible for sale in the European Union. 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. Currently TobacAlert is available at approximately 5,400 CVS/pharmacy® stores across the U.S. as well as online at www.drugstore.com. Nymox has entered into distribution and marketing agreements with companies and organizations in the U.S., the U.K., and Spain for these products.

Our NicAlert and TobacAlert products face competition from clinical laboratories such as Lab One, 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 Techologies Inc. and Cozart Bioscience Ltd, and diagnostic system manufacturers such as Roche Diagnostics, Abbott and Diagnostic Products Corporation. NicAlert and TobacAlert also face competition from distributors who supply yes-no smoking status tests such as SmokeCheck, NicQuick, and QuickScreen, from NicCheck I, an FDA-cleared smoking status test being marketed by Mossman & Associates Ltd, and, in the United Kingdom, from SmokeScreen, a chemical color-based tobacco test being marketed by Mermaid Diagnostics, Ltd..

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

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

AlzheimAlert : An Aid to the Diagnosis of Alzheimer s Disease

We offer AlzheimAlert , a proprietary diagnostic aid for Alzheimer s disease, through our government inspected clinical reference laboratory in New Jersey. AlzheimAlert is an improved version of our AD7C test, which has been on the market since 1997. AlzheimAlert offers a more technically advanced means to detect elevated levels of NTP in urine. It is a proprietary assay in the competitive affinity format and has significant advantages of easy adaptability to systems and equipment present in all modern clinical laboratories. It is a urine test, where the patient provides a first-morning urine sample for testing. The patient s doctor then forwards the sample to our laboratory where our technical staff performs the test. We then report the results to the doctor. The AlzheimAlert test is intended as an aid to diagnosis, to be considered together with patient history, physical examination and other relevant medical data. The test does not replace a physician s diagnosis.

Our AlzheimAlert test is the latest generation of our NTP testing technology. It measures the level of a brain protein called neural thread protein (NTP) which is elevated early in Alzheimer s disease as reported both in the scientific literature and at scientific conferences. Researchers at the Massachusetts General Hospital and Brown University led by Doctors Suzanne de la Monte and Jack Wands first found large amounts of the protein in the brain tissue of patients known to have died with Alzheimer s disease. Subsequent research led to the characterization of NTP and the gene that produces it. Nymox succeeded in developing a highly sensitive test to detect the presence of NTP in the spinal fluid and, most recently, in the urine of patients with Alzheimer s disease. Recent studies (*J. Neuropathol Exp Neurol* (2001; 60: 195-207) *Journal of Alzheimer s Disease* (2004; 231-242)) have provided further evidence that increased production of NTP leads to a marked increase in nerve cell death and have shown that the cells subjected to NTP died in a programmed fashion similar to the way the nerve cells in the brains of patients with Alzheimer s disease die. One of the characteristic signs of Alzheimer s disease is widespread brain cell loss.

Nymox believes that its AlzheimAlert test can assist a physician faced with the task of diagnosing whether a patient has Alzheimer s disease (AD). In a recent prospective blinded study at eight U.S. specialty clinics for the evaluation of cognitive or memory disorder or dementia, 91% of subjects with a clinical diagnosis of probable AD had an elevated NTP measurement while 90.7% of the subjects diagnosed as definite non-AD had a normal NTP measurement. 37.7% of subjects categorized with the clinical diagnosis of possible AD, and 48.6% of subjects diagnosed with mild cognitive impairment (MCI) also had elevated NTP measurements. The low rate of positive results for patients without the disease is important for doctors investigating patients with subtle or marginal symptoms of mental, emotional, cognitive, or behavioral changes. If the doctor can rule out Alzheimer s with more assurance, a great deal of patient and family anguish and anxiety will be avoided. A low test

score will help the doctor to be more certain that Alzheimer s disease is not the cause of the patient s symptoms and to target the other, often reversible causes of the patient s symptoms, such as depression. There can be no assurance that further studies will repeat the same level of success experienced to date.

Many studies published in scientific publications or presented at scientific conferences over the past decade have confirmed the accuracy of NTP as a biochemical marker for Alzheimer s disease. Recent publications in the peer-reviewed literature include, for example, the *Journal of Clinical Investigation* (1997; 100: 3093-3104); *Journal of Contemporary Neurology* (1998; art. 4a); *Journal of Clinical Laboratory Analysis* (1998; 12: 285-288) and (1998; 12: 223-226); *Alzheimer s Reports* (1999; 2: 327-332), (2000; 3: 177-184), (2001; 4: 61-65) and (2002; 5: 1-6); *Neurology* (2000; 54: 1498-1504) and (2000; 55: 1068); *Journal of Alzheimer s Disease* (2001; 3: 345-353) and (2004; 6(3): 231-42); *Cellular and Molecular Life Sciences* (2001; 58: 844-849) and (2003; 60: 2679-91); *Neurology and Clinical Neurophysiology* (2002; 1: 2-7); *Journal of Neuropathology and Experimental Neurology* (2001; 60: 195-207) and (1996; 55: 1038-1050), and *Frontiers in Bioscience* (2002; 7: d989-96). Reports about this Nymox technology have also been featured in prestigious trade and lay publications such as *Clinica* (Sept.25, 2000), *Genetic Engineering News* (Oct.1, 2000), *Clinical Laboratory News* (Sept., 1999 and Oct., 2000), *Modern Maturity* (Dec., 2000), *ADVANCE for Administrators of the Laboratory* (June, 2001), *ASRT Scanner* (August, 2001), *RN magazine* (August, 2001), *Clinical Geriatrics* (Nov., 2000), *LabMedica International* (June, 1998), and *Clinical Laboratory International* (October, 1998).

There is a large unmet need for a simple, non-invasive test that can aid in the diagnosis of Alzheimer s disease. Alzheimer s disease is the most common cause of dementia in persons 65 years of age and older and is the fourth leading cause of death among the elderly. There are an estimated 4.5 million people with Alzheimer s disease in the United States alone; by 2050 this number is projected to increase almost three times to 13.2 million. Worldwide estimates of the current number of people with Alzheimer s disease range from 15 to 20 million. The annual national direct and indirect costs of caring for Alzheimer patients in the U.S. alone are estim