NYMOX PHARMACEUTICAL CORP Form 20-F March 15, 2011

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, 2010
or
[ ] Transition Report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934
or
[ ] Shell Corporation Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of event requiring this Shell Corporation Report for the transition period from to
Commission File Number: 001-12033

# NYMOX PHARMACEUTICAL CORPORATION

(Exact name of registrant as specified in its charter)

### Canada

(Jurisdiction of incorporation or organization)

9900 Cavendish Blvd., Suite 306

St. Laurent, Quebec, Canada, H4M 2V2

(Address of principal executive offices)

Contact person: Roy Wolvin

Tel. 800-936-9669, e-mail: rwolvin@nymox.com,fax: 514-332-2227

(name, telephone, e-mail and/or facsimile number and address of company contact person)

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

# Title of each class

# Name of each exchange on which registered

Common Stock

The NASDAQ Stock Market LLC (NASDAQ Capital Market)

Securities registered or to be registered pursuant to Section 12(g) of the Act
None
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act
None
Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.
32,573,856 shares as of December 31, 2010
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes [ ] No [ X ]
If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Yes [ ] No [ X ]
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes [ X ] No [ ]
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website; if any, every interactive Date File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232-405 of this chapter) during the preceding twelve months (or for such shorter period that the registrant was required to submit and post such files).
Yes [ ] No [ ]
1

Indicate by check mark whether the reg filer. See definition of accelerated file		ccelerated filer, or a non-accelerated 2b-2 of the Exchange Act. (Check one):
Large accelerated filer [ ] Accelerated	filer [ X ] Non-accelerated filer [ ]	
Indicate by check mark which basis of a in this filing:	accounting the registrant has used to pr	repare the financial statements included
	International Financial Reporting	
U.S. GAAP [ ]	Standards [ ]	Other [X]
	as issued by the International Accounting Standards Board.	
If Other has been checked in responsible registrant has elected to follow:	se to the previous question, indicate by	check mark which financial statement item
Item 17 [ ] Item 18 [ X ]		
If this is an annual report, indicate by confidence of the Exchange Act).	heck mark whether the registrant is a sh	hell Company (as defined in Rule 12b-2
Yes [ ] No [ X ]		
2		

In this annual report, the terms Nymox, The Corporation, we and us refers to both Nymox Pharmaceutical Corpora 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 sime expressions.

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

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

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

### PART I

# **ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS**Not Applicable

# ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable

## **ITEM 3. KEY INFORMATION**

### **Selected Financial Data**

The following table sets forth selected consolidated financial data for Nymox for the periods indicated, derived from financial statements prepared in accordance with 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, 2006, 2007, 2008, 2009 and 2010 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)

(III O.D. dollars)					
	Dec. 31,	Dec. 31,	Dec. 31,	Dec. 31,	Dec. 31,
	<u>2010</u>	<u>2009</u>	<u>2008</u>	<u>2007</u>	<u>2006</u>
CANADIAN GAAP					
Current Assets	\$ 13,470,096	\$ 1,074,279	\$ 480,505	\$ 430,960	\$ 379,194
Property & Equipment	14,730	16,152	21,525	19,710	7,839
Patents & Intellectual Property	0	0	220,855	441,708	662,564
Total Assets (3)	13,502,222	1,090,431	749,879	989,372	1,155,590
Total Liabilities	15,556,836	1,742,597	1,256,885	1,294,745	2,144,312
Share Capital	62,855,147	57,955,147	53,850,147	50,155,147	44,443,350
Shareholders Equity	(2,854,614)	(1,452,166)	(1,307,006)	(1,105,373)	(1,788,722)
Total Revenues	692,641	415,980	428,409	433,933	442,861
Sales	582,383	415,980	426,675	412,923	437,440
Research & Development Expenditures (1) (3)	4,551,719	3,043,219	2,388,911	3,468,273	3,171,428
Net Loss (3)	6,956,033	5,130,074	4,637,103	5,746,149	5,282,231
Loss per Share (basic & diluted) (3)	\$ 0.22	\$ 0.17	\$ 0.16	\$ 0.20	\$ 0.19
Weighted Avg. No. of Common Shares	31,940,584	30,717,822	29,749,000	29,005,342	27,644,749

U.S. GAAP (2)					
Net Loss	\$ 7,190,670	\$ 5,282,534	\$ 4,590,345	\$ 5,290,431	\$ 4,893,685
Loss per Share	0.23	0.17	0.15	0.18	0.18
Shareholders Equity (2)	465,912	2,102,997	2,400,617	2,555,492	1,416,424

- (1) We earn research tax credits by making qualifying research and development expenditures. These amounts shown are net of research tax credits.
- (2) Reference is made to Note 15 of Nymox s audited financial statements as at and for the years ended December 31, 2010, 2009 and 2008 for a reconciliation of differences between Canadian and U.S. GAAP.
- (3) Net loss, loss per share (basic & diluted), research and development expenditures, patents and intellectual property, total assets and shareholders—equity reflect the impact of the change in accounting policy as described in Note 3 (a) to the audited consolidated financial statements.

### **Risk Factors**

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

# Our Clinical Trials for our Therapeutic Products in Development, Such as NX-1207, May Not Be Successful and We May Not Receive the Required Regulatory Approvals Necessary to Commercialize These Products

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

# Our Clinical Trials for Our Therapeutic Products, Such as NX-1207, May Be Delayed, Making it Impossible to Achieve Anticipated Development or Commercialization Timelines

Delays in the initiation, conduct or completion of clinical trials are not uncommon. If one or more of our clinical trials is delayed, we may be unable to meet our anticipated development or commercialization timelines. Either circumstance could cause the price of our shares to decline, increase clinical trial and product development costs, and affect the Corporation s business, operations, product development programs and financial condition.

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

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

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

- design of the protocol;
- the size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the drug under study;
- availability of competing therapies;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- availability of clinical trial sites.

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

## A Setback in Any of Our Clinical Trials Would Likely Cause a Drop in the Price of Our Shares

We have successfully completed several Phase 1 and Phase 2 multi-center, blinded and controlled clinical trials, and follow-up studies, in the U.S. for NX-1207, our drug candidate for the treatment of enlarged prostate (benign prostatic hyperplasia or BPH), and we are currently in Phase 3. The clinical testing of drug candidates is fraught with uncertainties and positive results from earlier clinical trials may not be repeated in later trials. As well, government regulators such as the U.S. Food and Drug Administration, or FDA, may require additional testing or further documentation relating to the preclinical testing, clinical studies, manufacturing or other issues at any time. These requirements may result in substantial delays in obtaining regulatory approval or make obtaining such approval much more difficult. Setbacks in any phase of the clinical development of our product candidates could have a negative impact on our business, operations, product development programs and financial condition, could jeopardize FDA or other regulatory approval and would likely cause a drop in the price of our shares.

# We May Not be Able to Make Adequate Arrangements with Third Parties for the Commercialization of Our Product Candidates, such as NX-1207

In order to commercialize our product candidates successfully, we intend, on a product-by-product basis, either to make arrangements with third parties to perform some or all of these services or to expand our existing sales, marketing and distribution capabilities. We currently have limited sales and marketing capabilities and limited experience in developing, training or managing a large marketing or sales force. We currently rely primarily upon distributors for the sales of our existing products. The cost of establishing and maintaining a larger sales force would be substantial and may exceed its cost effectiveness. In addition, in marketing our products, we would likely compete with many companies that currently have extensive and well-funded marketing and sales operations. Despite our marketing and sales efforts, we may be unable to compete successfully against these companies. We may make arrangements with third parties to market and sell some or all of our products under development in certain territories, rather than establish our own sales force. We may not be able to do so on favorable terms. If we contract with third parties for the sales and marketing of our products, our revenues will depend upon the efforts of these third parties, whose efforts may not be successful.

We anticipate entering into co-development and co-marketing agreements with one or more partners with established sales, marketing and regulatory capabilities in order to assist in the completion of the development and commercialization of NX-1207. We may not be able to do so on favourable terms. If we fail to establish or make adequate arrangements with third parties for such purposes, our business, operations, product development programs and financial condition will be materially adversely affected.

In December 2010, the Corporation signed a license and collaboration agreement with Recordati, a European pharmaceutical group, for the development and commercialization of NX-1207 in Europe including Russia and the CIS, the Middle East, the Maghreb area of North Africa and South Africa (the Licensed Territory). The license and collaboration agreement covers the use of NX-1207 for the treatment of BPH as the initial indication for development and commercialization. The success of this agreement is contingent on Recordati s ability to secure marketing approval from the European Medicines Agency (EMA) and other government regulatory agencies in the Licensed Territory. Failure to secure such approvals, inability to establish satisfactory reimbursement prices for sale of approved products, and difficulties with commercialization in the Licensed Territory could significantly impact our revenues from this agreement.

## We May Not Achieve Our Projected Development Goals in the Time Frames We Announce and Expect

We make public statements regarding 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 approximately \$4.6 million in 2008, \$5.1 million in 2009 and \$7.0 million in 2010. As of December 31, 2010, Nymox s accumulated deficit was approximately \$62.9 million.

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

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

Nymox has funded its operations primarily by selling shares of its common stock. Since late 1998, a small portion of the funds came from sales. However, sales have not been, and may not be in the foreseeable future, sufficient to meet our anticipated financial requirements. In December 2010, the Corporation received an upfront payment of 10 million (US\$13.1 million) pursuant to a license and collaboration agreement with Recordati for the development and commercialization of NX-1207 in the Licensed Territory. Future payments under this agreement are contingent in part on Recordati s ability to secure regulatory approvals in the licensed territory and may be delayed or not occur.

We will continue to need to raise substantial amounts of capital for our business activities including our research and development programs, the conduct of clinical trials needed to obtain regulatory approvals and the marketing and sales of our products. We anticipate being able to fund our current total annual budgeted expenditures of approximately \$5.5 - 7 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. (Lorros-Greyse). The Corporation must comply with general covenants in order to draw on its facility including maintaining its stock exchange listing and registration requirements and having no material adverse effects, as defined in the agreement, with respect to the business and operations of the Corporation. Clinical trials will substantially increase cash requirements. We anticipate being able to meet these requirements as they arise. We plan to raise capital either through a new round of financing and/or through partnering with a major pharmaceutical corporation. The financial crisis in the United States and the global economic recession has had a negative impact on the availability of liquidity in the market and may have an effect on the liquidity of Lorros-Greyse. Additional financing may not be available when needed, or, if available, may not be available on acceptable terms. If adequate funds on acceptable terms are not available, we may have to curtail or eliminate expenditures for research and development, testing, clinical trials, promotion and marketing for some or all of our products.

# We Face Challenges in Developing, Manufacturing and Improving Our Products

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

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

Developing and improving our diagnostic products is also challenging. The science and technology of the detection and measurement of very small amounts of biochemicals in bodily fluids and tissue is evolving rapidly. We may need to make significant expenditures in research and development costs and licensing fees in order to take advantage of new technologies. If any major changes to our testing technologies used in our AlzheimAlert 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 corporation or other partner in order to manufacture a therapeutic for market.

### Our Products and Services May Not Receive Necessary Regulatory Approvals

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

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

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

Any changes in the Centers for Medicare and Medicaid Services ( CMS ) or state law requirements or in the U.S. Food and Drug Administration ( FDA ) regulations could have a detrimental impact on our ability to offer or market any reference laboratory services and/or on our ability to obtain reimbursement from the Medicare and Medicaid programs and providers.

We have developed a diagnostic kit based on AlzheimAlert for sale to third parties. We will require prior approval from the FDA before we can market, distribute or sell this product in the United States. In July 2005, an FDA advisory panel voted 5-2 against approval of our kit, citing the need for further studies, such as long term follow-up and autopsy confirmation.

Similar requirements exist in many other countries. Obtaining these approvals and complying with the subsequent 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. The Corporation reported positive results in 2007 and 2008 in several follow-up studies of BPH patients. 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). In February 2009, the Corporation reported concluding a positive and productive End of Phase 2 ( EOP2 ) meeting with the FDA concerning the Phase 3 program for NX-1207. In June 2009, the Corporation began conducting the first of two pivotal double blind placebo controlled Phase 3 trials for NX-1207 that incorporate the specific protocol design recommendations provided to the Corporation by the FDA. The

two pivotal Phase 3 studies for NX-1207 are being conducted at well known investigational sites across the U.S. with planned enrollment of 1,000 patients. We cannot predict with any certainty the outcome of this program, what further steps may be required in order to apply for final FDA approval for this drug or whether the FDA will ultimately grant us such approval. Similar requirements exist in many other countries.

# We Face Significant and Growing Competition

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

• vaccines and other immunotherapies for Alzheimer s disease. A number of pharmaceutical and biotechnology companies including Wyeth, Elan, Novartis, and Baxter are working on such therapies.

- 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 Bristol-Myers Squibb and Merck 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 Elan, Lilly, Pfizer and Prana Biotechnology are working on such therapies.
- drugs designed to enhance cognition from AstraZeneca and Roche among others.
- antihistamines such as Dimebon from Medivation.

There is also ongoing research into possible methods of preventing Alzheimer s disease such as taking certain cholesterol-lowering drugs called statins, estrogen replacement therapies, anti-oxidants such as vitamin E and ginkgo biloba, nutraceuticals such as resveratrol and docosahexanoic acid (DHA) (an omega 3 fatty acid), or anti-inflammatory drugs such as ibuprofen (*e.g.*, Advil® or Motrin®). The successful development of a treatment or method of preventing Alzheimer s disease could significantly impact on our ability to develop or market a competing treatment for Alzheimer s disease.

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

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

# We May Not Be Able to Successfully Market Our Products

To increase our marketing, distribution and sales capabilities both in the United States and around the world, we will need to enter into licensing arrangements, contract sales agreements and co-marketing deals. We cannot assure you that we will be able to enter into agreements with other companies on terms acceptable to us, that any licensing arrangement will generate any revenue for the Corporation or that the costs of engaging and retaining the services of a contract sales organization will not exceed the revenues generated.

### Protecting Our Patents and Proprietary Information is Costly and Difficult

We believe that patent and trade secret protection is important to our business, and that our success will depend, in part, on our ability to obtain strong patents, to maintain trade secret protection and to operate without infringing the proprietary rights of others.

Obtaining and maintaining our patent position is costly. We pay for the filing, prosecution and fees of several hundred patents and patent applications in countries around the world, including the United States, Europe, Japan, Canada, Australia, New Zealand and South Korea. In the United States alone, Nymox has twenty-three patents issued or allowed relating to its technology. Our subsidiary, Serex, Inc. has thirteen patents.

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

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

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

We are not currently involved in patent litigation. In the pharmaceutical and biotechnology industry patent disputes are frequent and can preclude the commercialization of products. Patent litigation is costly and the outcome often difficult to predict. It can expose us to significant liabilities to third parties and may require us to obtain third-party licenses at a material cost or cease using the technology or product in dispute.

## **We Face Changing Market Conditions**

The healthcare industry is in transition with a number of changes that affect the market for therapeutic and diagnostic test products. The U.S. federal and various state governments have under consideration a number of proposals that may have the effect of directly or indirectly limiting drug prices in the U.S. markets. In March 2010, the United States enacted health care reform legislation. Important market reforms began this year and will continue through full implementation in 2014. The new law is expected to expand access to health care to more than 32 million Americans by the end of the decade. These changes may adversely affect the prices we may charge for any therapeutic drug we develop. Funding changes and budgetary considerations can lead major health care payers and providers to make changes in reimbursement policies for our products. These changes can seriously impact the potential for growth for the market for our products, either favorably when the decision is to offer coverage for our products at a reasonable price or negatively when the decision is to deny coverage altogether. Changes in the healthcare delivery system have resulted in consolidations and in the formation of multi-hospital alliances, reducing the number of institutional customers for therapeutic and diagnostic test products. There can be no assurance that Nymox will be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with these institutional customers.

### Health Care Plans May Not Cover or Adequately Pay for Our Products and Services

Throughout the developed world, both public and private health care plans are under considerable financial and political pressure to contain their costs. The two principal methods of restricting expenditures on drugs and diagnostic products and services are to deny coverage or, if coverage is granted, to limit reimbursement. For single-payer government health care systems, a decision to deny coverage or to severely restrict reimbursement for one of our products can have an adverse effect on our business and revenues.

In the United States, where, to a significant degree, the patient population for our products is elderly, Medicare and Medicaid are sources of reimbursement. In general, any restriction on reimbursement, coverage or eligibility under either program could adversely affect reimbursement to Nymox for products and services provided to beneficiaries of the Medicare and/or Medicaid programs. Many elderly people are covered by a variety of private health care organizations either operating private health care plans or Medicare or Medicaid programs subject to government regulation. These organizations are also under considerable financial constraints and we may not be able to secure coverage or adequate reimbursement from these organizations. Without coverage, we will have to look to the patients themselves who may be unwilling or unable to pay for the product; in turn, doctors may be reluctant to order or prescribe our products in the absence of coverage of the product for the patient.

# We Are Subject to Continuing Potential Product Liability Risks, Which Could Cost Us Material Amounts of Money.

We may be subject to product liability which could task our critical resources, delay the implementation of our business strategy, result in products being recalled or removed from the market, and materially and adversely harm our business and financial condition due to the costs of defending such legal actions or the payment of any judgments or settlements relating to such actions or both. Our business exposes us to the risk of product liability claims that is inherent in the development and marketing, distribution, and sale of pharmaceutical and diagnostic products. If any of our product candidates or marketed products harms people, or is alleged to be harmful, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, patients, health care providers, corporate partners or others.

We have product liability insurance covering our ongoing clinical trials and marketed products. Our insurance coverage may not be sufficient to cover fully all potential claims, nor can we guarantee the solvency of any of our insurers. If our claims experience results in higher rates, or if product liability insurance otherwise becomes costlier because of general economic, market or industry conditions, then we may not be able to maintain product liability coverage on acceptable terms. If sales of our products increase materially, or if we add significant products to our portfolio, then we will require increased coverage and may not be able to secure such coverage at reasonable rates or terms. If our insurance coverage is not sufficient to cover fully all potential claims, the Corporation would be exposed to the risk that our litigation costs and liability could exceed our total assets and our ability to pay.

## The Issuance of New Shares May Dilute Nymox s Stock

The Corporation relies almost exclusively on financing to fund its operations. In order to achieve the Corporation s business plan and realization of its assets and liabilities in the normal course of operations, the Corporation anticipates the need to raise additional capital and/or achieve sales and other revenue generating activities. The 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 32,588,856 common shares of Nymox issued and outstanding as of March 15, 2011. In addition, 5,328,000 share options are outstanding, of which 4,618,625 are currently vested. Expiry dates for Nymox options range from 1 month to 9.3 years (see note 8(b) to our consolidated financial statements). These options have been granted to employees, officers, directors and consultants of the Corporation. Moreover, Nymox may use its shares as currency in acquisitions. The Corporation depends on financing under the Common Stock Private Purchase Agreement to fund its operations. In order to achieve its business plan and the realization of its assets and liabilities in the normal course of operations, the Corporation anticipates the need to raise additional capital to meet the Corporation's requirements.

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

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

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

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

### ITEM 4. INFORMATION ON THE CORPORATION

### **History of the Corporation**

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

Nymox s principal executive offices are located at:

Nymox Pharmaceutical Corporation

9900 Cavendish Boulevard, Suite 306, St. Laurent, Quebec, Canada, H4M 2V2

Phone: (800) 936-9669 Fax: (514) 332-2227

Nymox s registered agent in the United States is:

CT Corporation System 111 Eighth Avenue, 13<sup>th</sup> Floor New York, NY, 10011

Nymox s two subsidiaries are located at:

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

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

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

## Acquisition of a Majority Interest in Serex, Inc.

In March 2000, we acquired a controlling interest in Serex, Inc., a privately held diagnostic Corporation based in New Jersey and now own approximately 99% of its common stock.

Serex s patented diagnostic technologies include its particle valence technology, a highly sensitive, new method to detect very small amounts of biochemical indicators in body fluids such as blood, urine and saliva. This technology can be adapted to detect a wide range of biochemical indicators for diseases, conditions and drug use. Our NicAlert and TobacAlert employ this technology to measure levels of one of the metabolic products of nicotine in human urine, in order to determine whether a person is using or has been exposed to a tobacco product. NicAlert and TobacAlert are currently being distributed by Nymox and Jant Pharmacal Corporation.

### **Products**

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

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

Smoking and other tobacco product use is a serious public health problem around the world. Smoking kills. According to the Centers for Disease Control and Prevention, cigarette smoking is responsible for more than 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 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., the U.K., and Spain for these products.

Our NicAlert and TobacAlert products face competition from clinical laboratories such as LabCorp and Quest Diagnostics which provide off-site lab testing for cotinine, the by-product of the body s breakdown of nicotine measured by NicAlert and TobacAlert , and from assay suppliers, including immunoassay developers such as OraSure Technologies Inc. and Abraxis LLC, and diagnostic system manufacturers such as Roche Diagnostics, Abbott and Diagnostic Products Corporation. NicAlert and TobacAlert also face competition from distributors who supply yes-no smoking status tests such as NicQuick, and QuickScreen, from NicCheck I, an FDA-cleared smoking status test being

marketed by Mossman & Associates Ltd, from SmokeScreen, a chemical color-based tobacco test being marketed by Mermaid Diagnostics, Ltd. in the United Kingdom, and from carbon monoxide (CO) monitors such as SmokeCheck.

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

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

Independent studies published in peer-reviewed medical and scientific journals reported finding that the Corporation's NicAlert Saliva product provides an accurate, convenient and cost-effective way to verify self-reported smoking status with broad potential applications both in the clinic and in large research trials and surveys. In 2008, one such study, Fiona Cooke et al. Diagnostic accuracy of NicAlert cotinine test strips in saliva for verifying smoking status, *Nicotine Tob Res.* 2008;10:607-12, was published in *Nicotine & Tobacco Research*, the official journal of the Society for Research on Nicotine and Tobacco (SRNT).

Other published studies include *Cancer Epidemiol Biomarkers Prev.* 2007; 16:1858-62 and *Int J Circumpolar Health.* 2007; 66 Suppl 1:29-38.

NicAlert Saliva was also reported used in research studies where there was a need to verify or monitor smoking status or nicotine replacement therapy (NRT): see, for example, *Am J Prev Med.* 2007; 33:297-305 (monitoring NRT in smoking cessation research involving pregnant women), *Int J Behav Med.* 2006; 13:16-25 (verifying smoking status in a smoking study of cancer patients), and *Neuropsychopharmacology* 2008; 33:480 490 (confirming non-smoking status for entry into the study).

# AlzheimAlert; an Aid to the Diagnosis of Alzheimer s Disease

We have developed AlzheimAlert , a proprietary urine assay that can aid physicians in the diagnosis of Alzheimer s disease. We have developed a kit version of the AlzheimAlert assay for sale in Europe. The AlzheimAlert kit has the CE Mark. The kit allows clinical reference laboratories to perform the AlzheimAlert assay on site with urine samples sent directly to the laboratory. We filed a premarket approval (PMA) application for the diagnostic kit version of the AlzheimAlert test with the FDA in February 2004. On July 15, 2005, an FDA advisory panel voted 5-2 against approval of the kit, citing the need for further studies, such as long term follow-up and autopsy confirmation.

The AlzheimAlert assay is based on research by scientists at the Massachusetts General Hospital and Brown University and on years of clinical studies to establish and confirm the accuracy of the assay technology as an aid to the diagnosis of Alzheimer s disease. In 1997, Nymox succeeded in developing a commercial assay that used spinal fluid samples. Subsequently, Nymox was able to develop an assay that used more easily obtained first morning urine samples. The AlzheimAlert assay represents the latest generation of development of this testing technology.

Nymox licensed the technology that led to the development of the AlzheimAlert assay in 1997 from the Massachusetts General Hospital as part of a sponsored research and licensing agreement, under which Nymox sponsored the research of the principal investigators into the use of neural thread protein (NTP), its antibodies or genes for diagnostic or therapeutic purposes. Nymox also paid the patent costs for the patent applications filed arising out of this research. In return, Nymox received an exclusive worldwide license of the patents to sell products and to use processes encompassed by them. Nymox is to pay the Massachusetts General Hospital a 4% royalty of the net sales price of any product developed and sold under the license. Nymox currently pays this royalty on its sales of its AlzheimAlert product. The license and the obligation to pay patent costs and royalties continue for the life of the patents, which run until November 2014 at the earliest. The Massachusetts General Hospital has the right to terminate the license in any country where, after the first commercial sale of the product in the country, there is a continuous two year period in which no product is sold in such country. There are eight issued U.S. patents under license and a larger number of patents and patent applications in Europe, Japan, Canada, Australia, New Zealand and South Korea. The sponsored research portion of this agreement terminated in March 1999. Nymox retained the exclusive license to the rights to the AlzheimAlert -related patents owned by the Massachusetts General Hospital.

Effective March 1999, Nymox entered into a similar sponsored research and licensing agreement with Brown University and the Rhode Island Hospital. Under the terms of this agreement, Nymox continued to sponsor research into the uses of neural thread proteins, their antibodies or genes for diagnostic, therapeutic and research purposes and to pay the patent costs for any patent applications filed arising out of this research. In return, Nymox received an exclusive worldwide license of any such patents to sell products and to use processes encompassed by them. The Rhode Island Hospital has the right to terminate the license in any country where, after the first commercial sale of the product in the country, there is a continuous two year period in which no product is sold in such country. Nymox is to pay the Rhode Island Hospital a 4% royalty of the net sales price of any product developed and sold under the license. The sponsorship of this agreement expired in March 2005; however, Nymox retains the exclusive license to patent

rights on certain NTP-based technology including a license to two issued U.S. patents.

The successful results of a multi-center double blind independent clinical study of the Corporation's urinary AlzheimAlert test were published in the January 2007 issue of the *Journal of the American Medical Directors Association (J Am Med Dir Assoc.* Jan 2007; 8:21-30; A multi-center blinded prospective study of urine neural thread protein measurements in patients with suspected Alzheimer's disease, Goodman I et al.). The independent peer-review study from 8 prestigious centers across the U.S. found the level of accuracy of the AlzheimAlert urine test to be over 90%. The study was double-blind and involved expert assessments and state of the art clinical correlations and continued evaluations.

In January 2007, a second peer-reviewed report was published in the *Journal of Clinical Laboratory Analysis* providing further positive data on the accuracy and utility of the Corporation's urinary AlzheimAlert test (*J Clin Lab Anal.* Jan 2007;21:24-33, Competitive ELISA studies of neural thread protein in urine in Alzheimer's disease ). The paper reported excellent performance in laboratory studies and impressive reproducibility of clinical test results for patients and controls who were re-tested at intervals ranging from 2 days to 4.5 years.

Recent publications in the peer-reviewed literature concerning the clinical utility of the assay in the diagnosis of Alzheimer's disease include, for example, the *Journal of Clinical Investigation* (1997; 100: 3093-3104); *Journal of Contemporary Neurology* (1998; art. 4a); *Journal of Clinical Laboratory Analysis* (1998; 12: 285-288) and (1998; 12: 223-226); *Alzheimer's Reports* (1999; 2: 327-332), (2000; 3: 177-184), (2001; 4: 61-65) and (2002; 5: 1-6); *Neurology* (2000; 54: 1498-1504) and (2000; 55: 1068); *Journal of Alzheimer's Disease* (2001; 3: 345-353) and (2004; 6(3): 231-42); *Cellular and Molecular Life Sciences* (2001; 58: 844-849) and (2003; 60: 2679-91); *Neurology and Clinical Neurophysiology* (2002; 1: 2-7); *Journal of Neuropathology and Experimental Neurology* (2001; 60: 195-207) and (1996; 55: 1038-1050), *Frontiers in Bioscience* (2002; 7: d989-96), *Journal of the American Medical Directors Association* (Jan 2007; 8:21-30), *Journal of Clinical Laboratory Analysis* (Jan 2007; 21:24-33), *Expert Review of Molecular Diagnostics* (January 2008; 8:21-28) and *Journal of the American Medical Directors Association* (Article in press; published online October 1, 2010; doi:10.1016/j.jamda.2010.03.004).

Nymox believes that its AlzheimAlert test can assist a physician faced with the task of diagnosing whether a patient has Alzheimer's disease. A recently published independent peer-reviewed double blind study from 8 prestigious centers across the U.S. found the level of accuracy of the AlzheimAlert urine test to be over 90% (*Journal of the American Medical Directors Association* Jan 2007; 8:21-30; A multi-center blinded prospective study of urine neural thread protein measurements in patients with suspected Alzheimer's disease, Goodman I *et al.*). This study confirmed several earlier Corporation funded trials of the AlzheimAlert technology. In earlier studies, the test results were positive for over 87% of the patients with verified Alzheimer disease and negative in over 89% of subjects without the disease (known as a low false positive rate). The low rate of positive results for patients without the disease is important for doctors investigating patients with subtle or marginal symptoms of mental, emotional, cognitive, or behavioral changes. If the doctor can rule out Alzheimer's with more assurance, a great deal of patient and family anguish and anxiety will be avoided. A low test score will help the doctor to be more certain that Alzheimer's disease is not the cause of the patient's symptoms and to target the other, often reversible causes of the patient's symptoms, such as depression. There can be no assurance that further studies will repeat the same level of success experienced to date.

There is a large need for a simple, non-invasive test that can aid in the diagnosis of Alzheimer's disease. According to 2010 Alzheimer's Disease Facts and Figures, U.S. Alzheimer's Association, Alzheimer's disease is the most common cause of dementia and is the seventh leading cause of death in the United States. It is estimated that as many as 5.3 million people have Alzheimer's disease in the United States alone. By 2050 this number is projected to increase to between 11 and 16 million Americans. The annual national direct and indirect costs of caring for Alzheimer patients in the U.S. alone are estimated to be over \$200 billion a year. The human toll on patients, families and caregivers is incalculable. Despite the need for an accurate clinical test, the definitive diagnosis of the disease is possible only after the death of the patient by expert, pathologic examination of brain tissue.

The U.S. Surgeon General s Report on Mental Health, released on December 13, 1999, identified the importance and the need for the early detection and diagnosis of Alzheimer s disease. The report described the current approach to Alzheimer s disease diagnosis, clinical examination and the exclusion of other common causes of its symptoms, as time- and labor-intensive, costly and largely dependent on the expertise of the examiner. As a result, the illness is currently under-recognized, especially in primary care settings, where most older patients seek care. The report joined other experts writing in the field in recognizing the need for a better, more reliable method for diagnosing the disease in living patients and in particular, the need for a simple, accurate and convenient test that could detect a biochemical change early in patients with Alzheimer s disease. We believe our AlzheimAlert product provides such a test.

The early diagnosis of Alzheimer s disease is important to physicians, patients and their families and enables them to make informed and early social, legal and medical decisions about treatment and care. Early diagnosis of Alzheimer s disease has become increasingly important with new improvements in drug treatment and care. Even a modest delay in institutionalization can mean substantial social and financial savings. Conversely, any testing procedure that could rule out Alzheimer s disease would eliminate the tremendous uncertainty and anxiety patients and their families otherwise face and would allow physicians to focus on the other, often reversible, causes of cognitive changes.

Early diagnosis as facilitated by the AlzheimAlert test represents a potentially large cost-savings in the form of a reduced number of office visits, lab tests, scans and other procedures required by the traditional methods of diagnosis.

In the field of Alzheimer s disease diagnosis, our AlzheimAlert test faces growing competition which could detrimentally impact on our ability to successfully market and sell our diagnostic test. Our competitors include:

• Athena Diagnostics, Inc., which is currently marketing three tests claimed to aid in the diagnosis of Alzheimer's disease: a genetic test for the rare cases of familial, early-onset Alzheimer's disease; a genetic test

for a relatively common mutation of a gene said to increase the likelihood of a person with at least one of the genes contracting the disease; and a test for two proteins in the spinal fluid of patients.

- Innogenetics NV, a Solvay Pharmaceuticals Corporation, which currently markets tests and kits for two proteins and a variant of one of these proteins in the spinal fluid of patients and a genetic test for a relatively common mutation of a gene said to increase the likelihood of a person developing the disease.
- Amorfix Life Sciences Ltd. currently markets a research test to detect aggregated amyloid protein in brain test and has under development related blood and CSF test.

There are also a number of other proposed biochemical signs of the disease that could potentially be developed into a commercial diagnostic test as well as various scanning and imaging technologies which compete for a portion of the diagnostic market for Alzheimer's disease. On January 20, 2011, an FDA Advisory Committee panel recommended against the approval at that time of Lilly's Amyvid (florbetapir), a molecular imaging tool developed to detect beta-amyloid plaque in the brain. The Committee's decision left open the possibility of approval at a later time after a further study is completed. A number of companies, including GE, are actively working to develop imaging technologies for the diagnosis of Alzheimer's disease. In June 2004, the CMS approved limited coverage of a Positronic Emission Tomography (PET) imaging procedure for helping to more precisely distinguish Alzheimer's disease from a rarer type of dementia when clinical evaluation has been inconclusive. In October 2004, the National Institute on Aging in conjunction with other Federal agencies, private companies and organizations launched the Alzheimer's disease Neuroimaging Initiative, a \$60 million initiative to test whether various scanning and imaging technologies, biochemical markers, and clinical and neuropsychological testing can be combined to help diagnose early Alzheimer's disease.

## **Products in Development:**

# NX-1207 for Enlarged Prostate (BPH)

We are developing treatments for enlarged prostate (benign prostatic hyperplasia or BPH), using novel compounds. Our lead candidate NX-1207, which successfully completed a multi-center, double-blind, placebo-controlled Phase 2 trial in September 2006, is presently in Phase 3. We cannot predict with any certainty the outcome of this trial, what further steps may be required in order to apply for final FDA approval for this drug or whether the FDA will ultimately grant us such approval.

There is a significant need for an effective treatment for BPH. More than half of men in their sixties and as many as 90% of men in their seventies and eighties have the symptoms or signs of BPH according to the 2010 AUA Guideline on the Management of Benign Prostatic Hyperplasia, American Urological Association. Symptoms include more frequent urination (especially at night), difficulty urinating, incomplete emptying of the bladder and sometimes complete inability to urinate. More serious cases may require surgical intervention to reduce the size of the prostate. There is a need for a simple, effective treatment for BPH, particularly in cases where existing drug treatments have proven to be ineffective and where more intrusive procedures such as surgery may be inadvisable or bring unacceptable risks.

NX-1207 showed positive results for the treatment of BPH in Phase 1 and 2 clinical trials in the U.S. The Corporation successfully completed a 43 site prospective randomized double-blinded placebo controlled Phase 2 U.S. clinical trial of NX-1207 in 2006, which showed statistically significant efficacy and a good safety profile. In February 2008, the Corporation reported positive results in a 32 site U.S. Phase 2 prospective randomized blinded clinical trial, with statistically significant improvement compared to an approved BPH drug (finasteride). Nymox reported positive results in twelve follow-up studies of available subjects from the completed Phase 1 and 2 clinical trials.

In February 2009, the Corporation reported concluding a positive and productive EOP2 meeting with the FDA concerning the Phase 3 program for NX-1207. In June 2009, the Corporation began conducting the first of two pivotal double blind placebo controlled Phase 3 trials for NX-1207 that incorporate the specific protocol design recommendations provided to the Corporation by the FDA. The two pivotal Phase 3 studies for NX-1207 are being conducted at well known investigational sites across the U.S. with planned enrollment of 1,000 patients.

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

### NX-1207 for Prostate and Liver Cancer

We are also developing NX-1207 as a focal treatment for certain types of cancer. On August 26, 2009, Nymox announced that NX-1207 has been shown to produce strongly positive results when given to animals with hepatocellular carcinoma (HCC). In the experimental studies, the cancers were significantly reduced in size after 2 local injections of NX-1207. On October 14, 2009, we announced that NX-1207 had been shown to produce strongly positive results in laboratory studies of human prostate cancer. In addition, local injection of NX-1207 showed activity in animals with transplanted human prostate carcinoma. The NX-1207 used in these studies is a higher dosage from that of NX-1207 used to treat benign prostatic hyperplasia (BPH).

The Corporation intends to advance NX-1207 into human clinical trials for the treatment of HCC and for the focal treatment of localized prostate cancer. We cannot predict with any certainty whether the use of NX-1207 for any oncological indication will successfully complete preclinical testing, whether government regulatory agencies, such as the FDA, will permit such products to proceed to human trials, or whether ultimately the use of NX-1207 for any such indications will be granted approval for sale and marketing in the U.S., Canada, or elsewhere in the world. The development of cancer therapeutics in particular is associated with high risks and many uncertainties and a drug candidate that shows efficacy in pre-clinical testing and in animal models may fail in human trials or take a long period (7 years or more) to achieve regulatory approval.

## NXC-4720 for E. coli Contamination of Meat

We are developing novel antibacterial agents for the treatment of *E. coli* O157:H7 bacterial contamination in hamburger meat and other food and drink products and for the treatment of urinary tract and other bacterial infections in humans which have proved highly resistant to conventional antibiotic treatments.

*E. coli* contamination of food and drink is a serious public health problem worldwide and a major concern for meat processors in particular. *E. coli* bacteria occur normally and usually harmlessly in the gastrointestinal tracts of humans, cows and other animals. However, one mutant variety of the E. coli bacteria, *E. coli* O157:H7, can cause life-threatening illness and has been implicated in cases of severe diarrhea, intestinal bleeding and kidney failure, leading, in some cases, to death in children and the elderly. *E. coli* contamination in hamburger meat and other food products and in drinking water affects about 70,000 people in the United States a year.

There is a well-recognized need in the beef industry to address the problem of *E. coli* contamination in meat processing and in livestock. *E. coli* contamination has triggered massive recalls of ground beef in the U.S. Cattle are a natural reservoir for the deadly strain of *E. coli*. Water contamination from cattle operations have led to public health tragedies.

Nymox developed a potent new antibacterial agent, NXC-4720. Tests of NXC-4720 show it to be highly effective against all known substrains of *E. coli* O157:H7, destroying the bacteria efficiently, rapidly and at a very low dose. In 1999, we began further laboratory trials for this agent as a treatment for food and drink contamination and entered into agreements with various collaborators. NXC-4720, which is being developed as a treatment of meat at the processing stage, has been shown to be capable of substantially reducing the level of potentially fatal *E. coli* O157:H7 contamination on fresh beef according to laboratory studies. Other projects in this area, such as treating *E. coli* O157:H7 infection in livestock, are in preliminary stages of development. Further pre-clinical testing and development is required before we can apply for regulatory approval for use of this agent on the processing of food and drink for human consumption.

The problem of *E. coli* O157:H7 contamination of hamburger meat and other food products is also well-known and a number of companies and researchers have been pursuing various potential solutions, including irradiation with x-rays, better detection of contamination, electronic pasteurization, vaccination and competitive exclusion of the pathogenic *E. coli* bacteria by harmless bacteria. The development of alternative solutions to the problem of E. coli infection may adversely affect the market for our treatment for *E. coli* O157:H7 infection in cattle and contamination of food products.

Nymox has also developed three other novel antibacterial agents, NXB-4221 for the treatment of difficult chronic and persistent urinary tract infections; NXB-5886 for the treatment of streptococcal infection; and NXT-1021 for the treatment of staphylococcal infection. Urinary tract infections in women caused by bacteria such as *E. coli* are a common and significant infection often resistant to conventional antibiotic treatment. Some varieties of streptococcus and staphylococcus bacteria, a common source of infection in humans, have acquired a broad immunity to antibiotic treatments. Infections from these antibiotic resistant bacteria are difficult to treat and can be life threatening.

Nymox s three antibacterial agents for the treatment of infectious disease have all shown the ability to kill their bacterial targets in culture with no signs of toxicity. Further pre-clinical testing and development is required before we can apply for regulatory approval to begin initial testing in humans.

A similar competitive reality prevails in the field of novel anti-infectives. Over the past ten years, there has been an increasing awareness of the medical need and of emerging market opportunities for new treatments for antibiotic

resistant bacterial infections. Many of the major pharmaceutical companies are developing anti-infective drugs that either modify their existing drugs or involve new anti-bacterial properties. Many biotechnology companies are developing new classes of anti-bacterial drugs. At least three major pharmaceutical companies have vaccines against bacterial infections in development. To the extent that these companies are able to develop drugs or vaccines that offer treatment for some or all of the indications for our anti-infectives, the market for our products may be adversely affected.

Nymox has patent rights to these and other antibacterial agents.

### The Use of Statin Drugs for the Treatment or Prevention of Alzheimer's Disease

In October 2002, we were issued a United States patent for the use of statin drugs to treat, prevent or reduce the risk of the onset of Alzheimer s disease and have issued patents or pending patent applications elsewhere, including Europe, Japan, Canada and Australia. Statins are a class of commonly prescribed cholesterol lowering drugs that have a well-established safety record and are widely available. The potential of statin drugs for AD has been featured in a cover story in Newsweek, as well as in the New York Times, Fortune, Los Angeles Times, and The Wall Street Journal. Some of the recent scientific studies and reviews concerning the potential for statin drugs to treat or reduce the risk of AD or loss of cognitive function include Neurology. 2007; 69:1873-80; Expert Opinion on Ther Targets. 2007; 11:1257-60; CNS Drugs. 2007;21:449-62; Neurosci Lett. 2007;416:279-84; Curr Med Chem. 2007;14:103-12; Neurol Res. 2006; 28:630-6, Acta Neurol Scand 2006; 114 (Suppl. 185): 78-86, Acta Neurol Scand 2006; 114 (Suppl. 185): 3 7, J.Neurochem. 2006; 97:716-723; Restor. Neurol. Neurosci 2006; 24:79-95; Neuromolecular Med. 2006; 8:319-328, Neurology 2005; 65:1388-1394, J. Neurol. Neurosurg. Psychiatry 2005; 76:1624-1629, The American Journal of Medicine 2005; 118: 48S-53S; The Lancet Neurology 2005; 4:841-852; Current Opinions in Lipidology 2005;16: 619-623; The Lancet Neurology 2005; 4: 521-2, Arch Neurol 2005; 62:1047-51, Neurology 2005; 64:1531-8, Arch Neurol 2005; 62:753-7, J Neurol Sci 2005; 229-230:147-50, Arch Gen Psychiatry 2005; 62:217-24. International Journal of Geriatric Psychiatry (2004; 19:327-32), Neuroepidemiology (2004; 23:94-8); Neuron (2004; 41:7-10); Archives of Neurology (2000; 57:1439-1443); Lancet (2000; 356:1627-1631); Archives of Neurology (2002; 59:223-227); Journals of Gerontology: Biological Sciences and Medical Sciences (2002; 57:M414-M418); and Journal of the American Geriatrics Society (2002;50:1852-1856). Some studies, however, have not found evidence that statins may help treat or prevent Alzheimer s disease and research in this area is ongoing. No statin drug has been approved for use in the treatment or prevention of Alzheimer s disease.

## **Research and Development of New Products**

## New Therapeutics for Alzheimer s Disease

Nymox has a number of proprietary drug development programs aimed at treatments for Alzheimer's disease and other indications. One program targets NTP and its role in the extensive brain cell loss associated with AD. Another program is 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. A third program is based on a novel drug candidate, NXD-5150, for neurodegenerative disease.

At present, there is no cure for Alzheimer s disease. There are five drugs approved by the FDA, tacrine (brand-name Cognex®), donepezil HCI (brand-name Aricept®), rivastigmine (brand-name Exelon®), galantamine hydrobromide (brand name Razadyne®) and memantine (brand name Namenda®) for the treatment of Alzheimer s disease. However, at most these drugs offer symptomatic relief for the loss of mental function associated with the disease and possibly help to delay the progression. There is no consensus as to the cause of Alzheimer s disease or even whether it is one disease or many.

There is an urgent need for an effective treatment for the illness, caused in part by the rising health care, institutional and social costs for the treatment and care of Alzheimer's disease sufferers. The Surgeon General's Report on Mental Health released on December 13, 1999, put the direct health care costs for the illness in the United States at almost \$18 billion for 1996. In April 2002, the National Institute on Aging reported that the cost of care to family, caregivers and society in general was estimated to exceed \$100 billion per year.

These costs are expected to rise sharply as the baby boom generation ages and more people become at risk for the disease. According to the National Institute on Aging s 2009 Progress Report on Alzheimer s Disease: Discovery and Hope, experts agree that the number of people with AD will increase significantly if current population trends continue and no preventive treatments become available. As people live longer, they become more at risk of developing Alzheimer s disease. The U.S. Census Bureau estimates that the number of people in the U.S. aged 65 and older is expected to double to about 72 million people in the next 25 years. Moreover, the 85-and-older age group is now the fastest growing segment of the U.S. population.

Nymox s research into drug treatments for Alzheimer s disease is aimed at compounds that could arrest the progression of the disease and therefore are targeted for long term use.

### **Drugs Targeting Spherons**

We are a leader in research and development into drugs for the treatment of Alzheimer's disease that target spherons. Nymox researchers believe that spherons are a cause of senile plaques, the characteristic lesion found abundantly in the brains of patients with Alzheimer's disease and believed by many researchers to play a pivotal role in the fatal illness. Spherons are tiny balls of densely packed protein found in brain cells scattered throughout the brains of all humans from age one. Nymox researchers have found that as humans age the spherons grow up to a hundred times larger until they become too large for the cells that hold them. Once released from the cells, the researchers believe that the spherons burst, creating senile plaques, contributing to the cellular damage and biochemical changes pivotal to the symptoms and signs of Alzheimer's disease.

The substantial evidence linking spherons to senile plaques and Alzheimer s disease has been published in journals such as the

Journal of Alzheimer s Disease, Drug News & Perspectives and Alzheimer Reports. There are 20 important criteria of validity which have been set forth correlating the disappearance of spherons in old age with the appearance of senile plaques and implicating spherons as a major cause in Alzheimer s disease. In 2000, Nymox researchers published important findings in Alzheimer Reports (2000; 3: 177-184) confirming that spherons contain key proteins that are also known to be in senile plaques and showing that, like senile plaques, spherons contain unusually old proteins in terms of the human body s metabolism, with an average age of 20 to 40 years. In 2003, Nymox announced the discovery that spherons contain toxic molecules termed spherotoxins which its researchers believe contribute significantly to the cell death and symptoms characteristic of Alzheimer's disease.

Nymox researchers believe that stopping or inhibiting the transformation of spherons into senile plaques will help stop or slow the progress of this illness. However, there is no consensus among researchers about the causes or possible treatments of Alzheimer s disease and not all researchers share this belief that spherons are a causative factor in Alzheimer s disease or are a target for the development of treatments for the disease.

Based on the research findings discussed above and the spheron-based approach to the treatment of the disease, we have developed novel, proprietary drug screening methods based on spherons and used them to discover, develop and test drug candidates to inhibit the formation of Alzheimer plaques from spherons. We believe these candidates have the potential to slow or stop the progression of the disease.

We have two distinct new drug candidates, NXD-3109 and NXD-1191, neither of which demonstrate significant toxicity and both of which had positive animal testing results. These candidates are at the stage of pre-clinical testing.

Such drug candidates will require regulatory approval in order to begin clinical studies for humans, but there is no guarantee that any of these drug candidates will ever be approved for marketing as a treatment for Alzheimer s disease. Drug candidates that look promising in early studies in the laboratory or with animals often prove on further testing to be unsafe, ineffective or impractical to use with human patients. The cost of bringing a drug candidate through the necessary clinical trial and regulatory approvals is very high and may require us to seek substantial financing through various sources including the issuing of more stock, the borrowing of funds secured by financial instruments such as bonds or agreements with major pharmaceutical companies. We risk not being able to secure such funding in the necessary amounts or on sufficiently favorable terms.

Nymox holds global patent rights covering both methods for using spherons as targets for developing drugs and for the actual drug candidates discovered.

## Neural Thread Protein Based Drugs

Nymox developed a drug screening system, based on the research that led to its AlzheimAlert test, to identify other potential drug candidates for the treatment of Alzheimer's disease. There is a substantial body of evidence showing that NTP may play a key role in Alzheimer's disease, including such published studies as *Journal of the Neurological Sciences* (1996; 138: 26-35), *Journal of Neuropathology and Experimental Neurology* (1996; 55: 1038-50) and (2001; 60: 195-207), *Journal of Clinical Investigation* (1997; 100: 3093-3104), *Alzheimer's Reports* (1999; 2: 327-332), *Journal of Alzheimer's Disease* (2001; 3: 345-353) and (2005; 7(1): 45-61), and *Cellular and Molecular Life Sciences* (2001; 58: 844-849) and (2003; 60:2679-91).

Nymox licensed the NTP technology in 1997 from Harvard University and the Massachusetts General Hospital as part of a sponsored research and licensing agreement. Under the terms of this agreement, Nymox sponsored the research of the principal investigators into the use of neural thread protein, its antibodies or genes for diagnostic or therapeutic purposes. Nymox also paid the patent costs for the patent applications filed arising out of this research. In return, Nymox received an exclusive worldwide license of the patents to sell products and to use processes encompassed by them. Nymox is to pay the Massachusetts General Hospital a 4% royalty of the net sales price of any product developed and sold under the license. Nymox currently pays this royalty on its sales of its AlzheimAlert product. The license and the obligation to pay patents costs and royalties continue for the life of the patents, which run until November, 2014 at the earliest. The Massachusetts General Hospital has the right to terminate the license in any country where, after the first commercial sale of the product in the country, there is a continuous two year period in which no product is sold in such country. There are eight issued U.S. patents under license and a larger number of patents and patent applications in Europe, Japan, Canada, Australia, New Zealand and South Korea. The sponsored research portion of this agreement terminated in March, 1999. Nymox retained the exclusive license to the rights to the NTP-related patents owned by the Massachusetts General Hospital.

Effective March 1999, Nymox entered into a similar sponsored research and licensing agreement with Brown University and the Rhode Island Hospital. Under the terms of this agreement, Nymox continued to sponsor research into the uses of neural thread proteins, their antibodies or genes for diagnostic, therapeutic and research purposes and to pay the patent costs for any patent applications filed arising out of this research. In return, Nymox received an exclusive worldwide license of any such patents to sell products and to use processes encompassed by them. The Rhode Island Hospital has the right to terminate the license in any country where, after the first commercial sale of the product in the country, there is a continuous two year period in which no product is sold in such country. Nymox is to pay the Rhode Island Hospital a 4% royalty of the net sales price of any product developed and sold under the license.

The sponsorship agreement expired in March 2005; however, Nymox retains the exclusive license to patent rights on certain NTP-based technology including a license to two issued U.S. patents.

Nymox has screened compounds for their ability to impede the process of premature cell death and thus potentially help slow or halt the loss of brain cells in the Alzheimer s disease brain. This screening process identified promising drug candidates. The Corporation has developed a candidate, NXD-9062, which has shown significant progress in preclinical studies but successful completion of other pre-clinical studies is necessary before it can move into formal regulatory studies.

The Corporation s third program is based on a new drug candidate for neurodegenerative disease, NXD-5150, which successfully completed important pre-clinical milestones. Nymox has exclusive rights to two patent applications covering NXD-5150 as well as other related drug candidates for neurodegenerative disorders.

Nymox faces intense competition for the development of an effective treatment for Alzheimer's disease. The market conditions for an Alzheimer's disease drug strongly favor the entry of other corporations into the area. This market is expected to grow rapidly as new drugs enter the market and as the baby boom generation becomes more at risk for developing Alzheimer's disease. As a result, most of the major pharmaceutical companies and many biotechnology companies have ongoing research and development programs for drugs and treatments for Alzheimer's disease. Many of these companies have much greater scientific, financial and marketing resources than we have and may succeed in developing and introducing effective treatments for Alzheimer's disease before we can. At present, four drugs for Alzheimer's disease are being widely marketed in the United States, Aricept® by Pfizer, Exelon® by Novartis, Razadyne® by Janssen and Namenda® by Forest. These four drugs only treat some of the symptoms of Alzheimer's disease by enhancing memory and other mental functions and not the underlying causes of the illness.

## **Oncology products**

We are in the preclinical stage of developing therapeutic products for oncological indications based on technology licensed from the Massachusetts General Hospital. We cannot predict with any certainty whether any such product 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 any such product will be granted approval for sale and marketing in the U.S., Canada, or elsewhere in the world.

### New Diagnostic Products

Nymox has a number of proprietary diagnostic markers and technologies, including a patented platform for point-of-care testing, and has tests utilizing these technologies in the early stages of development. Nymox also has U.S. patents for a method and device for using saliva to determine cholesterol levels and for a method of testing for osteoporosis. The Corporation also owns patent rights to several novel biochemical indicators for Alzheimer s disease.

## **Manufacturing Arrangements**

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

## **Property and Equipment**

Nymox and Serex laboratory facilities in Hasbrouck Heights, New Jersey comprise 4,799 square feet of leased space. That lease agreement expires October 31, 2013. Nymox office and research facilities in St. Laurent, Quebec, Canada comprise 11,210 square feet of leased space. The lease agreement expires on August 31, 2012. Nymox Pharmaceutical Corp. and its two US subsidiaries Nymox Corp. and Serex, Inc. own a full complement of equipment used in all aspects of their research and development work. Nymox believes that its facilities are adequate for its current needs and that additional space, if required, would be available on commercially reasonable terms.

# **Governmental Regulation**

Our AlzheimAlert test is subject to extensive government regulation in the United States. Any changes in CMS or state law requirements or in the FDA regulations could have an impact on our future ability to offer or market any reference laboratory services and/or on our ability to obtain reimbursement from the Medicare and Medicaid programs and providers.

We have developed a diagnostic kit version of the AlzheimAlert test. We will need to obtain FDA approval before we can market or sell such a diagnostic kit version outside of the clinical reference laboratory setting in the United States. Such approval for this type of commercial development is necessary for all in vitro diagnostic kits. On July 15, 2005, an FDA advisory panel voted 5-2 against recommending approval of our PMA application for the kit, citing the need for further studies, such as long term follow-up and autopsy confirmation. We cannot predict with any certainty when or if FDA approval will be forthcoming and we anticipate that more clinical testing or further documentation will be required before approval. If approved, the diagnostic kit would then be subject to postmarketing record and reporting obligations and manufacturing requirements.

Similar requirements exist in many other countries. In November 2004, Nymox satisfactorily completed the testing and registration required by European regulatory, environmental and quality standards in order to obtain a CE Mark for the AlzheimAlert kit. The CE Mark makes the AlzheimAlert kit eligible for sale in the European Union and enables European clinical and hospital laboratories to perform the AlzheimAlert test in their own facilities in Europe.

The regulatory process leading to such approval can be time-consuming and expensive and can result in an outright denial or a very limited approval only. AlzheimAlert will be subject to premarketing and postmarketing requirements applicable to such devices, including those governing:

- clinical testing;
- design control procedures;
- prior FDA approval of a 510(k) application, where the FDA has determined that our diagnostic device is substantially equivalent to a marketed device, or a premarket approval application, where the FDA has been satisfied with clinical studies demonstrating the safety and efficacy of our device;
- postmarketing record and reporting obligations; and
- good manufacturing practices.

The requirements for a premarket approval application are analogous to those for the approval of a new drug and include four categories of information: indications for use, device description and manufacturing methods, alternative practices and procedures for the diagnosis of the disease and clinical and nonclinical studies. The requirements for a 510(k) application are generally less onerous but still include indications for use, safety and effectiveness data as well as manufacturing and quality assurance data and information. There can be no assurance that the AlzheimAlert test or any other medical device that we may develop in the future will obtain the necessary approvals within a specified time framework, if ever. In addition, the FDA may impose certain postmarketing requirements that may significantly increase the regulatory costs associated with our product. The FDA has recourse to a wide range of administrative sanctions and civil and criminal penalties in order to enforce the applicable laws, rules and regulations.

Our therapeutic products under development by Nymox would also have to receive regulatory approval. This is a costly, lengthy and risky process. In the United States, in order for a product to be marketed, it must go through four distinct development and evaluation stages:

#### **Product Evaluation**

We must conduct preliminary studies of potential drug candidates using various screening methods to evaluate them for further testing, development and marketing.

## Optimization of Product Formulation

The activities in this stage of development involve consultations between us and investigators and scientific personnel. Preliminary selection of screening candidates to become product candidates for further development and further evaluation of drug efficacy is based on a panel of research based biochemical measurements. Extensive formulation work and in vitro testing are conducted for each of various selected screening candidates and/or product candidates.

## Clinical Screening and Evaluation

During this phase of development, portions of which may overlap with product evaluation and optimization of product formulation, initial clinical screening of product candidates is undertaken and full scale clinical trials commence. The FDA must approve any clinical testing on healthy subjects (Phase 1) and on patients (Phase 2 and 3).

## Final Product Development

The activities to be undertaken in final product development include performing final clinical evaluations, conducting large-scale experiments to confirm the reproducibility of clinical responses, making clinical lots for any additional extensive clinical testing that may be required, performing any further safety studies required by the FDA, carrying out process development work to allow pilot scale production of the product, completing production demonstration runs for each potential product, filing new drug applications, product license applications, investigational device exemptions (and any necessary supplements or amendments) and undergoing comprehensive regulatory approval programs and processes.

We cannot assure you that we will successfully complete the development and commercialization of any therapeutic products.

In the United States, obtaining the necessary FDA approval for any drug is a lengthy, expensive and often arduous process. We cannot predict with any certainty the amount of time the FDA will take to approve one of our drugs or even whether any such approval will be forthcoming. Similar requirements exist in many other countries.

In the United States, the FDA approval procedure is a two-step process. We must file an investigational new drug (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 benign prostatic hyperplasia. We cannot predict with any certainty the outcome of future trials, what further steps may be required in order to apply for final FDA approval for this drug or whether the FDA will ultimately grant us such approval.

We must also obtain approval for our drugs or diagnostic devices from the comparable regulatory authority in other countries before we can begin marketing our product in that country. The approval procedure varies from country to country and can involve additional testing. The time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general each country has its own procedures and requirements, many of which are time-consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed.

After such approvals are obtained, further delays may be encountered before the products become commercially available. If, subsequent to approval, new information becomes available concerning the safety or effectiveness of any approved product, the regulatory authority may require the labeling for the affected product to be revised or the product to be withdrawn. Our manufacturing of any approved drug must conform with the FDA s good manufacturing practice regulations which govern the production of pharmaceutical products and be subject to inspections and compliance orders.

Government regulation also affects our ability to receive an appropriate level of reimbursement for our products. Throughout the developed world, both public and private health care plans are under considerable financial and political pressure to contain their costs. The two principal methods of restricting expenditures on drugs and diagnostic products and services are to deny coverage or, if coverage is granted, to limit reimbursement. For single-payer government health care systems, a decision to deny coverage or to severely restrict reimbursement for one of our products can have an adverse effect on our business and revenues.

In the United States, where, to a significant degree, the patient population for our products is elderly, Medicare and Medicaid are sources of reimbursement. In general, any restriction on reimbursement, coverage or eligibility under either program could adversely affect reimbursement to Nymox for products and services provided to beneficiaries of the Medicare and/or Medicaid programs. Many elderly people are covered by a variety of private health care organizations either operating private health care plans or Medicare or Medicaid programs subject to government regulation. These organizations are also under considerable financial constraints and we may not be able to secure coverage or adequate reimbursement from these organizations. Without coverage, we will have to look to the patients themselves who may be unwilling or unable to pay for the product; in turn, doctors may be reluctant to order or prescribe our products in the absence of coverage of the product for the patient.

In response to rising health care costs, there have been a number of legislative and administrative proposals in the U.S. for the reform of the heathcare system. In 1997 the U.S. Congress implemented sweeping changes to the U.S. Medicare and Medicaid systems. Under Part C: Medicare + Choice programs, beneficiaries can opt for a variety of health delivery models, including coordinated care plans, HMOs, preferred provider organizations and provider sponsored organizations, private fee-for-service plans and medical savings account plans. In addition, states have the option to require Medicaid recipients to enroll with managed health care plans without first obtaining a waiver, making it substantially easier for the states to meet their Medicaid obligations through private managed care organizations. All these health care delivery systems, including the original Medicare and Medicaid systems, are subject to funding formulas and spending caps and may compensate for these restrictions by limiting coverage, eligibility and/or payments. In 2003, the U.S. government added insurance coverage to help pay for prescription drugs to Medicare. In March 2010, the United States enacted health care reform legislation. Important market reforms began this year and will continue through full implementation in 2014. The new law is expected to expand access to health care to more than 32 million Americans by the end of the decade. These changes may adversely affect the prices we may charge for any therapeutic drug we develop. The long-term impact of legislative changes in terms of their efficiency, effectiveness and financial viability in delivering health care services to an aging population is uncertain at present. Any legislative or regulatory actions to reduce or contain federal spending under either the Medicare or

Medicaid programs could adversely affect our ability to participate in either program as a provider or supplier of services or products and the amount of reimbursement under these programs potentially available to us.

Our AlzheimAlert test, and any of the new diagnostic and therapeutic products and services that we may develop, will be subject to coverage determinations by health care providers and payers. Federal and state regulations and law and internal coverage policies of health care organizations affect our ability to obtain payments for our products and services. The Medicare program will not pay for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Historically, CMS interpreted this provision in order to exclude from Medicare coverage those medical and health care services that are not demonstrated to be safe and effective by acceptable clinical evidence. CMS recently revised both its national coverage policies and procedures in general and specifically its coverage of diagnostic laboratory tests and constituted a Medicare Coverage Advisory Committee to provide advice on the effectiveness and appropriateness of medical items and services that are eligible for coverage under Medicare. It is unknown how these changes will affect our ability to obtain Medicare coverage for our products and services. However, an adverse national coverage decision with respect to one of our products or services will make it impossible to receive reimbursement from Medicare for that product and more difficult to convince private health care organizations to provide coverage for it. Even if we receive a favorable coverage decision for one of our products or services, there is no guarantee that the level of reimbursement for it will be close to our retail price for it or commensurate with the costs of developing and marketing it.

# **Patents and Proprietary Information**

We believe that patent and trade secret protection is important to our business, and that our success will depend, in part, on our ability to obtain strong patents, to maintain trade secret protection and to operate without infringing the proprietary rights of others.

The commercial success of products incorporating our technologies may depend, in part, upon our ability to obtain strong patent protection. We cannot assure you that additional patents covering new products or improvements will be issued or that any new or existing patents will be of commercial benefit or be valid and enforceable if challenged.

We pursue a policy of seeking patent protection for valuable patentable subject matter of our proprietary technology and require all employees, consultants and other persons who may have access to its proprietary technology to sign confidentiality agreements.

The Corporation currently owns or has licensed exclusive rights to several hundred patents and patent applications in the U.S. and other countries around the world in support of its proprietary product development programs. Nymox has twenty-three U.S. patents issued or allowed and a corresponding larger number of patents and patent applications worldwide. Nymox has issued patents in the main European markets, including Great Britain, Germany, France, Italy, The Netherlands, Sweden and Spain among others and in other countries such as Japan, Canada and Australia. These patents and patent applications cover much of our current product development and technologies, including new drug candidates, proprietary screening technologies for finding drugs, promising diagnostic markers, new diagnostic assay methods, methods of treating meat and other food products; and anti-infective agents. The earliest expiry date for our issued patents was July 2010 and the rest range from 2013 through 2021.

Nymox's subsidiary, Serex, has thirteen patents issued or allowed in the United States and a corresponding larger number of patents and patent applications worldwide. These patents and patent applications cover such areas as Serex's proprietary diagnostic technologies and methodologies. The expiry dates for its patents range from 2012 to 2017.

Nymox also has exclusive rights to twelve issued U.S. patents as well as a corresponding larger number of patents and patent applications worldwide through research and license agreements. The earliest of these patents expires in 2014.

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

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

Neither Nymox nor Serex are currently involved in litigation over patent and other intellectual property rights but significant litigation over these matters in the pharmaceutical and biotechnology industry is not uncommon. The validity and extent of patent rights can be very difficult to determine and involve complex legal, factual and scientific questions. Important legal issues about patent protection in the field of biotechnology have not been resolved. Patent litigation is costly and time-consuming and can consume substantial resources. An adverse decision can preclude the marketing of a product, expose us to significant liabilities or require us to obtain third party licenses, which may not be available at commercially reasonable prices.

We also rely upon trade secrets, know-how, and continuing technological advancement to develop and maintain our competitive position. We control the disclosure and use of our know-how and confidential information through agreements with the parties involved. In addition, we have confidentiality agreements with our key employees, consultants, officers and directors. There can be no assurance, however, that all confidentiality agreements will be honored, that others will not independently develop equivalent technology, that disputes will not arise as to the ownership of intellectual property, or that disclosure of our trade secrets will not occur. Furthermore, there can be no assurance that others have not obtained or will not obtain patent protection that will exclude us from using our trade secrets and confidential information. To the extent that consultants or research collaborators use intellectual property owned by others in their work with us, disputes may also arise as to the rights to related or resulting know-how or inventions.

## Competition

Rapidly evolving technology and intense competition are the hallmarks of modern pharmaceutical and biotechnology industries.

Our competitors include:

- major pharmaceutical, diagnostic, chemical and biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours;
- biotechnology companies, either alone or in collaborations with large, established pharmaceutical companies to support research, development and commercialization of products that may be competitive with ours; and

• academic institutions, government agencies and other public and private research organizations which are conducting research into Alzheimer s disease and which increasingly are patenting, licensing and commercializing their products either on their own or through joint ventures.

In the field of Alzheimer s disease diagnosis, our AlzheimAlert test faces growing competition which could detrimentally impact on our ability to successfully market and sell our diagnostic test. Our competitors include:

- Athena Diagnostics, Inc., a wholly owned subsidiary of Thermo Fischer Scientific, which is currently marketing three tests claimed to aid in the diagnosis of Alzheimer's disease: a genetic test for the rare cases of familial, early-onset Alzheimer's disease; a genetic test for a relatively common mutation of a gene said to increase the likelihood of a person with at least one of the genes contracting the disease; and a test for two proteins in the spinal fluid of patients.
- Innogenetics NV which currently markets tests and kits for two proteins and a variant of one of these proteins in the spinal fluid of patients and a genetic test for a relatively common mutation of a gene said to increase the likelihood of a person developing the disease.
- Amorfix Life Sciences Ltd. currently markets a research test to detect aggregated amyloid protein in brain test and has under development related blood and CSF test.

There are also a number of other proposed biochemical signs of the disease that could potentially be developed into a commercial diagnostic test as well as various scanning and imaging technologies which compete for a portion of the diagnostic market for Alzheimer's disease. On January 20, 2011, an FDA Advisory Committee panel recommended against the approval at that time of Lilly's Amyvid (florbetapir), a molecular imaging tool developed to detect beta-amyloid plaque in the brain. The Committee's decision left open the possibility of approval at a later time after a further study is completed. A number of companies, including GE, are actively working to develop imaging technologies for the diagnosis of Alzheimer's disease. In June 2004, the CMS approved limited coverage of a Positronic Emission Tomography (PET) imaging procedure for helping to more precisely distinguish Alzheimer's disease from a rarer type of dementia when clinical evaluation has been inconclusive. In October 2004, the National Institute of Aging in conjunction with other Federal agencies, private companies and organizations launched the Alzheimer's Disease Neuroimaging Initiative, a \$60 million initiative to test whether various scanning and imaging technologies, biochemical markers, and clinical and neuropsychological testing can be combined to help diagnose early Alzheimer's disease.

Our NicAlert and TobacAlert products face competition from clinical laboratories such as LabCorp and Quest Diagnostics which provide off-site lab testing for cotinine, the by-product of the body s breakdown of nicotine measured by NicAlert and TobacAlert , and from assay suppliers, including immunoassay developers such as OraSure Technologies Inc. and Abraxis LLC, and diagnostic system manufacturers such as Roche Diagnostics, Abbott and Diagnostic Products Corporation. NicAlert and TobacAlert also face competition from distributors who supply simple yes-no smoking status tests such as NicQuick, and QuickScreen, from NicCheck I, an FDA-cleared smoking status test being marketed by Mossman & Associates Ltd, from SmokeScreen, a chemical color-based tobacco test being marketed by Mermaid Diagnostics, Ltd. in the United Kingdom, and from carbon monoxide (CO) monitors such as SmokeCheck.

We also face intense competition for the development of an effective treatment for Alzheimer s disease. The market conditions for an Alzheimer s disease drug strongly favor the entry of other corporations into the area. This market is expected to grow rapidly as new drugs enter the market and as the baby boom generation becomes more at risk for developing Alzheimer s disease. As a result, most of the major pharmaceutical companies and many biotechnology companies have ongoing research and development programs for drugs and treatments for Alzheimer s disease. Many

of these companies have much greater scientific, financial and marketing resources than we have and may succeed in developing and introducing effective treatments for Alzheimer s disease before we can. At present, four drugs for Alzheimer s disease are being widely marketed in the United States, Aricept® by Pfizer, Exelon® by Novartis, Razadyne® by Janssen and Namenda® by Forest. These four drugs only treat some of the symptoms of Alzheimer s disease by enhancing memory and other mental functions and not the underlying causes of the illness.

A similar competitive reality prevails in the field of novel anti-infectives. Over the past ten years, there has been an increasing awareness of the medical need and of emerging market opportunities for new treatments for antibiotic resistant bacterial infections. Many of the major pharmaceutical companies are developing anti-infective drugs that either modify their existing drugs or involve new anti-bacterial properties. Many biotechnology companies are developing new classes of anti-bacterial drugs. At least three major pharmaceutical companies have vaccines against bacterial infections in development. To the extent that these companies are able to develop drugs or vaccines that offer treatment for some or all of the indications for our anti-infectives, the market for our products may be adversely affected.

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

The problem of *E. coli* O157:H7 contamination of hamburger meat and other food products is also well-known and a number of companies and researchers have been pursuing various potential solutions, including irradiation with x-rays, better detection of contamination, electronic pasteurization, vaccination and competitive exclusion of the pathogenic *E. coli* bacteria by harmless bacteria. The development of alternative solutions to the problem of E. coli infection may adversely affect the market for our treatment for *E. coli* O157:H7 infection in cattle and contamination of food products.

## Marketing

Our AlzheimAlert test is certified with a CE Mark, making the device eligible for sale in the European Union.

At present, we do most of our marketing ourselves. 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.

If successfully developed and approved, we plan to market and sell our therapeutic and diagnostic products directly or through co-promotion arrangements or other licensing arrangements with third parties. In cases where we have sole or shared marketing rights, we plan to build a small, focused sales force if and when such products approach marketing approval in some markets, including Europe. Implementation of this strategy will depend on many factors, including the market potential of any products we develop as well as on our financial resources. To the extent we will enter into co-promotion or other licensing arrangements, any revenues received by us will be dependent on the efforts of third parties.

#### **Principal Markets**

The Corporation markets its products for sale principally in the United States, Canada and overseas. Set forth below is a breakdown of the Corporation s revenues by geographic market for the last three years.

		United	]	Europe &
Revenues:	Canada	States		Other
2010	\$ 17,091	\$ 505,897	\$	169,653
2009	\$ 11,386	\$ 328,564	\$	76,030
2008	9,637	347,764		71,008

# ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

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

#### General

Nymox Pharmaceutical Corporation is a biopharmaceutical Corporation with three proprietary products on the market, and an R&D pipeline of drug and diagnostic products in development.

We have developed the AlzheimAlert test as an aid to the diagnosis of Alzheimer s disease. The kit version of the AlzheimAlert test is certified with a CE Mark in Europe. AlzheimAlert is an improved version of our AD7C test, from which we began generating revenue from sales in 1997. In July 2005, an FDA advisory panel voted 5-2 against approval of our kit, citing the need for further studies, such as long term follow-up and autopsy confirmation.

We also market NicAlert and TobacAlert, our two products which determine a person is level of exposure to tobacco products. These products are also certified with a CE Mark, making the devices eligible for sale in the European Union.

We have under development therapeutic agents for the treatment of Alzheimer s disease, the treatment of enlarged prostate (BPH) and of certain antibiotic-resistant infections as well as antibacterial agents for E. coli contamination of food and drink products.

In September, 2006, we announced the successful completion of a multi-center, double-blind, placebo-controlled Phase 2 trial of NX-1207, our lead candidate for the treatment of BPH. In February 2009, the Corporation reported concluding a positive and productive End of Phase 2 ( EOP2 ) meeting with the FDA concerning the Phase 3 program for NX-1207. In June 2009, the Corporation began conducting the first of two pivotal double blind placebo controlled Phase 3 trials for NX-1207 that incorporate the specific protocol design recommendations provided to the Corporation by the FDA.

We also have the rights to a U.S. patent for the use of statin drugs for the treatment or prevention of Alzheimer s disease.

We have incurred operating losses throughout our history. Management believes that such operating losses will continue for at least the next few years. The costs relating to clinical trials for our potential therapeutic products will increase expenditures and delay profitability, despite anticipated increases in sales revenue in the coming years.

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

Similar requirements exist in many other countries. Obtaining these approvals and complying with the subsequent regulatory requirements can be both time-consuming and expensive.

# **History of Capital Funding**

We have funded our operations and projects primarily by selling shares of Nymox s common stock. However, since 1997, a small portion of our funding also comes from sales. Since its incorporation in May, 1995, Nymox raised the capital necessary to fund its on-going research and development work and its marketing and sales operations primarily through private placements of its shares.

On December 1, 1997, our common shares began trading on the Nasdaq Stock Market. Nymox s common shares also traded on the Montreal Exchange from December 18, 1995 to November 19, 1999.

On January 27, 2003 we entered into a Common Stock Private Purchase Agreement with an investment corporation, Lorros-Greyse, for the future issuance and purchase of Nymox s common shares.

Under the terms of this agreement, which has since been replaced annually by new agreements with Lorros-Greyse, we may give notice to Lorros-Greyse requiring it to purchase a specified dollar amount of our shares. The amount specified in any one notice may be up to \$500,000 but not less than \$100,000. The maximum amount can be higher if both parties agree. The number of shares Nymox will issue to Lorros-Greyse in return for that money will be equal to the amount specified in the notice divided by 97% of the average market price of our common shares for the five trading days preceding the giving of the notice. The Corporation must comply with general covenants in order to draw on its facility, including maintaining its stock exchange listing and registration requirements and having no material adverse effects, as defined in the agreement, with respect to the business and operations of the Corporation. The Corporation may terminate the agreement before the 24-month term, if it has issued at least \$8 million of common shares under the agreement.

Under the agreement dated November 16, 2007, we received a total of \$3,695,000 during 2008 and under the agreement dated November 10, 2008, we received \$4,105,000 during 2009.

On November 2, 2009, we signed a new Common Stock Private Purchase Agreement, whereby Lorros-Greyse is committed to purchase up to \$15 million of Nymox s common shares over the twenty-four month period beginning in November 2009, subject to the same terms and conditions as before.

Under this agreement dated November 2, 2009, which became effective December 10, 2009, we received a total of \$4,700,000 for the following shares under this Common Stock Private Purchase Agreement:

- January 22, 2010, 117,925 common shares were issued at a price of \$4.24 per share.
- March 1, 2010, 298,913 common shares were issued at a price of \$3.68 per share.

- May 4, 2010, 91,743 common shares were issued at a price of \$3.27 per share.
- June 3, 2010, 34,965 common shares were issued at a price of \$4.29 per share
- June 14, 2010, 47,059 common shares were issued at a price of \$4.25 per share.
- June 28, 2010, 64,935 common shares were issued at a price of \$3.85 per share.
- July 23, 2010, 34,247 common shares were issued at a price of \$2.92 per share.
- August 4, 2010, 24,450 common shares were issued at a price of \$4.09 per share.
- August 13, 2010, 46,729 common shares were issued at a price of \$4.28 per share.
- August 27, 2010, 25,445 common shares were issued at a price of \$3.93 per share.
- September 2, 2010, 54,201 common shares were issued at a price of \$3.69 per share.
- September 13, 2010, 41,436 common shares were issued at a price of \$3.62 per share.
- September 23, 2010, 35,112 common shares were issued at a price of \$3.56 per share.
- September 29, 2010, 124,269 common shares were issued at a price of \$3.42 per share.
- October 26, 2010, 49,261 common shares were issued at a price of \$4.06 per share.
- November 4, 2010, 50,251 common shares were issued at a price of \$3.98 per share.
- November 15, 2010, 49,751 common shares were issued at a price of \$4.02 per share.
- November 24, 2010, 50,125 common shares were issued at a price of \$3.99 per share.

On November 1, 2010, we signed a new Common Stock Private Purchase Agreement, whereby Lorros-Greyse is committed to purchase up to \$15 million of Nymox s common shares over the twenty-four month period beginning in November 2010, subject to the same terms and conditions as before.

Under this agreement dated November 1, 2010, which became effective November 25, 2010, we received a total of \$200,000 for the following shares under this common stock private purchase agreement:

• December 9, 2010, 49,261 common shares were issued at a price of \$4.06 per share.

As of March 15, 2011, Nymox had approximately \$14.8 million of financing available under the facility. We expect this Common Stock Private Purchase Agreement to provide sufficient financing to enable us to advance our research and product development for the next two years.

Also, the Corporation has received total proceeds of approximately \$1.03 million from the exercise of 346,400 options since 1995. No options were exercised in 2010 and no options have been exercised since May 2007.

Pursuant to the share purchase agreement we entered into in March 2000 to acquire a controlling interest of Serex, Inc., a total of 257,607 additional shares and 158,526 warrants were issued in exchange for the shares of Serex. Since January 2004, 131,940 of these warrants have been exercised under a cashless exercise, whereby the warrant holder receives a number of shares equivalent in value to the net difference between the strike price on the warrant and the average market price on the day before the date of the cashless exercise, according to a formula contained in the warrant agreement. The net effect of these cashless exercises has been the issuance of 22,061 shares of Nymox common stock. Another 1,090 of these warrants were exercised resulting in the issuance of 1,090 shares of Nymox, for proceeds of \$4,033.

In total, Nymox has raised over \$62.9 million through the issuance of common stock or securities exercisable for shares of common stock, since its incorporation in May 1995.

We have no financial obligations of significance other than long-term lease commitments for our premises in the United States and Canada of \$31,793 per month in 2011. Total commitments in 2011 and beyond are summarized in note 9 to the consolidated financial statements.

# MANAGEMENT'S DISCUSSION AND ANALYSIS (in US dollars)

This Management's discussion and analysis ("MD&A") comments on the Corporation's operations, performance and financial condition as at and for the years ended December 31, 2010, 2009 and 2008. This MD&A should be read together with the audited Consolidated Financial Statements and the related notes. This MD&A is dated March 15, 2011. All amounts in this report are in U.S. dollars, unless otherwise noted.

All financial information contained in this MD&A and in the Consolidated Financial Statements has been prepared in accordance with Canadian generally accepted accounting principles (GAAP). The audited Consolidated Financial Statements and this MD&A were reviewed by the Corporation's Audit and Finance Committee and were approved by our Board of Directors.

Additional information about the Corporation can be obtained on EDGAR at www.sec.gov or on SEDAR at www.sedar.com.

#### Overview

## **Corporate Profile**

Nymox Pharmaceutical Corporation is a biopharmaceutical company with a significant R&D pipeline in development. Nymox is developing NX-1207, a novel treatment for benign prostatic hyperplasia which is in Phase 3 trials in the U.S. In December 2010, the Corporation signed a license and collaboration agreement with Recordati, a European pharmaceutical group, for the development and commercialization of NX-1207 in Europe including Russia and the CIS, the Middle East, the Maghreb area of North Africa and South Africa. The licensing and collaboration agreement covers the use of NX-1207 for the treatment of BPH as the initial indication for development and commercialization. NX-1207 showed positive results for the treatment of BPH in Phase 1 and 2 clinical trials in the U.S. The Corporation successfully completed a 43 site prospective randomized double-blinded placebo controlled Phase 2 U.S. clinical trial of NX-1207 in 2006, which showed statistically significant efficacy and a good safety profile. In February 2008, the Corporation reported positive results in a 32 site U.S. Phase 2 prospective randomized blinded clinical trial, with statistically significant improvement compared to an approved BPH drug (finasteride). Nymox reported positive results in twelve follow-up studies of available subjects from the completed Phase 1 and 2 clinical trials. In February 2009, the Corporation reported concluding a positive and productive End of Phase 2 (EOP2) meeting with the FDA concerning the Phase 3 program for NX-1207. In June 2009, the Corporation began conducting the first of two pivotal double blind placebo controlled Phase 3 trials for NX-1207 that incorporate the specific protocol design recommendations provided to the Corporation by the FDA. The two pivotal Phase 3 studies for NX-1207 are being conducted at well known investigational sites across the U.S. with planned enrollment of 1,000 patients. The Corporation is also developing new treatments for bacterial infections in humans and for the treatment of E. coli O157:H7 contamination in food products. Nymox has candidates which are under development as drug treatments aimed at the causes of Alzheimer's disease, and has several other drug candidates in development. Nymox has U.S. and global patent rights for the use of statin drugs for the treatment and prevention of Alzheimer's disease. Nymox developed the AlzheimAlert<sup>TM</sup> test, which is certified with a CE Mark in Europe. AlzheimAlert<sup>TM</sup> is an accurate, non-invasive aid in the diagnosis of Alzheimer's disease. Nymox developed and markets NicAlert<sup>TM</sup> and TobacAlert<sup>TM</sup>; which are tests that use urine or saliva to detect use of and exposure to tobacco products. NicAlert<sup>TM</sup> has received clearance from the U.S. Food and Drug Administration (FDA) and is also certified with a CE Mark in Europe. TobacAlert<sup>TM</sup> is the first test of its kind to accurately measure second and third hand smoke exposure in individuals.

#### **Risk Factors**

The business activities of the Corporation since inception have been devoted principally to research and development. Accordingly, the Corporation has had limited revenues from sales and has not been profitable to date. We refer to the Risk Factors section of our Form 20-F filed on EDGAR and of our Annual Information Form filed on SEDAR for a discussion of the management and investment issues that affect the Corporation and our industry. The risk factors that could have an impact on the Corporation's financial results are summarized as follows:

- Our Clinical Trials for our Therapeutic Products in Development, such as NX-1207, May Not be Successful and We May Not Receive the Required Regulatory Approvals Necessary to Commercialize These Products
- Our Clinical Trials for our Therapeutic Products, such as NX-1207, May be Delayed, Making it Impossible to Achieve Anticipated Development or Commercialization Timelines
- A Setback in Any of our Clinical Trials Would Likely Cause a Drop in the Price of our Shares
- We May Not be Able to Make Adequate Arrangements with Third Parties for the Commercialization of our Product Candidates, such as NX-1207
- We May Not Achieve our Projected Development Goals in the Time Frames We Announce and Expect
- Even If We Obtain Regulatory Approvals for our Product Candidates, We Will be Subject to Stringent Ongoing Government Regulation
- It is Uncertain When, if Ever, We Will Make a Profit
- We May Not Be Able to Raise Enough Capital to Develop and Market Our Products
- We Face Challenges in Developing, Manufacturing and Improving Our Products
- Our Products and Services May Not Receive Necessary Regulatory Approvals
- We Face Significant and Growing Competition

- We May Not Be Able to Successfully Market Our Products
- Protecting Our Patents and Proprietary Information is Costly and Difficult
- We Face Changing Market Conditions
- Health Care Plans May Not Cover or Adequately Pay for our Products and Services
- We Are Subject to Continuing Potential Product Liability Risks, Which Could Cost Us Material Amounts of Money
- We Face Potential Losses Due to Foreign Currency Exchange Risks

#### **Critical Accounting Policies**

The consolidated financial statements of the Corporation have been prepared under Canadian generally accepted accounting principles and include a reconciliation to accounting principles generally accepted in the United States (see Canadian/US reporting differences in the Notes to the Consolidated Financial Statements). The Corporation's functional and reporting currency is the United States dollar. Our accounting policies are described in the notes to our annual audited consolidated financial statements. We consider the following policies to be the most critical in understanding the judgments that are involved in preparing our financial statements and the matters that could impact our results of operations, financial condition and cash flows. Revenue Recognition The Corporation has generally derived its revenue from product sales, collaboration agreements and interest. Revenue from product sales is recognized when the product has been delivered or obligations as defined in the agreement are performed. Collaboration agreements that include multiple deliverables are considered to be multiple-element arrangements. Under this type of arrangement, the identification of separate units of accounting is required and revenue is allocated among the separate units based on their relative fair values.

Payments received under a collaboration agreement may include upfront payments, milestone payments, sale of goods, royalties and license fees. Revenue for each unit of accounting are recorded as described below:

# (i) Upfront payments:

Upfront payments are deferred and recognized as revenue on a systematic basis over the estimated service period.

Changes in estimates are recognized prospectively when changes to the expected term are determined.

#### (ii) Milestone payments:

Revenue subject to the achievement of milestones is recognized only when the specified events have occurred and collectibility is reasonably assured.

Specifically, the criteria for recognizing milestone payments are that (i) the milestone is substantive in nature, (ii) the achievement was not reasonably assured at the inception of the agreement, and (iii) the Corporation has no further involvement or obligation to perform associated with the achievement of the milestone, as defined in the related collaboration arrangement.

## (iii) Sale of goods:

Revenue from the sale of goods is recognized when the Corporation has transferred to the buyer the significant risks and rewards of ownership of the goods, there is no continuing management involvement with the goods, and the amount of revenue can be measured reliably.

# (iv) Royalties and license fees:

Royalties and license fees are recognized when conditions and events under the license agreement have occurred and collectibility is reasonably assured.

# Valuation of Long-lived Assets

Property and equipment are stated at cost and are amortized on a straight-line basis over the estimated useful lives. The Corporation reviews the unamortized balance of property and equipment, and recognizes any impairment in carrying value when it is identified. Factors we consider important, which could trigger an impairment review include:

- Significant changes in the manner of our use of the acquired assets or the strategy for our overall business; and
- Significant negative industry or economic trends.

Impairment is assessed by comparing the carrying amount of an asset with its expected future net undiscounted cash flows from use together with its residual value (net recoverable value). If such assets are considered impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds its fair value. Management's judgment regarding the existence of impairment indicators is based on legal factors, market conditions and operating performances. Future events could cause management to conclude that impairment indicators exist and that the carrying values of the Corporation's property and equipment are impaired.

#### **Stock-based Compensation**

Stock-based compensation is recorded using the fair value based method for stock options issued to employees and non-employees. Under this method, compensation cost related to employee awards is measured at fair value at the date of grant, net of forfeitures, and is expensed over the award's vesting period. The Corporation uses the Black-Scholes options pricing model to calculate stock option values, which requires certain assumptions, including the future stock price volatility and expected time to exercise. Changes to any of these assumptions, or the use of a different option pricing model, could produce different fair values for stock-based compensation, which could have a material impact on the Corporation's earnings. The Corporation has no unvested non-employee awards.

#### Valuation of Future Income Tax Assets

Management judgment is required in determining the valuation allowance recorded against future tax assets. We have recorded a full valuation allowance as of December 31, 2010, due to uncertainties related to our ability to utilize all of our future tax assets, primarily consisting of net operating losses carried forward and other unclaimed deductions, before they expire. In assessing the realizability of future tax assets, management considers whether it is more likely than not that some portion or all of the future tax assets will not be realized. The ultimate realization of future tax assets is dependent upon the generation of future taxable income and tax planning strategies. The generation of future taxable income is dependent on the successful commercialization of the Corporation's products and technologies.

## **Results of Operations**

<b>Selected Annual Information</b>		2010	2009	2008
Total revenues		\$692,641	\$415,980	\$428,409
Net loss (i)		\$(6,956,033)	\$(5,130,074)	\$(4,637,103)
Loss per share (basic & diluted) (i)		\$(0.22)	\$(0.17)	\$(0.16)
Total assets (i)		\$13,502,222	\$1,090,431	\$749,879
Quarterly Results	Q1 – 2010	Q2 - 2010	Q3 – 2010	Q4 - 2010
Total revenues	\$247,443	\$104,550	\$26,950	\$313,698
Net loss (i)	\$(1,269,550)	\$(1,745,798)	\$(1,760,474)	\$(2,180,211)
Loss per share (basic & diluted) (i)	\$(0.04)	\$(0.05)	\$(0.05)	\$(0.07)
-	Q1 - 2009	Q2 - 2009	Q3 - 2009	Q4 - 2009
Total revenues	\$96,226	\$80,341	\$71,904	\$167,509
Net loss (i)	\$(1,004,259)	\$(1,220,152)	\$(1,362,840)	\$(1,542,823)
Loss per share (basic & diluted) (i)	\$(0.03)	\$(0.04)	\$(0.04)	\$(0.05)
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<sup>(</sup>i) Net loss, loss per share (basic & diluted) and the total assets reflect the impact of the change in accounting policy as described in Note 3 (a) to the audited consolidated financial statements.

#### Results of Operations – 2010 compared to 2009

Net losses were \$2,180,211, or \$0.07 per share, for the quarter and \$6,956,033, or \$0.22 per share, for the year ended December 31, 2010, compared to \$1,542,823 or \$0.05 per share, for the quarter and \$5,130,074 or \$0.17 per share for the year ended December 31, 2009. Net losses include stock compensation charges of \$898,585 for the year ended December 31, 2010 and \$1,085,164 for the same period in 2009. The increase in net losses is attributable to higher clinical trial expenditures compared to 2009. The weighted average number of common shares outstanding for the year ended December 31, 2010 was 31,940,584 compared to 30,717,822 for the same period in 2009.

#### Revenues

Revenues from sales amounted to \$204,076 for the quarter and \$582,383 for the year ended December 31, 2010, compared with \$167,509 for the quarter and \$415,980 for the year ended December 31, 2009. Sales to new clients explain the increase in sales for the quarter and the year ended December 31, 2010 compared to the same period in 2009. The development of therapeutic candidates and moving therapeutic product candidates through clinical trials is a priority for the Corporation at this time. The growth of sales will become more of a priority once these candidates have reached the marketing stage. The Corporation expects that revenues will increase if and when product candidates pass clinical trials and are launched on the market.

For the year ended December 31, 2010, an amount of \$109,067 was recognized as revenue related to the upfront payment received from Recordati in December 2010. At December 31, 2010, the deferred revenue related to this transaction recorded on the balance sheet amounted to \$12,978,933.

#### Research and Development

Research and development expenditures were \$1,330,216 for the quarter and \$4,787,820 for the year ended December 31, 2010, compared with \$1,172,863 for the quarter and \$3,183,134 for the year ended December 31, 2009. Research and development expenditures include costs incurred in advancing Nymox's BPH product candidate NX-1207 through clinical trials, as well as costs related to its R&D pipeline in development. The increase in expenses is attributable to higher expenditures on the clinical trial for NX-1207 compared to 2009. Expenditures in 2010 were increased principally on payroll by approximately \$317,000 and clinical site and laboratory services by approximately \$1,390,000 compared to the same period in 2009 with corresponding increases for the quarter. Research tax credits amounted to \$236,101 compared to \$139,915 in 2009 as a result of additional expenditures claimed for refundable tax credits in 2010 compared to 2009. The Corporation expects that research and development expenditures will decrease as product candidates finish development and clinical trials. However, because of the early stage of development of the Corporation's R&D projects, it is impossible to outline the nature, timing or estimated costs of the efforts necessary to complete these projects, nor the anticipated completion dates for these projects. The facts and circumstances indicating the uncertainties that preclude us from making a reasonable estimate of the costs and timing necessary to complete projects include the risks inherent in any field trials, the uncertainty as to the nature and extent of regulatory requirements both for safety and efficacy, and the ability to manufacture the products in accordance with current good manufacturing requirements (cGMP) and in sufficient quantities both for large scale trials and for commercial use. A drug candidate that shows efficacy can take a long period (7 years or more) to achieve regulatory approval. There is also uncertainty whether we will be able to successfully adapt our patented technologies or whether any new products we develop will pass proof-of-principle testing both in the laboratory and in clinical trials, and whether we will be able to manufacture such products at a commercially competitive price. In addition, given the very high costs of development of therapeutic products, we anticipate having to partner with larger pharmaceutical companies to bring therapeutic products to market. The terms of such partnership arrangements along with our related financial obligations cannot be determined at this time and the timing of completion of the approval of such products will likely not be within our sole control.

#### Marketing Expenses

Marketing expenditures amounted to \$41,631 for the quarter and \$147,609 for the year ended December 31, 2010, compared with \$37,326 for the quarter and \$138,396 for the year ended December 31, 2009. The increase for the quarter and the year is due to an increase in costs of communications in 2010 compared to 2009. The Corporation expects that marketing expenditures will increase if and when new products are launched on the market.

# General and Administrative Expenses

General and administrative expenses amounted to \$915,814 for the quarter and \$1,716,515 for the year ended December 31, 2010, compared with \$182,024 for the quarter and \$799,784 for the year ended December 31, 2009. The increase for the year is due to higher expenditures on shareholder relations by approximately \$80,000, travel by approximately \$40,000, other professional fees by approximately \$97,000 and by \$705,000 in professional fees incurred related to entering into the license agreement compared to 2009 with corresponding increases for the quarter. The Corporation expects that general and administrative expenditures will increase as new product development leads to expanded operations.

# **Stock-based Compensation**

The Corporation accounts for stock option grants using the fair value method, with compensation cost measured at the date of grant and amortized over the vesting period. In 2010, stock-based compensation costs of \$780,880 were recorded for the 3,565,500 options granted in 2006 which vest quarterly over six years as well as costs of \$117,705

relating to the issuance of new options to an employee and to the directors of the Corporation. In 2009, stock-based compensation costs of \$815,280 were recorded relating to the 2006 option grant mentioned above as well as costs of \$269,884 relating to the issuance of new options to employees and directors of the Corporation.

#### Foreign Exchange

The Corporation incurs expenses in the local currency of the countries in which it operates, which include the United States and Canada. Approximately 78% of 2010 expenses (76% in 2009) were in U.S. dollars. Foreign exchange fluctuations had no meaningful impact on the Corporation's results in 2010 or 2009.

#### **Inflation**

The Corporation does not believe that inflation has had a significant impact on its results of operations. <u>Results of Operations – 2009 compared to 2008</u>

Net losses were \$1,542,823, or \$0.05 per share, for the quarter and \$5,130,074, or \$0.17 per share, for the year ended December 31, 2009, compared to \$922,915 or \$0.03 per share, for the quarter and \$4,637,103 or \$0.16 per share for the year ended December 31, 2008. The increase of the net loss for the quarter and for the year ended December 31, 2009 is mainly attributable to expenses relating to the launch of the Phase 3 clinical trial. The weighted average number of common shares outstanding for the year ended December 31, 2009 was 30,717,822 compared to 29,749,000 for the same period in 2008.

#### Revenues

Revenues from sales amounted to \$167,509 for the quarter and \$415,980 for the year ended December 31, 2009, compared with \$119,826 for the quarter and \$426,675 for the year ended December 31, 2008. The increase for the quarter ended December 31, 2009 is due to an increase in the number of customers for NicAlert/TobacAlert in the US compared to the same period in 2008. The decrease for the year ended December 31, 2009 is due to a decrease in the sales of NicAlert/TobacAlert attributable to the economic slowdown during that period.

## Research and Development

Research and development expenditures were \$1,172,863 for the quarter and \$3,183,134 for the year ended December 31, 2009, compared with \$449,458 for the quarter and \$2,500,154 for the year ended December 31, 2008. Research and development expenditures include costs incurred in advancing Nymox's BPH product candidate NX-1207 through clinical trials, as well as costs related to its R&D pipeline in development. The increase in expenditures for the quarter and for the year compared to the same period last year is attributable to the increase in expenditures relating to the Phase 3 clinical trial. In 2009, research tax credits amounted to \$139,915 compared to \$111,243 in 2008 as a result of additional expenditures claimed for refundable tax credits in 2009 compared to 2008.

## **Marketing Expenses**

Marketing expenditures amounted to \$37,326 for the quarter and \$138,396 for the year ended December 31, 2009, compared with \$44,530 for the quarter and \$187,868 for the year ended December 31, 2008. The decrease for the quarter and the year is primarily due to reduced expenditures year-to-date on publicity by approximately \$22,000, and promotional activities by approximately \$27,000 during 2009 with proportional reductions for the quarter.

#### General and Administrative Expenses

General and administrative expenses amounted to \$182,024 for the quarter and \$799,784 for the year ended December 31, 2009, compared with \$267,311 for the quarter and \$1,064,903 for the year ended December 31, 2008. The decrease for the quarter and for the year compared to 2008 is due primarily to reduced expenditures on shareholder relations and related activities by approximately \$175,000, travel by approximately \$30,000, salaries and professional fees by approximately \$38,000 and insurance premiums by approximately \$14,000 during 2009 with proportional reductions for the quarter.

# **Stock-based Compensation**

The Corporation accounts for stock option grants using the fair value method, with compensation cost measured at the date of grant and amortized over the vesting period. In 2009, stock-based compensation costs of \$815,280 were recorded for the 3,565,500 options granted in 2006 which vest quarterly over six years, as well as costs of \$269,884 relating to the issuance of new options to employees and directors of the Corporation. In 2008, stock-based compensation was \$817,000 relating to the 2006 option grant mentioned above. An additional \$108,220 was recorded in 2008 for options granted to the Corporation's directors, and a consultant, and which were fully vested at the date of grant.

# **Contractual Obligations**

Nymox has no financial obligations of significance other than long-term lease commitments and other operating leases as follows:

Contractual Obligations	Total	Current	2-4 years
Rent	\$730,335	\$354,218	\$376,117
Operating Leases	\$32,346	\$10,853	\$21,493
Total Contractual Obligations	\$762,681	\$365,071	\$397,610

The Corporation has no binding commitments for the purchase of property, equipment or intellectual property. The Corporation has no commitments that are not reflected in the balance sheet except for operating leases.

#### **Transactions with Related Parties**

The Corporation had no transactions with related parties in 2010 or 2009.

#### **Financial Position**

# Liquidity and Capital Resources

As of December 31, 2010, cash totalled \$13,174,999 and receivables including tax credits totaled \$277,649. In December 2010, the Corporation received an upfront payment of €10 million (US\$13.1 million) pursuant to a license and collaboration agreement with Recordati for the development and commercialization of NX-1207 in Europe and other countries. In November 2009, the Corporation signed a common stock private purchase agreement, whereby Lorros-Greyse Investments Limited (the "Purchaser") is committed to purchase up to \$15 million of the Corporation's common shares over a twenty-four month period. The agreement became effective December 10, 2009. As at December 31, 2010, eighteen drawings were made under this purchase agreement, for total proceeds of \$4,700,000. On January 22, 2010, 117,925 common shares were issued at a price of \$4.24 per share. On March 1, 2010, 298,913 common shares were issued at a price of \$3.68 per share. On May 4, 2010, 91,743 common shares were issued at a price of \$3.27 per share. On June 3, 2010, 34,965 common shares were issued at a price of \$4.29 per share. On June 14, 2010, 47,059 common shares were issued at a price of \$4.25 per share. On June 28, 2010, 64,935 common shares were issued at a price of \$3.85 per share. On July 23, 2010, 34,247 common shares were issued at a price of \$2.92 per share. On August 4, 2010, 24,450 common shares were issued at a price of \$4.09 per share. On August 13, 2010, 46,729 common shares were issued at a price of \$4.28 per share. On August 27, 2010, 25,445 common shares were issued at a price of \$3.93 per share. On September 2, 2010, 54,201 common shares were issued at a price of \$3.69 per share. On September 13, 2010, 41,436 common shares were issued at a price of \$3.62 per share. On September 23, 2010, 35,112 common shares were issued at a price of \$3.56 per share. On September 29, 2010, 124,269 common shares were issued at a price of \$3.42 per share. On October 26, 2010, 49,261 common shares were issued at a price of \$4.06 per share. On November 4, 2010, 50,251 common shares were issued at a price of \$3.98 per share. On November 15, 2010, 49,751 common shares were issued at a price of \$4.02 per share. On November 24, 2010, 50,125 common shares were issued at a price of \$3.99 per share.

The Corporation negotiated a new agreement with the Purchaser on November 1, 2010, which became effective November 25, 2010, under the same terms and conditions of the previous agreement. The Corporation can draw down \$15,000,000 over 24 months under the new agreement. As at December 31, 2010, one drawing was made under this purchase agreement, for total proceeds of \$200,000. On December 9, 2010, 49,261 common shares were issued at a price of \$4.06 per share. At December 31, 2010, the Corporation can draw down \$14,800,000 over the remaining 22 months under the agreement. The Corporation intends to access financing under this agreement when appropriate to fund its research and development. The Corporation believes that cash balances, funds from operations as well as from existing financing agreements will be sufficient to meet the Corporation's cash requirements for the next twelve months.

The Corporation must comply with general covenants in order to draw on its facility including maintaining its stock exchange listing and registration requirements and having no material adverse effects, as defined in the agreement, with respect to the business and operations of the Corporation.

The Corporation relies almost exclusively on this 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.

In October 2010, the Corporation was informed that it had been awarded a grant of \$244,479 from the U.S Government under the Qualifying Therapeutic Discovery Project for its ongoing Phase III clinical trial program for NX-1207 for the treatment of BPH. The Corporation anticipates receiving the grant sometime in 2011. The Corporation will record this amount in its consolidated financial statements when it is received.

# **Capital Disclosures**

The Corporation's objective in managing capital is to ensure a sufficient liquidity position to finance its research and development activities, general and administrative expenses, working capital and overall capital expenditures, including those associated with patents.

The Corporation defines capital as total shareholders' equity. To fund its activities, the Corporation has followed an approach that relies almost exclusively on the issuance of common equity and most recently during 2010, entered into a collaboration agreement. Since inception, the Corporation has financed its liquidity needs primarily through private placements and since 2003 through a financing agreement with the Purchaser that has been replaced annually by a new agreement with the same investor. The Corporation intends to access financing under this agreement when appropriate to fund its research and development activities. The financial crisis in the United States and the global economic environment has had a negative impact on the availability of liquidity in the market. Since 2003 through to December 2010, the Purchaser has always complied with the drawdowns made pursuant to the agreement. The Corporation is not aware of any information that would lead it to believe that the Purchaser will not be able to meet its commitments under the current agreement. The Corporation believes that cash balances, funds from operations, as well as from existing financing agreements will be sufficient to meet the Corporation's cash requirements for the next twelve months.

The capital management objectives remain the same as for the previous fiscal year. When possible, the Corporation tries to optimize its liquidity needs by non-dilutive sources, including sales, collaboration agreements, investment tax credits and interest income. The Corporation's general policy on dividends is to retain cash to keep funds available to finance its research and development and operating expenses. The Corporation has no debt. The Corporation is not subject to any capital requirements imposed by external parties.

# **Outstanding Share Data**

As at March 15, 2011, there were 32,588,856 common shares of Nymox issued and outstanding. In addition, 5,328,000 share options are outstanding, of which 4,618,625 are currently vested. There are no warrants outstanding.

#### **Disclosure Controls and Procedures**

Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to senior management on a timely basis so that appropriate decisions can be made regarding public disclosure. The Corporation's Chief Executive Officer and its Chief Financial Officer are responsible for establishing and maintaining disclosure controls and procedures. They are assisted in this responsibility by the Corporation's disclosure committee, which is composed of members of senior management. Based on an evaluation of the Corporation's disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures were effective as of December 31, 2010.

## **Internal Control over Financial Reporting**

# Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting includes those policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting, as of December 31, 2010, based on the framework set forth in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its evaluation under this framework, management concluded that our internal control over financial reporting was effective as of December 31, 2010.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

KPMG LLP, an independent registered public accounting firm, which audited and reported on our financial statements in this Annual Report, has issued an unqualified audit report on the effectiveness of our internal control over financial reporting as of December 31, 2010.

## Changes in Internal Controls Over Financial Reporting

There have been no changes during fiscal 2010 in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# **Future Accounting Policies**

## **International Financial Reporting Standards**

In February 2008, Canada's Accounting Standards Board (AcSB) confirmed that Canadian generally accepted accounting principles, as used by publicly accountable enterprises, will be fully converged into International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board (IASB). The changeover date is for interim and annual financial statements relating to fiscal years beginning on or after January 1, 2011. Therefore the Corporation will be required to report under IFRS for its 2011 interim and annual financial statements. The Corporation will convert to these new standards according to the timetable set within these new rules. The Corporation is currently finalizing its assessment of the future impact of these new standards on its consolidated financial statements and progressing towards implementation.

As at December 31, 2010, Management has almost completed the process of change-over to IFRS as follows: (1) the significant accounting policy choices have been assessed, (2) expert outside consultants have been engaged and the training program is in progress, (3) the scoping study has been prepared, (4) the review of GAAP related covenants and contracts has been completed, and (5) the accounting policy review and IFRS implementation plan process is underway.

#### **Potential Impact of the Conversion**

The need for the US GAAP reconciliation will no longer be required upon IFRS conversion.

The detailed comparison of IFRS with Canadian GAAP has helped identify a number of areas of differences.

International Financial Reporting Standard ("IFRS") 1, *First-time Adoption of International Financial Reporting Standards*, provides entities adopting IFRS for the first time with a number of optional exemptions and mandatory exceptions, in certain areas, to the general requirement for full retrospective application of IFRS. The Corporation completed its analyses of the various accounting policy choices available based on what Management believed to be most appropriate in the circumstances.

The Corporation has concluded that it will apply the following available elective exemptions:

- it will not retrospectively restate the accounting of past business combinations; and
- it will not retrospectively apply IFRS 2, *Share-based Payment*, for equity instruments granted on or before November 7, 2002, and for equity instruments granted after November 7, 2002 that have vested before the transition date to IFRS.

The remaining elective exemptions have limited or no applicability to the Corporation.

The Corporation also followed the mandatory exemptions applicable to the Corporation as described below:

Estimates – Hindsight cannot be used to create or revise estimates. Estimates previously made under Canadian GAAP cannot be revised for application of IFRS, except where necessary, to reflect any difference in accounting policies.

Therefore, most adjustments required on transition to IFRS will be made retrospectively against opening retained earnings as of the date of the first comparative balance sheet presented based on standards applicable at December 31, 2011. Transitional adjustments relating to those standards where comparative figures are not required to be restated will only be made as of the first day of the year of adoption.

Set out below are the main areas where changes in accounting policies in conversion to IFRS may impact the Corporation's consolidated financial statements. The list and comments should not be construed as a comprehensive list of changes that will result from transition to IFRS, but rather highlights those areas of accounting differences Management currently believes to be most significant. Notwithstanding, analysis of changes is still in progress and will be completed during the first quarter of fiscal 2011.

Management has identified an IFRS / Canadian GAAP difference related to the presentation of the Corporation's preferred shares of a subsidiary which, based on the current IFRS standards, a portion of the \$800,000 related to the convertible preferred shares of a subsidiary currently reported outside of shareholders' equity, would need to be presented as a separate component of equity for IFRS purposes, based on International Accounting Standard 27, *Consolidated and Separate Financial Statements* (IAS 27).

Another IFRS/Canadian GAAP difference was identified by Management, which relates to the measurement of the Corporation's stock-based compensation expense. Based on IFRS 2, *Share-based Payment*, the Corporation's stock options that vest in installments need to be accounted for as though each installment is a separate stock option grant, and therefore the fair value will be required to be measured separately for each installment and recognized over the vesting period of each installment. The Corporation will complete the calculation of this difference and record the necessary adjustment at the transition date as an increase to deficit and an increase to additional paid-in capital.

In addition, the Corporation is currently working on its preliminary annual IFRS financial statements in accordance with International Accounting Standard 1, *Presentation of Financial Statements* (IAS 1), and on its preliminary interim IFRS financial statements in accordance with International Accounting Standard 34, *Interim Financial Reporting* (IAS 34). Certain additional disclosures will be required in the notes to the financial statements and the statement of operations will be modified to reflect a presentation by nature or by function, of which the Corporation has elected for a presentation by function.

# **Impact on Information Systems and Technology**

The transition had no impact on the Corporation's IT system.

# Impact on Internal Control over Financial Reporting and Disclosure Controls and Procedures

The Corporation's internal control over financial reporting will not be significantly affected by the transition to IFRS. The IFRS differences will mostly require presentation changes to report more detailed information in the notes to the consolidated financial statements, and it is not expected to lead to many differences in the accounting treatments of the Corporation. The Corporation's disclosure controls and procedures are adapted to take into consideration the changes in recognition, measurement and disclosures practices, but the impact is expected to be minimal.

## General

An update regarding the progress of the Corporation's conversion plan was provided to the Audit Committee of the Corporation prior to the release of these consolidated financial statements.

Based upon the work completed to date, the Corporation cannot reasonably determine the full impact that adopting IFRS may have on its financial position and future results.

#### **Forward Looking Statements**

Certain statements included in this MD&A may constitute "forward-looking statements" within the meaning of the U.S. *Private Securities Litigation Reform Act of 1995* and Canadian securities legislation and regulations, and are subject to important risks, uncertainties and assumptions. This forward-looking information includes amongst others, information with respect to our objectives and the strategies to achieve these objectives, as well as information with respect to our beliefs, plans, expectations, anticipations, estimates and intentions. Forward-looking statements generally can be identified by the use of forward-looking terminology such as "may", "will", "expect", "intend", "estimate", "anticipate", "plan", "foresee", "believe" or "continue" or the negatives of these terms or variations of them or similar terminology. We refer you to the Corporation's filings with the Canadian securities regulatory authorities and the U.S. Securities and Exchange Commission, as well as the "Risk Factors" section of this MD&A, and of our Form 20-F and of our Annual Information Form, for a discussion of the various factors that may affect the Corporation's future results. The results or events predicted in such forward-looking information may differ materially from actual results or events.

Forward-looking statements do not take into account the effect that transactions or non-recurring or other special items announced or occurring after the statements are made have on the Corporation's business. For example, they do not include the effect of business dispositions, acquisitions, other business transactions, asset writedowns or other charges announced or occurring after forward-looking statements are made. The financial impact of such transactions and non-recurring and other special items can be complex and necessarily depends on the facts particular to each of them.

We believe that the expectations represented by our forward-looking statements are reasonable, yet there can be no assurance that such expectations will prove to be correct. Furthermore, the forward-looking statements contained in this report are made as of the date of this report, and we do not undertake any obligation to update publicly or to revise any of the included forward-looking statements, whether as a result of new information, future events or otherwise unless required by applicable legislation or regulation. The forward-looking statements contained in this report are expressly qualified by this cautionary statement.

## Research and Development, Patents and Licenses

Nymox's research and development policies are targeted at the development of novel therapeutic and diagnostic proprietary products that are subject to patent rights either directly owned by the Corporation or licensed to the Corporation through exclusive licensing agreements of patent rights. Over the last three financial years, the Corporation's major research and development activities were in the following program areas:

- Diagnostic products for Alzheimer's disease. The major project in this area, the development and validation of a kit version of our AlzheimAlert<sup>TM</sup> product for sale to laboratories and hospitals was completed in 2004 and the kit subsequently received the CE mark in Europe, allowing it to be marketed there. The FDA has not approved our kit version for sale in the U.S. We are continuing to pursue further kit development and regulatory approvals. At this time, we cannot provide an estimate of the costs and timing to obtain FDA approval for such a kit as it is uncertain at this stage the nature and extent of FDA requirements for approval based on discussions with us.
- Therapeutic products for enlarged prostate (benign prostatic hyperplasia or BPH). We have successfully completed several Phase 1 and Phase 2 multi-center, double-blind, placebo-controlled clinical trials, and follow-up studies, in the U.S. for NX- 1207, our drug candidate for the treatment of enlarged prostate (benign prostatic hyperplasia or BPH), and are presently in Phase 3. We cannot predict with any certainty the outcome of any future trials nor estimate the costs of completing such trials, given the inherent uncertainties in conducting clinical trials, including as yet unknown response rates to our treatment candidate, unforeseeable safety issues, patient enrollment rates, manufacturing costs, and regulatory requirements. We anticipate starting a Phase 3 trial in the near future and subsequently filing a New Drug Application (NDA) with the FDA. Given the inherent uncertainties with any Phase 3 clinical trial, we cannot provide a more precise estimate of the costs and timing of the completion of this project. These uncertainties include the chances of success of any phase of the clinical trials, the nature and extent of FDA requirements to proceed with a Phase 3 and for filing an NDA, our ability to scale up manufacture in accordance with current good manufacturing requirements (cGMP) and in sufficient quantities for commercial use, and whether or when the FDA will ultimately grant us such approval.
- Anti-infectives. Our anti-bacterial agent, NXC-4720, which is being developed as a treatment of meat at the processing stage, has shown to be capable of substantially reducing the level of potentially fatal *E. coli* O157:H7 contamination on fresh beef according to laboratory studies. Other projects in this area, such as treating *E. coli* O157:H7 infection in livestock and treating bacterial infections in humans, are in preliminary stages of development with more uncertain prospects and timing and course of development. Because of the early stage of development of this project, it is impossible to outline the nature, timing or estimated costs of the efforts necessary to complete this project or the anticipated completion dates for this project. The facts and circumstances indicating the uncertainties that preclude us from making a reasonable estimate of the costs and timing necessary to complete this project include the risks inherent in any field trials of NXC-4720, the uncertainty as to the nature and extent of regulatory requirements both for safety and efficacy, and the ability to manufacture NXC-4720 in accordance with current good manufacturing requirements (cGMP) and in sufficient quantities both for large scale trials and for commercial use. In addition, we anticipate that we may need to partner with a larger Corporation in the food or agricultural sectors in order to finance and conduct field trials and to market any approved product; thus the timing of completion of the regulatory approval of such a product will not likely be within our sole control.
- *Tobacco exposure and other diagnostic tests*. We developed and validated NicAlert<sup>TM</sup>, which is an FDA-cleared test for tobacco product use, and TobacAlert<sup>TM</sup>, which is an over-the-counter test for second-hand smoke exposure. These are completed projects with any further research and development costs being related to

product improvement and obtaining regulatory approvals where required in order to expand the market for these products. The development of other new diagnostic tests using our patented diagnostic technologies are in early stage development. Because of the early stage of development of these projects, it is not possible to outline the nature, timing or estimated costs of the efforts necessary to complete any of them nor their anticipated completion dates. The facts and circumstances indicating the uncertainties that preclude us from making a reasonable estimate include the uncertainty about whether we will be able to successfully adapt our patented diagnostic technologies to these new diagnostic indicators, whether any new diagnostic tests we develop will pass proof-of-principle testing both in the laboratory and in clinical trials, and whether we will be able to manufacture such tests at a commercially competitive price.

• Therapeutic products for Alzheimer's disease. We are conducting early stage research and development work into preclinical development of novel drug candidates and original research into the role spherons play in the Alzheimer's disease process in order to pursue spheron-based therapeutics. Because of the early stage of development of this project, it is impossible to outline the nature, timing or estimated costs of the efforts necessary to complete this project, nor the anticipated completion dates for this project. The facts and circumstances indicating the uncertainties that preclude us from making a reasonable estimate include the inherent uncertainties in the pre-clinical and clinical development of therapeutic candidates, In addition, given the very high costs of development of a drug for Alzheimer's disease, we anticipate having to partner with a larger pharmaceutical corporation to conduct and finance clinical trials. The terms of such a partnership arrangement along with our related financial obligations cannot be determined at this time and the timing of completion of the approval of such a drug will likely not be within our sole control. Most pre-clinical drug candidates do not meet necessary milestones to enter clinical trials; of those which do, only a small percentage ultimately achieve regulatory approval and enter the marketplace. We also have global patent rights to the use of statins in the prevention or treatment of Alzheimer's disease. Various published epidemiological and other research studies have shown evidence that statins may help in the prevention or treatment of Alzheimer's disease; other studies have shown otherwise. Other companies and organizations are currently carrying out clinical trials into the use of statin drugs for Alzheimer's disease. The effect of the results of such trials on this program is uncertain.

• Oncology products. We are in the early stages of developing therapeutic products for oncological indications. Because of the early stage of development of this project, it is impossible to outline the nature, timing or estimated costs of the efforts necessary to complete this project nor its anticipated completion dates. The development of cancer therapeutics in particular is associated with high risks and many uncertainties and a drug candidate that shows efficacy can take a long period (7 years or more) to achieve regulatory approval.

Research and development expenses allocated to our major research and development programs are as follows:

	Year ended	Year ended	Year ended
	Dec 31, 2010	Dec 31, 2009	Dec 31, 2008
Alzheimer's Disease: Diagnostics	\$71,932	\$253,020	\$458,080
Alzheimer's Disease: Therapeutics	\$18,744	\$95,184	\$94,200
<b>Anti-Infectives</b>	\$5,091	\$5,963	\$0
<b>BPH</b> (Enlarged Prostate) Therapeutics	\$4,231,508	\$2,576,936	\$1,339,141
<b>Tobacco Exposure Tests:</b>			
	\$7,095	\$5,353	\$103,817
NicAlert™ and TobacAlert™			
Oncology	\$217,349	\$106,763	\$393,673
Total	\$4,551,719	\$3,043,219	\$2,388,911

For the earlier periods from 1995 to 1998, the Corporation did not maintain a cost accounting system that tracked research and development costs on a project-by-project basis. During the initial discovery stages, research and development is more general in nature and cannot be specifically categorized. During the periods 1995 to 2001, the general research expenses related primarily to the development of diagnostic products and therapeutic candidates for Alzheimer's disease. From 2002 to 2004, expenses related primarily to R&D in the areas of Alzheimer's disease and in BPH. Since 2005, expenses have primarily related to the development and clinical trials of NX-1207, our candidate for the treatment of BPH. The breakdown of research and development costs for these periods is as follows: 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 are \$37,423,569.

The Corporation expenses all research and development costs as incurred but does not currently maintain a cost accounting system to track, record and allocate staffing time on a specific project-by-project basis. We manage our ongoing research and development projects and programs in a dynamic, flexible manner. Our researchers, staff and management are typically involved in more than one of our research and development projects and the percentage of time an employee may be involved in a project varies according to the changing needs and progress of that project. As well, a significant portion of the Corporation's research and development expenses, such as laboratory supplies, travel, information systems and services and facilities costs, benefit multiple projects and are not necessarily individually tracked or allocated to a specific project when incurred. Research and development costs are allocated in reasonable and realistic proportion to the projects that benefited from those costs.

According to industry statistics, on average it takes 10 to 15 years to research, develop and bring to market a new prescription medicine in the United States. In light of the steps and complexities involved, the successful development of our product candidates is highly uncertain. Actual product timelines and costs are subject to enormous variability and are very difficult to predict. Accordingly, we cannot provide reliable estimates of the nature, timing and estimated costs of the efforts necessary to complete our programs. This is particularly the case for our programs in early stage development. The risk of failure to complete any such program is high because of uncertain feasibility and commercial viability, long lead times to program completion and potentially high costs in relation to anticipated returns. We update and change our product development programs to reflect the most recent preclinical and clinical

data and other relevant information. Many of our products under development require regulatory approval before being sold. The process of obtaining such approvals is often lengthy and uncertain and requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect our business. We cannot assure you that any such approvals required will be obtained on a timely basis, if at all.

# **Trend Information**

The Corporation does not currently know of any material trends that would be material to our operations.

# **Off-Balance Sheet Arrangements**

The Corporation has no existing off-balance sheet arrangements.

#### ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

# **Directors and Senior Management**

Paul Averback, M.D., D.A.B.P., 60, President and Director since September 1995 and Chairman since June of 2001, is the founder of Nymox and the inventor of much of its initial technology. Prior to founding Nymox, Dr. Averback served as President of Nymox's predecessor, DMS Pharmaceuticals Inc. He received his M.D. in 1975 and taught pathology at universities, including Cambridge University, England (1977-1980), during which time he initiated his research on Alzheimer's disease. He has practised medicine in numerous institutions as well as in private practice. Dr. Averback has published extensively in the scientific and medical literature.

Randall Lanham, Esquire, 47, has been a director since June 8, 2006. He attained his Juris Doctor from Whittier College School of Law in 1991 and a Bachelor of Science degree from the University of Delaware in 1987. Mr. Lanham has vast experience in both domestic and international corporate legal matters. Currently Mr. Lanham manages his own law office in California specializing in corporate mergers and acquisitions. In addition, Mr. Lanham has a broad base of entrepreneurial experience and currently owns and operates several small entertainment companies.

Paul F. McDonald, 85, has been a director since June 8, 2006. A graduate in law of McGill University, he has had a long and varied career as a member of the Canadian investment industry. Mr. McDonald was previously Vice-President of the Montreal Exchange, and he was principal owner and president of a stock exchange firm. His principal focus has been in the financing and development of growth companies in the high-tech and resources sectors, and he has had numerous appointments to corporate boards. He has devoted much time to committee work in the investment sector, as well as to public affairs, including a lengthy tenure as a director of the Quebec Industrial Development Corporation. Mr. McDonald currently works as a private consultant.

Professor David Morse, Ph.D., 54, has been a director since June 8, 2006. He is a world expert in the biochemistry, proteomics and genomics of cell function particularly as it relates to circadian regulation in single cell organisms. He received a Ph.D. from McGill University in 1984, completed a post-doctoral fellowship at Harvard University in 1989 and has been a Full Professor at the University of Montreal since 2001. He has published extensively in the peer-reviewed scientific literature, including papers in journals such as Science, Cell, Proceedings of the National Academy of Science, Journal of Biological Chemistry, and Nature. Dr. Morse has previously collaborated with Nymox scientists in research and development projects.

Roger Guy, M.D., 60, has been a director since June 8, 2006. He received his B.Sc., M.Sc. and M.D degrees from Memorial University of Newfoundland. He is a highly experienced medical doctor who has served as a national examiner. Dr. Guy has broad human clinical trial and business experience.

Jack Gemmell, 59, has been a Director since June, 2001 and is Nymox's General Counsel and Chief Information Officer. He graduated from the Faculty of Law at the University of Toronto in 1977 and was called to the bar in 1979. He practiced in private practice primarily in the area of litigation for over 19 years before joining Nymox in July, 1998.

Roy M. Wolvin, 56, has been Secretary-Treasurer and Chief Financial Officer since September 1995. Prior to September 1995, Mr. Wolvin was Account Manager, private business, for a Canadian chartered bank. Mr. Wolvin holds a degree in Economics from the University of Western Ontario.

Brian Doyle, B.Sc., M.B.A., 56, has been Senior Manager Global Sales and Marketing since May 2003. He received his B.Sc. in Microbiology and Immunology from McGill University, in 1979. He worked in the Experimental Surgery

department at McGill in cancer research, before completing his MBA at Concordia University, in 1983. He has wide sales, marketing and merchandising experience and spent 15 years at a technical sales representative firm, where he was National Sales Manager before joining Nymox.

# Compensation

# **Named Executive Officers**

The Summary Compensation Table and Outstanding Incentive Plan Awards tables below for Named Executive Officers summarize the total compensation paid during the Corporation's financial year ending on December 31, 2010 to the Named Executive Officers of the Corporation and all incentive plan awards outstanding at December 31, 2010 for the Named Executive Officers: The Named Executive Officers are the Corporation's Chief Executive Officer, Chief Financial Officer, and three most highly compensated executive officers.

During the financial year ended December 31, 2010, one executive received a grant of 25,000 options. No executive officer received any other share-based awards, or any bonuses or other non-equity incentive compensation. The Corporation does not have a share-based incentive plan, non-equity incentive plan or pension plan for its executive officers. The Corporation has not made any agreements or arrangements with any of its executive officers in connection with any termination or change of employment or change of control of the Corporation.

#### **Compensation Discussion and Analysis**

The Human Resources and Compensation Committee of the Board of Directors oversees the compensation of executive officers of the Corporation. The members of the Human Resources and Compensation Committee for the financial year ending December 31, 2010 were Dr. Roger Guy, Paul McDonald and Randall Lanham.

The Corporation's current compensation policy for its executive officers, including the Chief Executive Officer and the Named Executive Officers, emphasizes the granting of options over base salary as a means of attracting, motivating and retaining talented individuals. Such a policy is believed to better further the Corporation's business goals by allocating more financial resources to the Corporation's ongoing product development programs. Given the current stage of the Corporation's development, the Corporation has not established and does not use formal benchmarks, performance goals, review processes or other qualitative or quantitative criteria or targets relating to the performance of the Corporation or the individual in order to determine compensation. The Corporation does not have a non-equity incentive plan or a policy of annually granting performance bonuses or salary increases to its executive officers.

The Corporation grants option-based awards to its executive officers in accordance with a stock option plan approved by the shareholders. Further details of the stock option plan are provided below. The stock option plan provides long-term incentives to the Corporation's officers and employees to advance the Corporation's drug development programs towards commercialization and to enhance shareholder value. The Corporation endeavours to provide salaries and option grants that are internally equitable and that are consistent with both job performance and ongoing progress towards corporate goals. The amount of option grants is determined in part by the amount and terms of outstanding and expiring options, the experience and expertise of each executive officer and the needs of the Corporation, among other factors. The Human Resources and Compensation Committee of the Board of Directors reviews all proposals for awards of stock options to executive officers and decides on the appropriateness of the awards. In doing so, the Committee relies solely on discussion among the independent board members on the Committee without any formal pre-determined objectives, criteria or analytic processes but with a view to attracting and retaining executive officers who can help further the Corporation's business plan.

By relying on option grants as a primary means of compensating its executive officers, the Corporation's intention is to provide a direct link between corporate performance and executive compensation while maximizing shareholder value and controlling cash expenditures.

#### Directors

The Summary Compensation Table and Outstanding Incentive Plan Awards tables below for the directors of the Corporation summarize the total compensation paid during the Corporation's financial year ending on December 31, 2010 to the directors of the Corporation and all incentive plan awards outstanding at December 31, 2010 for the directors. Two current directors, Dr. Paul Averback, the President and CEO of the Corporation, and Jack Gemmell, General Counsel, are members of the senior management of the Corporation and do not receive any compensation for acting as a director. Their compensation as Named Executive Officers is summarized in the summary tables for compensation and incentive plans for Named Executive Officers below.

#### **Summary Compensation Table: Named Executive Officers**

					Non-equity incentive					
			Share-	Option-	plan compensation					
				1	(\$)					
Name and	Year	Salary	based	based	Annual	Long-term	Pension	All Other	Total	
principal position		(\$)	awards	awards	incentive	incentive	value	Compensation	n Compensation	

			(\$)	plans	plans	(\$)	(\$)	(\$)
Dr. Paul Averback	2010	190,000						190,000
CEO and President								-, -, -,
Mr. Roy Wolvin	2010	97,093						97,093
CFO								
Mr. Brian Doyle Global Sales Manage	2010	161,715						161,715
Mr. Jack Gemmell	71							
General Counsel, CIO	2010	116,512	25,000					116,512
Salaries are payable i		dian dollar	s, but expressed a	above in U	S\$.			
Surarres are paymere			.s, car enpressed :		<b>.</b>			
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# Outstanding Incentive Plan Awards as of December 31, 2010: Named Executive Officers

# Option-based Awards

	NT 1 C		option cut				
	Number of secu	rities underlying	unexercised			Value of	
Name	options (#) Unvested Total		Vested	Option exercise price (\$)	Option expiration date (mm/dd/yy)	unexercised in-the-money options (\$)	
Dr. Paul	500,000	. ,	500,000	\$3.00	10/24/13	\$2,020,000	
Averback	3,000,000	750,000	2,250,000	\$3.00	08/24/16	\$9,090,000	
	5,000		5,000	\$2.62	09/09/13	\$22,100	
Mr. Day Walvin	50,000		50,000	\$2.82	06/09/16	\$211,000	
Mr. Roy Wolvin	150,000	37,500	112,500	\$3.00	08/24/16	\$454,500	
	20,000		20,000	\$3.65	05/14/19	\$67,800	
	25,000		25,000	\$1.93	04/23/11	\$127,750	
Mr. In als	20,000		20,000	\$2.62	09/09/13	\$88,400	
Mr. Jack	210,000	52,500	157,500	\$3.00	08/24/16	\$636,300	
Gemmell	50,000		50,000	\$3.30	01/23/19	\$187,000	
	25,000		25,000	\$3.40	05/03/20	\$91,000	
Mr. Drian Davila	50,000		50,000	\$3.75	04/28/13	\$164,500	
Mr. Brian Doyle	50,000	11,250	38,750	\$3.00	08/24/16	\$156,550	

Option exercise prices and the values of unexercised in-the-money options are expressed in US\$. The Corporation does not have a share-based award plan.

(1) Unvested options vest quarterly over a 6 year period beginning in August 2006.

# **Summary Compensation Table: Directors**

Name	Year	Fees Earned S (\$)	share-based awards (\$)	Option-base awards	d Non-equity incentive plan compensation (\$)	Pension value (\$)	All other compensation (\$)	Total (\$)
Paul McDonald	2010	\$16,500		10,00				\$16,500
Randall Lanham	2010	\$16,000		10,00	0			\$16,000
Roger Guy, MD	2010	\$16,500		10,00	0			\$16,500
David Morse, Ph.D.	2010	\$14,500		10,00	0			\$14,500

# Outstanding Incentive Plan Awards as of December 31, 2010: Directors

Name		Option-based Awards						
	Number of securities	Option exercise price	Option expiration date	Value of unexercised				
	underlying unexercised			in-the-money options				
	options	(\$)	(mm/dd/yy)	(\$)				

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	(#)			
	10,000	\$2.74	07/17/16	\$43,000
	10,000	\$5.95	08/23/17	\$10,900
Paul McDonald	10,000	\$3.61	07/16/18	\$34,300
	10,000	\$4.83	07/09/19	\$22,100
	10,000	\$2.90	07/16/20	\$41,400
	10,000	\$2.74	07/17/16	\$43,000
	10,000	\$5.95	08/23/17	\$10,900
Randall Lanham	10,000	\$3.61	07/16/18	\$34,300
	10,000	\$4.83	07/09/19	\$22,100
	10,000	\$2.90	07/16/20	\$41,400
	10,000	\$2.74	07/17/16	\$43,000
	10,000	\$5.95	08/23/17	\$10,900
Roger Guy, MD	10,000	\$3.61	07/16/18	\$34,300
	10,000	\$4.83	07/09/19	\$22,100
	10,000	\$2.90	07/16/20	\$41,400
	10,000	\$2.74	07/17/16	\$43,000
	10,000	\$5.95	08/23/17	\$10,900
David Morse, Ph.D.	10,000	\$3.61	07/16/18	\$34,300
	10,000	\$4.83	07/09/19	\$22,100
	10,000	\$2.90	07/16/20	\$41,400

During the same period from 2000 to 2010, the salaries of Named Executive Officers increased from \$465,805US (2000) to \$565,320US (2010), an increase of 1.9% per annum over that eleven year period, or 21.4% in total. During the same period, the Corporation's stock price has increased approximately 261%.

#### **Share Ownership**

As of March 15, 2011, the number of common shares owned or controlled by directors and senior officers of the Corporation were as follows:

Name	Common Shares Owned and Controlled	Percentage of Commo Shares Owned and Controlled	on
Paul Averback, M.D.		13,115,395	40.3%
Randall Lanham		0	*
Paul McDonald		0	*
David Morse, Ph.D.		396	*
Roger Guy, MD		51,979	*
Jack Gemmell		13,725	*
Roy Wolvin		8,920	*
Brian Doyle		10,100	*
* Denotes less than 1%.			

#### **Options**

Nymox has created a stock option plan for its employees, officers and directors, and for consultants. The board of directors of Nymox administers the stock option plan and authorizes the granting of options in accordance with the terms of the plan. Each option gives the individual granted the option the right to purchase a common share of the Corporation at a fixed price during a specified period of no more than ten years. The board may also make all or a portion of the options granted effective only as of a specific future date or dates. The option price must not be less than the market price of the common shares when the option is granted. The total number of shares under option to any one individual may not exceed fifteen percent of the total number of issued and outstanding common shares of the Corporation. The options may not be assigned, transferred or pledged, and expire within three months of the termination of employment or active office with the Corporation and six months of the death of the individual.

No more than 5,500,000 common shares may be under option at any time and a maximum of 5,500,000 common shares are available to be issued under the stock option plan as the result of the exercise of options. Options that expire or terminate without being exercised become available to be granted again. Material changes to the stock option plan such as the number of shares available to be optioned require shareholder approval. On June 21, 2007, the shareholders approved amendments to the plan that included increasing the maximum number of shares that could be issued in total under the plan from 2,500,000 to 5,500,000, and to any one individual from 5% to 15% of the total number of issued shares. Since the inception of the stock option plan in 1995, 346,400 common shares have been issued as a result of the exercise of options granted under the plan.

#### **Board Practices**

Directors are elected at each annual meeting for a term of office until the next annual meeting. Executive officers are appointed by the board of directors and serve at the pleasure of the board. Other than Dr. Averback, no other officer or director previously was affiliated with DMS Pharmaceuticals Inc.

Nymox does not have written contracts with any of the directors named above. We do not have any pension plans or other type of plans providing retirement or similar benefits for directors, nor any benefits upon termination of service as a director.

Nymox's Audit Committee consists of three directors appointed by the Board who are independent of management and who are generally knowledgeable in financial and auditing matters. The Chairman of the Audit Committee is Paul McDonald; the other members are Randall Lanham and Roger Guy. The primary role of the Audit Committee is to provide independent oversight of the quality and integrity of the accounting, auditing, and reporting practices of Nymox with a particular focus on financial statements and financial reporting to shareholders. The Committee is responsible for the appointment, compensation, and oversight of the public accounting firm engaged to prepare or issue an audit report on our financial statements. It oversees all relationships between Nymox and the auditor, including reviewing on an ongoing basis any non-audit services and special engagements that may impact the objectivity or independence of the auditors. The auditors report directly to the Audit Committee. The Audit Committee reviews the scope and results of the audit with the independent auditors.

The Audit Committee meets at least four times a year to review with management and the independent auditors the Corporation's interim and year-end financial condition and results of operations. Its review includes an assessment of the adequacy of the internal accounting, bookkeeping and control procedures of the Corporation. The Audit Committee also has the responsibility for reviewing on an ongoing basis all material transactions between Nymox and its affiliates and other related parties such as officers, directors, other key management personnel, major shareholders and their close family members, affiliated companies or associated enterprises.

The Audit Committee has the power to conduct or authorize investigations into any matters within the Committee's scope of responsibilities, including the power and authority to retain and determine funding for independent counsel, accountants, or other advisors as it determines necessary to carry out its duties.

The Human Resources and Compensation Committee consists of the independent directors of the Board. The Chairman of the Committee is Roger Guy; the other members are Randall Lanham and Paul McDonald. The Committee establishes and reviews overall policy and structure with respect to compensation and employment matters, including the determination of compensation arrangements for directors, executive officers and key employees of the Corporation. The Committee is also responsible for the administration and award of options to purchase shares pursuant to our option and share purchase plans.

The Corporate Governance Committee consists of the independent directors of the Board. The Chairman of the Committee is Randall Lanham; the other members are Paul McDonald and David Morse. This Committee has the general mandate of providing an independent and regular review of the management, business and affairs of Nymox, including our corporate governance. This Committee also reviews and approves director nominations to ensure each nominee meets the requisite requirements under applicable corporate and securities laws, rules and regulations and otherwise possesses the skills, judgment and independence appropriate for a director of a public corporation.

#### **Employees**

In addition to the employees in its Hasbrouck Heights and St. Laurent laboratories and offices, Nymox carries out its work with the assistance of an extensive group of research collaborators, out-sourced manufacturing teams, research suppliers, research institutions, service providers and research consultants. To help carrying out its marketing, Nymox has independent medical representatives detailing its products.

In its Hasbrouck Heights and St. Laurent laboratories and offices, for the year 2010, employed on the average twenty-two persons (eighteen in research and development and four in administration and marketing); for the year 2009, the Corporation employed on the average twenty persons with sixteen in research and development and four in administration and marketing; for the year 2008, the Corporation employed on the average twenty-one persons (seventeen in research and development and four in administration and marketing).

### ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

#### **Major Shareholders**

The following table sets out as of March 15, 2011, the number of common shares owned and controlled by Dr. Paul Averback, the President and CEO of Nymox and a member of the Nymox board of directors, and by all directors and officers as a group.

Name of Shareholder	Number of Common Shares owned by Shareholder	Percent of Class of Common Shares
Dr. Paul Averback	13,115,395	40.3%
All directors and officers as a group	13,200,515	40.5%

The above shareholders have the same voting rights as all other shareholders. There has been no significant change in ownership for any of the persons listed above over the past three years.

Hal Pettigrew reported in a February 15, 2011 filing that he had dispositive power over 2,647,586 shares of Nymox or approximately 8.2% of Nymox's shares. Michael Starcher reported in a February 15, 2011 filing that he had dispositive power over 1,952,007 shares of Nymox or approximately 6.02% of Nymox's shares. The number of shares owned by Hal Pettigrew represents an increase of 252,486 shares from the number of shares reported as beneficially owned in the Schedule 13G filed with the Securities and Exchange Commission on March 31, 2010. The number of shares owned by Michael Starcher represents an increase of 157,007 shares from the number of shares reported as beneficially owned in the Schedule 13G filed with the Securities and Exchange Commission on November 20, 2008. Hal Pettigrew and Michael Starcher have the same voting rights as all other shareholders. Nymox does not know of any other shareholders that beneficially own or hold dispositive power over more than 5% of its shares.

According to information furnished to Nymox by the transfer agent for the common shares, as of March 15, 2011, total shares outstanding were 32,573,856 there were 199 holders of record of the common shares and 4,123 beneficial shareholders in total. Of these, 81 were holders of record of the common shares and 3,275 were beneficial shareholders with addresses in the United States and such holders owned an aggregate of 14,351,519 shares, representing approximately 44.1% of the outstanding shares of common stock.

#### **Related Party Transactions**

The Corporation did not have any related party transactions for the years ended December 31, 2010, 2009 and 2008.

#### ITEM 8. FINANCIAL INFORMATION

In 2010, revenues of Nymox Pharmaceutical Corporation's US Corporation were \$505,897 and revenues of its Canadian Corporation were \$186,744. We refer to Note 16 of the financial statements below.

#### **Dividends**

The Corporation has not issued dividends since inception.

# Cease Trade Orders, or Bankruptcies

To the knowledge of the Corporation, no director or officer of the Corporation or shareholder of the Corporation holding a sufficient number of securities of the Corporation to affect materially the control of the Corporation is, or has been within the past 10 years, a director or officer of any other Corporation that, while such person was acting in that capacity, was the subject of a cease trade or similar order or an order that denied such Corporation access to any exemptions under Canadian securities legislation for a period of more than 30 consecutive days, or was declared bankrupt or made a voluntary assignment in bankruptcy, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets.

#### **Penalties or Sanctions**

To the knowledge of the Corporation, no director, officer or control person of the Corporation has been subject to any penalties or sanctions imposed by a court relating to U.S. or Canadian securities legislation or by a U.S. or Canadian securities regulatory authority or has entered into a settlement agreement with a U.S. or Canadian securities authority, nor has any director, officer or control person of the Corporation been subject to any penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

# **Personal Bankruptcies**

To the knowledge of the Corporation, no director, officer or control person of the Corporation, nor any personal holding Corporation of any such person, has within the past 10 years, been declared bankrupt or made a voluntary assignment in bankruptcy, made a proposal under any legislation relating to bankruptcy or insolvency or been subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of that individual.

#### **Conflicts of Interest**

To the knowledge of the Corporation, there are no existing or potential material conflicts of interest between the Corporation, or subsidiary of the Corporation, and any director, officer or control person of the Corporation.

#### **Legal Proceedings**

The Corporation is not a party to any material legal proceedings.

Consolidated Financial Statements of

# NYMOX PHARMACEUTICAL CORPORATION

Years ended December 31, 2010, 2009 and 2008

 KPMG LLP
 Telephone
 (514) 840-2100

 Chartered Accountants
 Fax
 (514) 840-2187

Internet

www.kpmg.ca

600 de Maisonneuve Blvd. West

Suite 1500 Tour KPMG

Montréal (Québec) H3A 03A

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Nymox Pharmaceutical Corporation

We have audited the accompanying consolidated balance sheets of Nymox Pharmaceutical Corporation and subsidiaries as at December 31, 2010 and 2009 and the related consolidated statements of operations, shareholders equity and cash flows for each of the years in the three-year period ended December 31, 2010. These consolidated financial statements are the responsibility of the Corporation's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Corporation and subsidiaries as of December 31, 2010 and 2009 and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2010 in conformity with Canadian generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Corporation's internal control over financial reporting as of December 31, 2010, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2011 expressed an unqualified opinion on the effectiveness of the Corporation s internal control over financial reporting.

#### /s/ KPMG LLP

**Chartered Accountants** 

Montréal, Canada

March 15, 2011

\*CA Auditor permit no 20408

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KPMG LLPTelephone(514) 840-2100Chartered AccountantsFax(514) 840-2187600 de Maisonneuve Blvd. WestInternetwww.kpmg.ca

Suite 1500

Montréal (Québec) H3A 03A

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Tour KPMG

To the Shareholders and Board of Directors of Nymox Pharmaceutical Corporation

We have audited Nymox Pharmaceutical Corporation's ("the Corporation") internal control over financial reporting as of December 31, 2010, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Discussion and Analysis. Our responsibility is to express an opinion on the Corporation's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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("KPMG International"), a Swiss entity.

KPMG Canada provides services to KPMG LLP.

In our opinion, the Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the criteria established in Internal Control Integrated Framework issued by the COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of the Corporation and subsidiaries as at December 31, 2010 and 2009 and the related consolidated statements of operations, shareholders—equity and cash flows for each of the years in the three-year period ended December 31, 2010, and our report dated March 15, 2011 expressed an unqualified opinion on those consolidated financial statements.

#### /s/ KPMG LLP

**Chartered Accountants** 

Montréal, Canada

March 15, 2011

\*CA Auditor permit no 20408

# NYMOX PHARMACEUTICAL CORPORATION

Consolidated Financial Statements

Years ended December 31, 2010, 2009 and 2008

# **Financial Statements**

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Consolidated Balance Sheets

December 31, 2010 and 2009 (in US dollars)

Shareholders' equity:

	2010	2009
Assets		
Current assets:		
Cash (note 6)	\$ 13,174,999	\$ 668,702
Accounts receivable	11,278	66,354
Other receivables	30,270	24,657
Research tax credits receivable	236,101	251,158
Security deposit		26,994
Inventories	17,448	36,414
	13,470,096	1,074,279
Long-term security deposit	17,396	
Property and equipment (note 4)	14,730	16,152
	\$ 13,502,222	\$ 1,090,431
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,386,696	\$ 1,494,416
Accrued liabilities	191,207	235,535
Deferred revenue (note 6)	2,617,600	
Deferred lease inducement		12,646
	5,195,503	1,742,597
Deferred revenue (note 6)	10,361,333	
Preferred shares of a subsidiary (note 7)	800,000	800,000

Share capital (note 8)	62,855,147	57,955,147
Additional paid-in capital	5,386,950	4,488,365
Deficit	(71,096,711)	(63,895,678)
	(2,854,614)	(1,452,166)

Commitments (note 9)

\$ 13,502,222 \$ 1,090,431

See accompanying notes to consolidated financial statements.

On behalf of the Board:

/s/ Paul Averback MD

Director

/s/ Paul McDonald

Director

Consolidated Statements of Operations

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

	2010	2009	2008
Revenues:			
Sales	\$ 582,383	\$ 415,980	\$ 426,675
Licensing revenues:			
Upfront payment (note 6)	109,067		
Interest	1,191		1,734
	692,641	415,980	428,409
Expenses:			
Research and development	4,787,820	3,183,134	2,500,154
Less research tax credits	(236,101)	(139,915)	(111,243)
	4,551,719	3,043,219	2,388,911
General and administrative (note 6)	1,716,515	799,784	1,064,903
Marketing	147,609	138,396	187,868
Cost of sales	316,945	246,095	262,331
Depreciation of property and equipment	10,223	7,592	9,957
Amortization of intellectual property		220,855	220,856
Stock-based compensation (note 8 (c))	898,585	1,085,164	925,220
Interest and bank charges	7,078	4,949	5,466
	7,648,674	5,546,054	5,065,512
Net loss and comprehensive loss	\$ (6,956,033)	\$ (5,130,074)	\$ (4,637,103)
Basic and diluted loss per share (note 11)	\$ (0.22)	\$ (0.17)	\$ (0.16)
Weighted average number of common shares outstanding See accompanying notes to consolidated financial statements.	31,940,584	30,717,822	29,749,000

Consolidated Statements of Shareholders' Equity

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

	Share capital		Additional paid-in		
	Number	Dollars	capital	Deficit	Total
Balance, December 31, 2007	29,365,753	\$ 50,155,147	\$ 2,477,981	\$ (53,738,501)	\$ (1,105,373)
Issuance of share capital	812,854	3,695,000			3,695,000
Share issue costs				(184,750)	(184,750)
Stock-based compensation			925,220		925,220
Net loss				(4,637,103)	(4,637,103)
Balance, December 31, 2008	30,178,607	53,850,147	3,403,201	(58,560,354)	(1,307,006)
Issuance of share capital (note 8 (a))	1,085,171	4,105,000			4,105,000
Issuance of shares: Option surrender agreement	20,000				
Share issue costs				(205,250)	(205,250)
Stock-based compensation			1,085,164		1,085,164
Net loss				(5,130,074)	(5,130,074)
Balance, December 31, 2009	31,283,778	57,955,147	4,488,365	(63,895,678)	(1,452,166)
Issuance of share capital (note 8 (a))	1,290,078	4,900,000			4,900,000
Share issue costs				(245,000)	(245,000)

Stock-based compensation 898,585 898,585

Net loss (6,956,033) (6,956,033)

Balance, December 31, 2010 32,573,856 \$ 62,855,147 \$ 5,386,950 \$ (71,096,711 ) \$ (2,854,614 )

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

	2010	2009	2008
Cash flows from operating activities:			
Net loss	\$ (6,956,033)	\$ (5,130,074)	\$ (4,637,103)
Adjustments for:			
Depreciation of property and equipment	10,223	7,592	9,957
Amortization of intellectual property		220,855	220,856
Stock-based compensation	898,585	1,085,164	925,220
Write-down of long-term receivable			70,000
Amortization of lease inducement	(12,646)	(3,392)	(9,623)
Changes in operating assets and liabilities:			
Accounts and other receivables	49,463	(31,514)	883
Research tax credits receivable	15,057	(139,915)	(43,202)
Inventories	18,966	(2,507)	(4,476)
Security deposit	9,598		
Accounts payable and accrued liabilities	847,952	489,104	(24,907)
Deferred revenue	12,978,933		(3,333)
	7,860,098	(3,504,687)	(3,495,728)
Cash flows from financing activities:			
Proceeds from issuance of share capital	4,900,000	4,105,000	3,695,000
Share issue costs	(245,000)	(205,250)	(184,750)
	4,655,000	3,899,750	3,510,250
Cash flows from investing activities:			
Additions to property and equipment	(8,801)	(2,219)	(11,772)
Net increase in cash	12,506,297	392,844	2,750
Cash, beginning of year	668,702	275,858	273,108
Cash, end of year See accompanying notes to consolidated financial statements.	\$ 13,174,999	\$ 668,702	\$ 275,858

Notes to Consolidated Financial Statements

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

#### 1. Business activities:

Nymox Pharmaceutical Corporation (the "Corporation"), incorporated under the *Canada Business Corporations Act*, including its subsidiaries, Nymox Corporation, a Delaware Corporation, and Serex Inc. of New Jersey, is a biopharmaceutical corporation, which specializes in the research and development of products for the aging population. The Corporation developed AlzheimAlert<sup>TM</sup>, a urinary test that aids physicians in the diagnosis of Alzheimer s disease. The Corporation also markets NicAle<sup>TM</sup> and TobacAlert<sup>TM</sup>, tests that use urine or saliva to detect use of tobacco products. The Corporation is developing NX-1207, a novel treatment for benign prostatic hyperplasia which is in Phase 3 clinical trials. The Corporation is also developing therapeutics for the treatment of Alzheimer s disease and new anti-bacterial agents for the treatment of bacterial infections in humans, including a treatment for E. coli O157:H7 bacterial contamination in meat and other food and drink products.

Since 1989, the Corporation s activities and resources have been primarily focused on developing certain pharmaceutical technologies. The Corporation is subject to a number of risks, including the successful development and marketing of its technologies and maintaining access to existing financing arrangements under the Common Stock Private Purchase Agreement referred to in note 8 (a). The Corporation depends on this financing as well as collaboration agreements to fund its operations. In order to achieve its business plan and the realization of its assets and liabilities in the normal course of operations, the Corporation anticipates the need to raise additional capital and/or achieve sales and other revenue generating activities. Management believes that cash balances, funds from operations, as well as existing financing facilities will be sufficient to meet the Corporation's requirements for the next year.

The Corporation is listed on the NASDAQ Stock Market.

#### 2. Significant accounting policies:

#### (a) Consolidation:

The consolidated financial statements of the Corporation have been prepared under Canadian generally accepted accounting principles ( GAAP ) and include the accounts of its US subsidiaries, Nymox Corporation and Serex Inc. Intercompany balances and transactions have been eliminated on consolidation.

Consolidated financial statements prepared under US GAAP would differ in some respects from those prepared in Canada. The reconciliation of net loss and comprehensive loss, shareholders equity and cash flows reported in accordance with Canadian GAAP to US GAAP is presented in note 15.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

# 2. Significant accounting policies (continued):

#### (b) Financial assets and liabilities:

Financial instruments are classified into one of the following five categories: held-for-trading, held-to-maturity investments, loans and receivables, available-for-sale financial assets or other financial liabilities. All financial instruments, including derivatives, are included in the consolidated balance sheet and are measured at fair market value, with the exception of loans and receivables, held-to-maturity investments and other financial liabilities, which are measured at amortized cost.

The Corporation has classified its cash, accounts receivable and other receivables as loans and receivables , and its accounts payable and accrued liabilities as other financial liabilities .

# (c) Inventories:

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Inventories consist of finished goods and are carried at the lower of cost and net realizable value. Cost is determined on the basis of weighted average cost.

#### (d) Property and equipment and intellectual property:

Property and equipment and intellectual property are recorded at cost. Depreciation and amortization are provided using the straight-line method at the following rates:

Laboratory equipment20%Computer equipment33 %Office equipment and fixtures20%Intellectual property rights acquired10%	Asset	Kate
Office equipment and fixtures 20%	Laboratory equipment	20%
1 1	Computer equipment	33 %
Intellectual property rights acquired 10%	Office equipment and fixtures	20%
	Intellectual property rights acquired	10%

#### (e) Impairment and disposal of long-lived assets:

Long-lived assets, consisting of property and equipment, are tested for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for long-lived assets when the carrying amount of an asset to be held and used exceeds the sum of the undiscounted cash flows expected from its use and disposal; the impairment recognized is measured as the amount by which the carrying amount of the net asset exceeds its fair value.

Data

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

### 2. Significant accounting policies (continued):

### (f) Revenue recognition:

Revenue from product sales is recognized when the product has been delivered and obligations as defined in the agreement are performed. Collaboration agreements that include multiple deliverables are considered to be multiple-element arrangements. Under this type of arrangement, the identification of separate units of accounting is required and revenue is allocated among the separate units based on their relative fair values.

Payments received under a collaboration agreement may include upfront payments, milestone payments, sale of goods, royalties and license fees. Revenue for each unit of accounting are recorded as described below:

### (i) Upfront payments:

Upfront payments are deferred and recognized as revenue on a systematic basis over the estimated service period. Changes in estimates are recognized prospectively when changes to the expected term are determined.

#### (ii) Milestone payments:

Revenue subject to the achievement of milestones is recognized only when the specified events have occurred and collectibility is reasonably assured.

Specifically, the criteria for recognizing milestone payments are that (i) the milestone is substantive in nature, (ii) the achievement was not reasonably assured at the inception of the agreement, and (iii) the Corporation has no further involvement or obligation to perform associated with the achievement of the milestone, as defined in the related collaboration arrangement.

#### (iii) Sale of goods:

Revenue from the sale of goods is recognized when the Corporation has transferred to the buyer the significant risks and rewards of ownership of the goods, there is no continuing management involvement with the goods, and the amount of revenue can be measured reliably.

# (iv) Royalties and license fees:

Royalties and license fees are recognized when conditions and events under the license agreement have occurred and collectability is reasonably assured.

Interest is recognized on an accrual basis.

# (g) Research and development expenditures:

Research expenditures, net of research tax credits, are expensed as incurred. Development expenditures, net of tax credits, are expensed as incurred, except if they meet the criteria for deferral in accordance with generally accepted accounting principles. As at December 31, 2010 and 2009, no development expenditures have been deferred.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

### 2. Significant accounting policies (continued):

#### (h) Foreign currency translation:

The Corporation s measurement currency is the United States dollar. Monetary assets and liabilities of the Canadian and foreign operations denominated in currencies other than the United States dollar are translated at the rates of exchange prevailing at the balance sheet dates. Other assets and liabilities denominated in currencies other than the United States dollar are translated at the exchange rates prevailing when the assets were acquired or the liabilities incurred. Revenues and expenses denominated in currencies other than the United States dollar are translated at the average exchange rate prevailing during the year, except for depreciation and amortization which are translated at the same rates as those used in the translation of the corresponding assets. Foreign exchange gains and losses resulting from the translation are included in the determination of net earnings.

Foreign exchange gains (losses) included in the consolidated statements of operations for fiscal 2010 amounted to \$25,294 (2009 - \$58,068; 2008 - \$(23,020)).

### (i) Stock-based compensation:

The Corporation records stock-based compensation, net of forfeitures, relating to employee and non-employee stock options granted, using the fair value based method estimated using the Black-Scholes model. Under this method, compensation cost related to employee awards is measured at the date of grant, net of forfeitures, and is expensed over the award's vesting period. The Corporation has no unvested non-employee awards.

#### (j) Income taxes:

The Corporation accounts for income taxes using the asset and liability method of accounting for income taxes. Under this method, future income tax assets and liabilities are determined based on temporary differences (differences between the accounting basis and the tax basis of the assets and liabilities), and are measured using the currently enacted, or substantively enacted, tax rates and laws expected to apply when these differences reverse. A valuation allowance is recorded against any future income tax asset, if it is more likely than not that the asset will not be realized.

#### (k) Earnings per share:

Basic earnings per share are determined using the weighted average number of common shares outstanding during the period. Diluted earnings per share are computed in a manner consistent with basic earnings per share, except that the weighted average shares outstanding are increased to include additional shares from the assumed exercise of options and warrants, if dilutive. The number of additional shares is calculated by assuming that outstanding options were exercised, and that the proceeds from such exercises, as well as the amount of unrecognized stock-based compensation which is considered to be assumed proceeds, were used to acquire shares of common stock at the average market price

during the reporting period.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

### 2. Significant accounting policies (continued):

#### (1) Use of estimates:

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant areas requiring the use of management estimates include determining separate units of accounting in connection with revenue recognition relating to multiple element arrangements, estimating the service period used for the amortization of the upfront payment received in connection with a collaboration agreement, estimating the useful lives of long-lived assets, as well as estimating the recoverability of research tax credits receivable and future tax assets, and estimating stock-based compensation. The reported amounts and note disclosure are determined to reflect the most probable set of economic conditions and planned courses of action. Actual results could differ from those estimates.

# 3. Changes in accounting policies:

# (a) Accounting changes:

Goodwill and intangible assets

Effective with the commencement of its 2009 fiscal year, the Corporation adopted the Canadian Institute of Chartered Accountants ("CICA") Handbook Section 3064, *Goodwill and Intangible Assets*, which replaced Section 3062, *Goodwill and Other Intangible Assets*, and Section 3450, *Research and Development Costs*. The standard provides guidance on the recognition of intangible assets in accordance with the definition of an asset and the criteria for asset recognition, whether these assets are separately acquired or internally developed. This standard applies to interim and annual financial statements relating to fiscal years beginning on or after October 1, 2008, and has been adopted on a retrospective basis effective from the first quarter of fiscal 2009.

Prior to the adoption of Section 3064, the Corporation capitalized and amortized direct costs incurred to secure patents related to internally-generated assets on a straight-line basis over 17 years.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

#### 3. Changes in accounting policies (continued):

(a) Accounting changes (continued): Goodwill and intangible assets (continued)

As a result of adopting this Section, starting January 1, 2009, direct costs incurred to secure patents are no longer capitalized by the Corporation. As well, comparative financial information for previous financial periods reflects the financial position and results of operations that would have resulted if the patent costs had not been capitalized in those previous periods. The impact of adopting this Section, on a retrospective basis, is as follows:

2008

net	IOSS	ana	com	pren	ensive	loss:

As previously reported	\$ (4,590,345)
Effect of adopting this new accounting policy	(46,758)
As recast	\$ (4,637,103)

Basic and diluted loss per share:

As previously reported	\$ (0.15)
Effect of adopting this new accounting policy	(0.01)
As recast	\$ (0.16)

# (b) Future accounting changes:

**International Financial Reporting Standards** 

In February 2008, Accounting Standards Board ("AcSB") confirmed that Canadian GAAP, as used by publicly accountable enterprises, will be fully converged into International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board ("IASB"). The changeover date is for interim and annual financial statements relating to fiscal years beginning on or after January 1, 2011. Therefore, the Corporation will be required to report under IFRS for its 2011 interim and annual financial statements. The Corporation will convert to these new standards according to the timetable set within these new rules. The Corporation is currently finalizing its assessment of the future impact of these new standards on its consolidated financial statements and progressing towards

implementation.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

# 4. Property and equipment:

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	Cost	Accumulated depreciation and amortization	Net book value
Laboratory equipment	\$ 433,202	\$ 428,008	\$ 5,194
Computer equipment	22,596	16,599	5,997
Office equipment and fixtures	92,767	89,228	3,539
	\$ 548,565	\$ 533,835	\$ 14,730
			2009
	Cost	Accumulated depreciation and amortization	Net book value
Laboratory equipment	\$ 434,751	\$ 425,199	\$ 9,552
Computer equipment	24,455	20,387	4,068
Office equipment and fixtures	91,501	88,969	2,532
	\$ 550,707	\$ 534,555	\$ 16,152

# 5. Intellectual property:

			Cart		ccumulated	2010 and 2009 Net book
			Cost	ar	nortization	value
59	Intellectual property rights acquired	\$ 2,222	2,661	\$	2,222,661	\$

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

#### 6. Licensing revenues and deferred revenue:

On December 16, 2010, the Corporation signed a license and collaboration agreement with Recordati Ireland Ltd. (Recordati), a European pharmaceutical group, for the development and commercialization of NX-1207 in Europe, including Russia and the CIS, the Middle East, the Maghreb area of North Africa and South Africa. The license and collaboration agreement covers the use of NX-1207 for the treatment of benign prostatic hyperplasia ("BPH") as the initial indication for development and commercialization. Recordati made an upfront payment to the Corporation of 10 million (US\$13,088,000), in December 2010, and will make regulatory approval and sales milestones payments, and tiered supply and royalty payments of a minimum of 26% to increase progressively up to 40% of total net sales in the case specific contractual conditions are achieved.

The upfront payment of \$13,088,000 has been deferred and is being recognized as revenue on a systematic basis over the estimated service period. This period may be modified in the future based on additional information that may be received by the Corporation. In 2010, an amount of \$109,067 (2009 - nil) was recognized as revenue related to this upfront payment based on the portion of the financial year during which the agreement was effective (December 16 to 31, 2010). As at December 31, 2010, the deferred revenue related to this transaction amounted to \$12,978,933 (2009 - nil).

In 2010, the Corporation incurred \$705,000 of professional fees related to entering into the license and collaboration agreement with Recordati, which is recorded in general and administrative expenses.

## 7. Preferred shares of a subsidiary:

The preferred shares of a subsidiary relate to redeemable and/or convertible preferred shares of Serex in the amount of \$800,000. Up to 50% of the preferred shares are redeemable at any time at the option of the preferred shareholders at their issue price, subject to holders with at least 51% of the face value of the preferred shares asking for redemption, and sufficient funds being available in Serex. The preferred shares are also convertible at the option of the holders into common shares of Serex at a price of \$3.946 per share.

#### NYMOX PHARMACEUTICAL CORPORATION

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

#### 8. Share capital:

2010 2009

Authorized:

An unlimited number of common shares

Issued and outstanding:

32,573,856 common shares (2009 - 31,283,778 shares)

\$ 62,855,147 \$ 57,955,147

The holders of common shares are entitled to receive dividends as declared, which is at the Corporation s discretion, and are entitled to one vote per share at the annual general meeting of the Corporation. The Corporation has never paid any dividends.

### (a) Common Stock Private Purchase Agreement:

In November 2009, the Corporation entered into a Common Stock Private Purchase Agreement with an investment company (the "Purchaser") that established the terms and conditions for the purchase of common shares by the Purchaser. In November 2010, this agreement was terminated and a new agreement was concluded with the Purchaser. In general, the Corporation can, at its discretion, require the Purchaser to purchase up to \$15 million of common shares over a 24-month period based on notices given by the Corporation. The Corporation must comply with general covenants in order to draw on its facility, including maintaining its stock exchange listing and registration requirements and having no material adverse effects, as defined in the agreement, with respect to the business and operations of the Corporation.

The number of shares to be issued in connection with each notice shall be equal to the amount specified in the notice, divided by 97% of the average price of the Corporation's common shares for the five days preceding the giving of the notice. The maximum amount of each notice is \$500,000 and the minimum amount is \$100,000. The Corporation may terminate the agreement before the 24-month term, if it has issued at least \$8 million of common shares under the agreement.

In 2010, the Corporation issued 1,290,078 common shares (2009 - 1,085,171) to the Purchaser for aggregate proceeds of \$4,900,000 (2009 - \$4,105,000) under the agreements. As at December 31, 2010, the Corporation can require the Purchaser to purchase up to \$14,800,000 of common shares over the remaining 22 months of the agreement, provided the Corporation adheres to its covenants.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

#### 8. Share capital (continued):

#### (b) Stock options:

The Corporation has established a stock option plan (the Plan ) for its key employees, its officers and directors, and certain consultants. The Plan is administered by the Board of Directors of the Corporation. The Board may, from time to time, designate individuals to whom options to purchase common shares of the Corporation may be granted, the number of shares to be optioned to each, and the option price per share. The option price per share cannot involve a discount to the market price at the time the option is granted. The maximum number of shares is 5,500,000 and the maximum number of shares which may be optioned to any one individual is 15% of the total issued and outstanding common shares. Options under the Plan expire ten years after the grant and vest either immediately or over periods up to six years.

The following table provides the activity of stock option awards during the year and for options outstanding and exercisable at the end of the year, the weighted average exercise price, the weighted average years to expiration and the aggregate intrinsic value. The aggregate intrinsic value represents the pre-tax intrinsic value based on the Corporation s closing stock price on December 31, 2010 of \$7.04, which would have been received by option holders had they exercised their options at that date and sold their shares at market price.

		Options outstanding			Non-vested option		
	Number	Weighted average exercise price	Weighted average years to expiration	Aggregate intrinsic value	Number	Weighted average grant date fair value	
Outstanding,							
December 31, 2008	4,869,000 \$	3.11	6.90	\$ 1,868,920	2,073,750	\$ 1.38	
Granted	112,000	3.90					
Expired	(157,000)	4.53					
Cancelled	(100,000)	3.88					
Vested					(592,500)	1.38	

Outstanding,

	December 31, 2009 Granted Expired	4,724,000 65,000 (175,000)	3.07 3.09 3.13	6.24	7,121,335	1,481,250 (62,500)	1.38
	Vested					(567,500)	1.38
	Outstanding, December 31, 2010	4,614,000	\$ 3.06	5.32	\$ 18,341,930	851,250 \$	1.38
62	Options exercisable	3,762,750	\$ 3.08	5.25	\$ 14,902,880	N/A	N/A

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 8. Share capital (continued):

(b) Stock options (continued):

As at December 31, 2010, options outstanding and exercisable were as follows:

Options outstanding	Options exercisable	Exercise price per share	Expiry date
28,000	28,000	\$ 1.93	April 23, 2011
1,500	1,500	4.20	November 9, 2011
75,000	75,000	4.33	November 13, 2011
50,000	50,000	3.75	April 28, 2013
37,000	37,000	2.62	September 9, 2013
500,000	500,000	3.00	October 24, 2013
200,000	200,000	2.82	June 9, 2016
40,000	40,000	2.74	July 17, 2016
3,415,500	2,564,250	3.00	August 24, 2016
40,000	40,000	5.95	August 23, 2017
40,000	40,000	3.61	July 16, 2018
10,000	10,000	3.03	November 26, 2018
50,000	50,000	3.30	January 23, 2019
2,000	2,000	3.05	March 24, 2019
20,000	20,000	3.65	May 14, 2019
40,000	40,000	4.83	July 9, 2019
25,000	25,000	3.40	May 3, 2020
40,000	40,000	2.90	July 16, 2020
4,614,000	3,762,750	\$ 3.06	

## (c) Stock-based compensation:

2010 2009 2008

Stock-based compensation pertaining to general and administrative	\$ 200,265	\$ 348,684	\$ 171,920
Stock-based compensation pertaining to marketing	10,320	10,320	12,040
Stock-based compensation pertaining to research and development	688,000	726,160	741,260

\$ 898,585 \$ 1,085,164 \$ 925,220

As at December 31, 2010, the unrecognized compensation cost related to non-vested awards was \$1,171,320 and the remaining weighted average recognition period was approximately 18 months.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 8. Share capital (continued):

### (c) Stock-based compensation (continued):

The fair value of the options granted during the year was determined using the Black-Scholes pricing model using the following weighted average assumptions:

	2010	2009	2008
Risk-free interest rate	2.62%	2.09%	3.16%
Expected volatility	68.63%	74.71%	73.37%
Expected life in years	5	5	5
Dividend yield			

The weighted average grant-date fair value of options granted during the year ended December 31, 2010 was \$1.81 per option (2009 - \$2.41 per option; 2008 - \$2.16 per option).

Dividend yield was determined to be nil, since it is the present policy of the Corporation to retain all earnings to finance operations.

### 9. Commitments:

Operating leases

Minimum lease payments under operating leases that were entered into by the Corporation for the next four years are as follows:

2011	\$ 365,071
2012	299,988
2013	94,395
2014	3,227

762,681

In 2010, the Corporation entered into operating lease agreements for its Canadian and US premises, which will expire on August 31, 2012 and October 31, 2013, respectively.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 10. Income taxes:

The following table reconciles income tax at the statutory rate with the income tax expense for the year:

			2010		2009	2008
	Loss before income taxes:					
	Canadian operations	\$	(6,047,919)	\$	(4,838,856)	\$ (4,135,885)
	US operations		(908,114)		(291,218)	(501,218)
			(6,956,033)		(5,130,074)	(4,637,103)
	Basic income tax rate		29.9 %		30.9%	30.9%
	Income tax recovery at statutory tax rates		(2,079,854)		(1,585,193)	(1,432,865)
	Adjustments in income taxes resulting from:					
	Change in valuation allowance		1,834,000		1,249,694	1,159,503
	Permanent differences		245,854		335,499	273,362
	Income taxes	\$		\$		\$
The	major components of income tax expense in 2010 are as follo	ws	:			
	Current income tax expense, exclusive of the effects of the co	om	ponent listed be	lov	v	\$ 2,423,054
	Reduction in income tax expense arising from the recognition loss	n o	of previously unr	ec	ognized tax	(2,423,054)
65	Income taxes					\$

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

#### 10. Income taxes (continued):

The income tax effect of temporary differences that give rise to the net future tax asset is presented below:

	2010	2009
Future tax assets:		
Deferred revenue	\$ 3,531,000	\$
Non-capital losses	9,524,000	11,388,000
Scientific research and experimental development expenditures	1,581,000	1,429,000
Property and equipment and patents	1,894,000	1,876,000
Share issue costs	124,000	127,000
	16,654,000	14,820,000
Less valuation allowance	(16,654,000)	(14,820,000)
Net future tax asset	\$	\$

In assessing the realizability of future tax assets, management considers whether it is more likely than not that some portion or all of the future tax assets will not be realized. The ultimate realization of future tax assets is dependent upon the generation of future taxable income. The generation of future taxable income is dependent on the successful commercialization of the Corporation's products and technologies.

The Corporation has non-capital losses carried forward and accumulated scientific research and development expenditures, which are available to reduce future years taxable income. These expire as follows:

	Federal	Provincial
Non-capital losses:		
2014	\$ 447,000	\$ 370,000
2015	3,544,000	3,544,000
2026	3,808,000	3,745,000
2027	3,609,000	3,529,000
2028	2,750,000	2,750,000
2029	3,509,000	3,509,000

Scientific research and development expenditures:
Indefinitely 4,038,000 8,201,000

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 10. Income taxes (continued):

The Corporation also has investment tax credits available in the amount of approximately \$737,000 to reduce future years Canadian federal taxes payable. These credits expire as follows:

2018	\$ 5,000
2019	9,000
2020	23,000
2021	24,000
2022	53,000
2023	69,000
2024	23,000
2025	29,000
2026	66,000
2027	73,000
2028	72,000
2029	117,000
2030	174,000

In addition, the Corporation s US subsidiaries have losses carried forward of approximately \$11,993,000 which expire as follows:

2011 2012 2018 2019 2020	\$ 1,035,000 1,932,000 2,781,000 1,078,000 813,000
2021	664,000
2022	522,000
2023	565,000

737,000

2024	353,000
2025	264,000
2026	355,000
2027	373,000
2028	351,000
2029	86,000
2030	821,000

\$ 11,993,000

## 11. Earnings per share:

The diluted loss per share was the same amount as basic loss per share, as the effect of options would have been anti-dilutive, because the Corporation incurred losses in each of the last three fiscal years. All outstanding options could potentially be dilutive in the future.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

### 12. Capital disclosures:

The Corporation's objective in managing capital is to ensure a sufficient liquidity position to finance its research and development activities, general and administrative expenses, working capital and overall capital expenditures, including those associated with patents. The Corporation makes every attempt to manage its liquidity to minimize shareholder dilution when possible.

The Corporation defines capital as total shareholders—equity. To fund its activities, the Corporation has followed an approach that relies almost exclusively on the issuance of common equity and most recently during 2010, entered into a collaboration agreement. Since inception, the Corporation has financed its liquidity needs primarily through private placements and since 2003 through a financing agreement with an investment company that has been replaced annually by a new agreement with the same purchaser (see note 8 (a) - Common Stock Private Purchase Agreement). The Corporation intends to access financing under this agreement when appropriate to fund its research and development activities. The recent financial crisis in the United States and the global economic environment have had a negative impact on the availability of liquidity in the market and may have an effect on the liquidity of the Purchaser to the Common Stock Private Purchase Agreement. Since 2003 through December 2010, the Purchaser has always complied with the drawdowns made pursuant to the agreement. The Corporation believes that cash balances, funds from operations, as well as from existing financing agreements will be sufficient to meet the Corporation—s cash requirements for the next twelve months.

In October 2010, the Corporation was informed that it had been awarded a grant of \$244,479 from the U.S. Government under the Qualifying Therapeutic Discovery Project for its ongoing Phase III clinical trial program for NX-1207 for the treatment of BPH. The Corporation anticipates receiving the grant sometime in 2011. The Corporation will record this amount in its consolidated financial statement when it is received.

The capital management objectives remain the same as for the previous fiscal year. When possible, the Corporation tries to optimize its liquidity needs by non-dilutive sources, including sales, collaboration agreements, investment tax credits and interest income. The Corporation's general policy on dividends is to retain cash to keep funds available to finance its research and development and operating expenses. The Corporation has no debt.

The Corporation is not subject to any capital requirements imposed by external parties.

#### 13. Financial risk management:

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

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

#### 13. Financial risk management (continued):

## (a) Foreign currency risk:

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

Approximately 78% of expenses that occurred during the year ended December 31, 2010 (2009 - 76%) were denominated in US dollars. Foreign exchange fluctuations had no meaningful impact on the Corporation s results in 2010, 2009 or 2008.

The following table provides significant items exposed to foreign exchange as at December 31:

	2010		2009
	C	CA\$	
Cash	\$ 26,736	\$	71,224
Accounts, other receivables and research tax credits receivable	30,106		291,671
Accounts payable and accrued liabilities	(299,776)		(330,357)
	\$ (242,934)	\$	32,538

The following exchange rates were applied for the years ended December 31:

	Averaş (twelve		• •	g date rate aber 31,
	2010	2009	2010	2009
US\$ - CA\$	1.0299	1.1419	0.9946	1.0510

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

#### 13. Financial risk management (continued):

## (a) Foreign currency risk (continued):

Based on the Corporation s foreign currency exposures noted above, varying the above foreign exchange rates to reflect a 5% strengthening of the US dollar would have reduced the net loss by less than \$15,000, assuming that all other variables remained constant.

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

#### (b) Credit risk:

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

The Corporation has a limited number of customers. Included in the consolidated balance sheet are trade receivables of \$11,278 (2009 - \$66,354), all of which were aged under 45 days. Four customers (2009 - four customers) accounted for 100% (2009 - 88%) of the trade receivables balance as at December 31, 2010. There was no amount recorded as bad debt expense for the year ended December 31, 2010 (a nominal amount was recorded for the year ended December 31, 2009).

As at December 31, 2010, the Corporation s maximum credit exposure corresponded to the carrying amount of cash, accounts receivable and other receivables.

#### (c) Interest rate risk:

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. Cash bears interest at a variable rate. Accounts receivable, other receivables, accounts payable and accrued liabilities bear no interest. The Corporation has no other interest-bearing financial instruments.

Based on the value of variable interest-bearing cash during the year ended December 31, 2010, an assumed 0.5% increase or 0.5% decrease in interest rates during such period would have had no significant effect on the net loss.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 13. Financial risk management (continued):

## (d) Liquidity risk:

Liquidity risk is the risk that the Corporation will not be able to meet its financial obligations as they fall due. The Corporation manages liquidity risk through the management of its capital structure, as outlined in note 12 - Capital disclosures. The Corporation does not have an operating credit facility and finances its activities through cash balances and an equity financing agreement with an investment company, as described in note 8 (a) - Common Stock Private Purchase Agreement. Furthermore, the Corporation has \$13 million of cash on hand at December 31, 2010, mainly as a result of receiving an upfront payment of \$13 million in December 2010 in connection with the license and collaboration agreement entered into with Recordati as referred to in note 6 - Licensing revenues and deferred revenue.

The following are the contractual maturities of financial liabilities as at December 31, 2010:

	Carrying amount	Less than 1 year	1 year to 5 years
Accounts payable and accrued liabilities	\$ 2,577,903	\$ 2,577,903	\$

#### 14. Financial instruments:

Fair value disclosure:

The Corporation has determined that the carrying value of its short-term financial assets and liabilities approximates their fair value due to the immediate or short-term maturity of these financial instruments.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 15. Canadian/US reporting differences:

(a) Consolidated statements of operations, shareholders' equity and cash flows:

The reconciliation of net loss and comprehensive loss, shareholders' equity and cash flows reported in accordance with Canadian GAAP to US GAAP is as follows:

	2010	2009	2008
Net loss and comprehensive loss, Canadian GAAP	\$ (6,956,033)	\$ (5,130,074)	\$ (4,637,103)
Costs to secure patents (i)	55,000	133,941	564,149
Amortization of patents (i)	(289,637)	(286,401)	(288,785)
Write-down of patent costs (i)			(228,606)
Net loss and comprehensive loss, US GAAP	\$ (7,190,670)	\$ (5,282,534)	\$ (4,590,345)
Basic and diluted loss per share, US GAAP	\$ (0.23)	\$ (0.17)	\$ (0.15)
Shareholders' equity, Canadian GAAP	\$ (2,854,614)	\$ (1,452,166)	\$ (1,307,006)
Adjustments:			
Noncontrolling interest (ii)	400,000	400,000	400,000
Costs to secure patents, net of amortization and write-down (i)	2,930,635	3,165,272	3,317,732
Stock-based compensation - options granted to non-employees (iii):			
Cumulative compensation expense	(1,425,143)	(1,425,143)	(1,425,143)
Additional paid-in capital	1,477,706	1,477,706	1,477,706
Change in reporting currency (iv)	(62,672)	(62,672)	(62,672)

3,320,526 3,555,163 3,707,623

Shareholders' equity, US GAAP (v) \$ 465,912 \$ 2,102,997 \$ 2,400,617

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 15. Canadian/US reporting differences (continued):

(a) Consolidated statements of operations, shareholders' equity and cash flows (continued): The reconciliation of net loss and comprehensive loss, shareholders' equity and cash flows reported in accordance with Canadian GAAP to US GAAP is as follows (continued):

	2010	2009	2008
Cash flows from operating activities, Canadian GAAP	\$ 7,860,098	\$ (3,504,687)	\$ (3,495,728)
Costs to secure patents	55,000	133,941	564,149
Changes in operating assets and liabilities:			
Accounts payable and accrued liabilities	276,901	(37,131)	(348,654)
Cash flows from operating activities,			
US GAAP	\$ 8,191,999	\$ (3,407,877)	\$ (3,280,233)
Cash flows from investing activities,			
Canadian GAAP	\$ (8,801)	\$ (2,219)	\$ (11,772)
Additions to patent costs	(331,901)	(96,810)	(215,495)
Cash flows from investing activities,			
US GAAP	\$ (340,702)	\$ (99,029)	\$ (227,267)
Non-cash transactions,			
Canadian GAAP	\$	\$	\$
Additions to patent costs included in accounts payable			
and accrued liabilities at year-end	321,404	598,305	561,174

Non-cash transactions, US GAAP

\$ 321,404 \$ 598,305 \$ 561,174

## (i) Costs to secure patents:

As disclosed in note 3 (a), the Corporation adopted the CICA Handbook Section 3064, *Goodwill and Intangible Assets*, effective January 1, 2009, on a retrospective basis. For US GAAP purposes, the Corporation continues to capitalize and amortize direct costs incurred to secure patents related to internally-generated intangible assets, on a straight-line basis over 17 years.

## (ii) Noncontrolling interest:

The noncontrolling interest of \$400,000 included in preferred shares of a subsidiary for Canadian GAAP purposes is presented as a separate component of equity for US GAAP purposes, retrospectively.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

### 15. Canadian/US reporting differences (continued):

(a) Consolidated statements of operations, shareholders' equity and cash flows (continued):

### (iii) Stock-based compensation:

For US GAAP purposes, on January 1, 2006, the Corporation adopted Topic 718, *Compensation - Stock Compensation*, in the Accounting Standards Codification ("ASC"), which requires the expensing of all options issued, modified or settled based on the grant date fair value over the period during which the employee is required to provide service. The Corporation adopted the guidance using the modified prospective approach, which requires application of the standard to all awards granted, modified or cancelled after January 1, 2006, and to all awards for which the requisite service has not been rendered as at such date.

Previously, the Corporation elected to follow the intrinsic value method of accounting under Accounting Principles Board ("APB") Opinion No. 25 ("APB 25"), *Accounting for Stock Issued to Employees*, in accounting for stock options granted to employees and directors. Under the intrinsic value method, compensation cost is recognized for the difference between the quoted market price of the stock at the grant date and the amount the individual must pay to acquire the stock. In addition, in accordance with Topic 718, compensation related to the stock options granted to non-employees has been recorded in the accounts based on the fair value of the stock options at the measurement date.

For Canadian GAAP purposes, the Corporation has been applying the fair value based method since January 1, 2004 to account for employee stock options. Prior to January 1, 2004, the Corporation applied the fair value based method only to stock-based payments to non-employees and applied the settlement method of accounting for employee stock options. Under the settlement method, any consideration paid by employees on the exercise of stock options was credited to share capital, and no compensation cost was recognized.

#### (iv) Change in reporting currency:

The Corporation adopted the US dollar as its reporting currency, effective January 1, 2000. For Canadian GAAP purposes, the financial information for 1999 was translated into US dollars at the December 31, 1999 exchange rate. For US GAAP reporting purposes, assets and liabilities for all years presented have been translated into US dollars at the ending exchange rate for the respective year, and the statement of earnings, at the average exchange rate for the respective year.

## (v) Redeemable noncontrolling interest:

The redeemable noncontrolling interest of \$400,000 is presented outside of permanent equity, representing the maximum redemption amount, as no dividends have been declared.

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 15. Canadian/US reporting differences (continued):

#### (b) Additional US GAAP disclosures:

## (i) Development stage company:

The Corporation is in the process of developing unique patented products, which are subject to approval by the regulatory authorities. The Corporation has had limited revenues to date on the sale of its products under development. Accordingly, the Corporation is a development stage company as defined in Topic 915, *Development Stage Entities*, in the ASC, and the following additional disclosures under US GAAP are provided:

since the date of inception of	since the date of inception of the		
	inception of		
incention of	_		
inception of	th a		
the			
Corporation	Corporation		
	to December		
31,	31,		
2010	2009		
Revenues:			
Sales \$ 4,245,245 \$	3,662,862		
Interest income 539,754	538,563		
License revenue 206,470	97,403		
Research contract 30,000	30,000		
Expenses:			
Gross research and development expenditures 34,292,912	29,560,092		
Other expenses 36,296,850	33,146,359		
Cash outflows from operations (40,631,527)	(48,823,526)		
Cash outflows from investing activities (5,213,687)	(4,872,985)		

Cash inflows from financing activities

59,020,214

54,365,214

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 15. Canadian/US reporting differences (continued):

## (b) Additional US GAAP disclosures (continued):

## (i) Development stage company (continued):

The statement of shareholders' equity since date of inception under US GAAP is presented below:

			Additional		Non-
	Number of shares	Common stock	paid-in capital	Accumulated deficit	controlling interest Total (note 15 (a) (ii) )
Year ended July 31, 1990: Common shares					(4) (-1)
issued	2,500,000	\$ 172,414	\$	\$	\$ \$ 172,414
Net loss				(109,241)	(109,241)
Balance, July 31, 1990	2,500,000	172,414		(109,241)	63,173
Year ended July 31, 1991:					
Net loss				(21,588)	(21,588)
Cumulative translation adjustment		1,499		(950)	549
Balance, July 31, 1991	2,500,000	173,913		(131,779)	42,134

Year ended July 31, 1992: Common shares				
issued Net loss	9,375	31,468	(45,555)	31,468 (45,555)
Cumulative translation adjustment		(6,086)	5,598	(488)
Balance, July 31, 1992	2,509,375	199,295	(171,736)	27,559
Year ended July 31, 1993:				
Common shares issued	201,250	159,944		159,944
Common shares cancelled	(500,000)		(20.004)	(20.004)
Net loss Cumulative translation			(38,894)	(38,894)
adjustment		(13,994)	12,830	(1,164)
Balance, July 31, 1993	2,210,625	345,245	(197,800)	147,445
Year ended July 31, 1994:				
Common shares issued	2,500	7,233		7,233
Net loss Cumulative			(53,225)	(53,225)
translation adjustment		(25,173)	15,808	(9,365)
Balance, July 31, 1994	2,213,125	327,305	(235,217)	92,088
Year ended July 31, 1995:				
Common shares issued	78,078	303,380		303,380
Net loss Cumulative			(285,910)	(285,910)
translation adjustment		5,196	(7,221)	(2,025)

Balance, July 31, 1995

carried forward 2,291,203 635,881 (528,348) 107,533

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 15. Canadian/US reporting differences (continued):

## (b) Additional US GAAP disclosures (continued):

## (i) Development stage company (continued):

The statement of shareholders' equity since date of inception under US GAAP is presented below (continued):

	Number of shares	Common stock	Additional paid-in capital	Accumulated deficit	Non- controlling interest (note 15 (a) (ii) )	Total
Balance, July 31, 1995						
brought forward	2,291,203	\$ 635,881	\$	\$ (528,348)	5	\$ 107,533
Period ended December 31, 1995: Adjustment necessary to increase the number of common shares Adjusted number of common shares	12,708,797 15,000,000	635,881		(528,348)		107,533
Common shares issued	2,047,082	2,997,284				2,997,284
Net loss Share issue costs	2,017,002	(153,810)		(1,194,226)		(1,194,226) (153,810)

Cumulative translation adjustment		2,858		(6,328)	(3,470)
Balance, December 31, 1995	17,047,082	3,482,213		(1,728,902)	1,753,311
Year ended December 31, 1996:					
Common shares issued Net loss	882,300	3,852,364		(3,175,587)	3,852,364 (3,175,587)
Share issue costs		(170,699)			(170,699)
Stock-based compensation			434,145		434,145
Cumulative					
translation adjustment		(16,769)	(2,217)	24,544	5,558
Balance, December 31, 1996	17,929,382	7,147,109	431,928	(4,879,945)	2,699,092
Year ended December 31, 1997:					
Common shares					
issued Net loss	703,491	3,180,666		(3,755,409)	3,180,666 (3,755,409)
Share issue costs		(161,482)		(3,733,107)	(161,482)
Capital stock subscription		352,324			352,324
Stock-based compensation			108,350		108,350
Cumulative translation		(200 222)	( <b>1.7-</b> 0.)		
adjustment		(299,275)	(21,578)	325,364	4,511
Balance, December 31, 1997	18,632,873	10,219,342	518,700	(8,309,990)	2,428,052
Year ended December 31,					

1998:					
Common shares issued	1,095,031	5,644,638			5,644,638
Net loss				(4,979,562)	(4,979,562)
Share issue costs		(54,131)			(54,131)
Stock-based compensation			274,088		274,088
Cumulative translation adjustment		(685,156)	(43,750)	720,173	(8,733)
Balance, December 31, 1998					
carried forward	19,727,904	15,124,693	749,038	(12,569,379)	3,304,352
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# NYMOX PHARMACEUTICAL CORPORATION

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

# 15. Canadian/US reporting differences (continued):

# (b) Additional US GAAP disclosures (continued):

# (i) Development stage company (continued):

The statement of shareholders' equity since date of inception under US GAAP is presented below (continued):

	Number of shares	Common stock	Additional paid-in capital	Accumulated deficit	Non- controlling interest (note 15 (a) (ii) )	Total
Balance, December 31, 1998					(4) (11) )	
brought forward	19,727,904	\$ 15,124,693	\$ 749,038	\$ (12,569,379)	\$	\$ 3,304,352
Year ended December 31, 1999:						
Common shares issued	275,900	969,253				969,253
Net loss				(3,409,166)		(3,409,166)
Share issue costs		(35,041)				(35,041)
Stock-based compensation			198,815			198,815
Cumulative translation adjustment		943,133	52,563	(884,178)		111,518
Balance, December 31,	20,003,804	17,002,038	1,000,416	(16,862,723)		1,139,731

Year ended December 31, 2000:						
issued	1,373,817	5,909,340				5,909,340
Warrants and options Net loss		421,638		(4,272,308)		421,638 (4,272,308)
Share issue costs		(353,204)		(1,-1-,-1)		(353,204)
Stock-based compensation Noncontrolling			257,690			257,690
interest (note 15 (a) (ii))					400,000	400,000
Balance, December 31, 2000	21,377,621	22,979,812	1,258,106	(21,135,031)	400,000	3,502,887
Year ended December 31, 2001:						
Common shares issued	919,904	2,554,254				2,554,254
Net loss				(3,095,133)		(3,095,133)
Share issue costs Stock-based		(120,944)				(120,944)
compensation			55,040			55,040
Balance, December 31, 2001	22,297,525	25,413,122	1,313,146	(24,230,164)	400,000	2,896,104
Year ended December 31, 2002:						
Common shares						
issued Net loss	723,429	3,031,043		(3,453,749)		3,031,043 (3,453,749)
Share issue costs		(166,842)		(5,755,177)		(166,842)
Stock-based compensation			41,140			41,140
	23,020,954	28,277,323	1,354,286	(27,683,913)	400,000	2,347,696

Balance, December 31, 2002						
Year ended December 31, 2003:						
Common shares issued	1,380,205	4,096,000				4,096,000
Net loss				(4,395,428)		(4,395,428)
Share issue costs		(220,819)				(220,819)
Stock-based compensation			41,140			41,140
Balance, December 31, 2003	24,401,159	32,152,504	1,395,426	(32,079,341)	400,000	1,868,589
Year ended December 31, 2004:						
Common shares issued	1,102,903	4,049,750	(375,717)			3,674,033
Net loss				(3,770,545)		(3,770,545)
Share issue costs		(210,939)				(210,939)
Stock-based compensation			41,140			41,140
Balance, December 31, 2004						
carried forward	25,504,062	35,991,315	1,060,849	(35,849,886)	400,000	1,602,278
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# NYMOX PHARMACEUTICAL CORPORATION

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

# 15. Canadian/US reporting differences (continued):

# (b) Additional US GAAP disclosures (continued):

# (i) Development stage company (continued):

The statement of shareholders' equity since date of inception under US GAAP is presented below (continued):

			Additional		Non-	
	Number of	Common	paid-in	Accumulated	controlling	
	shares	stock	capital	deficit	interest	Total
					(note 15	
					(a) (ii) )	
Balance, December 31, 2004						
brought forward	25,504,062	\$ 35,991,315	\$ 1,060,849	\$ (35,849,886) \$	400,000	\$ 1,602,278
Year ended December 31, 2005:						
Common shares issued	1,224,719	2,935,000				2,935,000
Net loss				(3,609,448)		(3,609,448)
Share issue costs		(166,942)		,		(166,942)
Stock-based compensation			41,140			41,140
Balance, December 31, 2005	26,728,781	38,759,373	1,101,989	(39,459,334)	400,000	802,028

Year ended December 31, 2006: Common shares issued Net loss Share issue costs Stock-based compensation	1,593,472	4,955,000 (284,227)	837,308	(4,893,685)		4,955,000 (4,893,685) (284,227) 837,308
Balance, December 31, 2006	28,322,253	43,430,146	1,939,297	(44,353,019)	400,000	1,416,424
Year ended December 31, 2007:						
Common shares issued Net loss Share issue costs Stock-based compensation	1,043,500	5,710,685 (296,446)	1,015,260	(5,290,431)		5,710,685 (5,290,431) (296,446) 1,015,260
Balance, December 31, 2007	29,365,753	48,844,385	2,954,557	(49,643,450)	400,000	2,555,492
Year ended December 31, 2008: Common shares issued Net loss Share issue costs Stock-based compensation	812,854	3,695,000 (184,750)	925,220	(4,590,345)		3,695,000 (4,590,345) (184,750) 925,220
Balance, December 31, 2008	30,178,607	52,354,635	3,879,777	(54,233,795)	400,000	2,400,617
Year ended December 31, 2009:	1,105,171	4,105,000				4,105,000

Common shares issued						
Net loss				(5,282,534)		(5,282,534)
Share issue costs		(205,250)				(205,250)
Stock-based compensation			1,085,164			1,085,164
Balance, December 31, 2009	31,283,778	56,254,385	4,964,941	(59,516,329)	400,000	2,102,997
Year ended December 31, 2010:						
Common shares issued	1,290,078	4,900,000				4,900,000
Net loss				(7,190,670)		(7,190,670)
Share issue costs		(245,000)				(245,000)
Stock-based compensation			898,585			898,585
Balance, December 31, 2010	32,573,856	\$ 60,909,385	\$ 5,863,526	\$ (66,706,999)\$	400,000	\$ 465,912

#### NYMOX PHARMACEUTICAL CORPORATION

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 15. Canadian/US reporting differences (continued):

- (b) Additional US GAAP disclosures (continued):
  - (ii) Accounting for tax uncertainties:

For US GAAP purposes, the Corporation adopted Financial Accounting Standards Board Interpretation ("FIN") No. 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109* ("FIN 48"), which was primarily codified in Topic 740, *Income Taxes*, in the ASC, on January 1, 2007. As of December 31, 2008, 2009 and 2010, the total amount of unrecognized tax benefits was nil.

The Corporation files income tax returns with the federal and provincial tax authorities within Canada. The Corporation's subsidiaries file income tax returns in the United States. In general, the Corporation is subject to examination by taxing authorities for years after 2001.

#### (iii) Share issue costs:

For US GAAP purposes, the Corporation presents share issue costs as a reduction of common stock, but for Canadian GAAP purposes, these costs are presented as an increase to deficit.

#### (iv) Subsequent events:

In May 2009, the FASB issued Topic 855, *Subsequent Events*, in the ASC, which establishes principles and requirements for subsequent events. Specifically, it sets forth guidance pertaining to the period after the balance sheet date during which management should consider events or transactions for potential recognition or disclosure, circumstances under which an event or transaction would be recognized after the balance sheet date and the required disclosures that should be made about events or transactions that occurred after the balance sheet date but before financial statements are issued or are available to be issued. This guidance was effective for interim or annual financial periods ending after June 15, 2009, and as such, became effective for the Corporation on June 30, 2009.

In February 2010, the FASB issued Accounting Standards Update ("ASU") 2010-09, *Subsequent Events (Topic 855):* Amendments to Certain Recognition and Disclosure Requirements, which amends Topic 855 to address certain implementation issued related to an entity s requirement to perform and disclose subsequent event procedures. ASU 2010-09 requires entities to make filings with Securities Exchange Commission ("SEC") to evaluate subsequent events through the date the financial statements are issued. The new guidance became effective immediately for financial statements that are issued or available to be issued.

#### NYMOX PHARMACEUTICAL CORPORATION

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

## 15. Canadian/US reporting differences (continued):

- (b) Additional US GAAP disclosures (continued):
  - (v) Recently issued accounting pronouncements:

#### Fair value measurements and disclosures

In January 2010, the FASB issued ASU 2010-06, *Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements*, which provides further disclosure requirements for recurring and non-recurring fair value measurements. These disclosure requirements include transfers in and out of Level 1 and 2 and additional information relating to activity in Level 3 fair value measurements. The ASU also provides clarification on the level of disaggregation for disclosure of fair value measurement. The new disclosures and clarifications are effective for interim and annual periods beginning after December 15, 2009, except for disclosures about activity in Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010, and for interim periods within those fiscal years. The adoption of this guidance did not have a significant impact on the consolidated financial statements of the Corporation.

#### 16. Segment disclosures:

The Corporation operates in one reporting segment - the research and development of products for the aging population. Geographic segment information is as follows:

	Canada	United States	Europe and other
Revenues:			
2010	\$ 17,091	\$ 505,897	\$ 169,653
2009	11,386	328,564	76,030
2008	9,637	347,764	71,008
Property and equipment:			
2010	10,121	4,609	
2009	7,470	8,682	

Revenues are attributed to geographic locations based on location of customers.

# NYMOX PHARMACEUTICAL CORPORATION

Notes to Consolidated Financial Statements, Continued

Years ended December 31, 2010, 2009 and 2008 (in US dollars)

# 16. Segment disclosures (continued):

Major customers

Two customers accounted for more than 10% of revenues from sales, as follows:

	2010	2009	2008
Customer A	28%	32%	41%
Customer B	25%	9%	

One customer accounted for 100% of licensing revenues in 2010 (2009 and 2008 - nil) (refer to note 6).

#### ITEM 9. OFFER AND LISTING DETAILS

Nymox s common shares trade on the NASDAQ Stock Market. Nymox s common shares traded on the NASDAQ National Market from December 1, 1997 until September 16, 1999 when they began trading on the NASDAQ SmallCap Market, now called the NASDAQ Capital Market. Nymox s common shares also traded on the Montreal Exchange from December 18, 1995 until November 19, 1999.

The following tables set out the high and low reported trading prices of the common shares on the NASDAQ Stock Market during the periods indicated.

# Annual High and Low Market Prices Past Five Years

<u>YEAR</u>	ANNUAL HIGH	ANNUAL LOW
2006	\$5.950	\$1.810
2007	\$7.500	\$3.370
2008	\$6.390	\$2.500
2009	\$7.070	\$2.200
2010	\$7.760	\$2.640

#### Quarterly High and Low Market Prices Past Two Years

<u>YEAR</u>	<b>QUARTERLY PERIOD</b>	<b>HIGH SALES PRICE</b>	<b>LOW SALES PRICE</b>
2009	1st Quarter	\$3.860	\$2.200
	2 <sup>nd</sup> Quarter	\$5.200	\$2.670
	3 <sup>rd</sup> Quarter	\$7.070	\$4.050
	4 <sup>th</sup> Quarter	\$5.400	\$4.050
2010	1st Quarter	\$5.140	\$3.400
	2 <sup>nd</sup> Quarter	\$5.000	\$2.850
	3 <sup>rd</sup> Quarter	\$4.630	\$2.640
	4 <sup>th</sup> Quarter	\$7.760	\$3.490

# Monthly High and Low Market Prices Most Recent Six Months

<u>DATE</u>	MONTHLY HIGH	MONTHLY LOW
October, 2010	\$4.500	\$3.490
November, 2010	\$4.280	\$3.880
December, 2010	\$7.760	\$4.020
January, 2011	\$8.805	\$6.610
February, 2011	\$7.490	\$6.000
March, 2011 (up to and including March 9, 2011)	\$6.760	\$6.100

#### ITEM 10. ADDITIONAL INFORMATION

#### **Memorandum and Articles of Association**

#### **Bylaws And Articles Of Incorporation**

The Corporation s Articles of Incorporation as amended, which we refer to as our articles of incorporation, are on file with the Corporations Directorate of Industry Canada under Corporation Number 315235-9. Our articles of incorporation do not include a stated purpose and do not place any restrictions on the business that the Corporation may carry on.

#### **Directors**

A director of our Corporation need not be a shareholder. In accordance with our bylaws and the Canada Business Corporations Act, at least 25% of our directors must be residents of Canada. In order to serve as a director, a person must be a natural person at least 18 years of age, of sound mind and not bankrupt. Neither our articles of incorporation or by-laws, nor the Canada Business Corporations Act, impose any mandatory retirement requirements for directors.

Our bylaws and the Canada Business Corporations Act authorize the directors from time to time to determine the remuneration for their services. There is no requirement for an independent quorum.

A director who is a party to, or who is a director or officer of or has a material interest in any person who is a party to, a material contract or transaction or proposed material contract or transaction with our Corporation must disclose to the Corporation the nature and extent of his or her interest at the time and in the manner provided by the Canada Business Corporations Act. The Canada Business Corporations Act prohibits such a director from voting on any resolution to approve the contract or transaction unless the contract or transaction:

- is an arrangement by way of security for money lent to or obligations undertaken by the director for the benefit of the Corporation or an affiliate;
- relates primarily to his or her remuneration as a director, officer, employee or agent of the Corporation or an affiliate:
- is for indemnity or insurance for director s liability as permitted by the Act; or
- is with an affiliate.

Our board of directors may, on behalf of the Corporation and without authorization of our shareholders:

- borrow money upon the credit of the Corporation;
- issue, reissue, sell or pledge debt obligations of the Corporation;
- give a guarantee on behalf of the Corporation to secure performance of an obligation of any person; and
- mortgage, hypothecate, pledge or otherwise create a security interest in all or any property of the Corporation, owned or subsequently acquired, to secure any obligation of the Corporation.

The Canada Business Corporations Act prohibits the giving of a guarantee to any shareholder, director, officer or employee of the Corporation or of an affiliated corporation or to an associate of any such person for any purpose or to any person for the purpose of or in connection with a purchase of a share issued or to be issued by the Corporation or its affiliates, where there are reasonable grounds for believing that the Corporation is or, after giving the guarantee, would be unable to pay its liabilities as they become due, or the realizable value of the Corporation s assets in the form of assets pledged or encumbered to secure a guarantee, after giving the guarantee, would be less than the aggregate of the Corporation s liabilities and stated capital of all classes.

These borrowing powers may be varied by the Corporation s bylaws or its articles of incorporation. However, our bylaws and articles of incorporation do not contain any restrictions on or variations of these borrowing powers.

# Common Shares

Our articles of incorporation authorize the issuance of an unlimited number of common shares. They do not authorize the issuance of any other class of shares.

The holders of the common shares of our Corporation are entitled to receive notice of and to attend all meetings of the shareholders of our Corporation and have one vote for each common share held at all meetings of the shareholders of our Corporation. Our directors are elected at each annual meeting of shareholders and do not stand for reelection at staggered intervals.

The holders of common shares are entitled to receive dividends and the Corporation will pay dividends, as and when declared by our board of directors, out of moneys properly applicable to the payment of dividends, in such amount and in such form as our board of directors may from time to time determine, and all dividends which our board of directors may declare on the common shares shall be declared and paid in equal amounts per share on all common shares at the time outstanding.

In the event of the dissolution, liquidation or winding-up of the Corporation, whether voluntary or involuntary, or any other distribution of assets of the Corporation among its shareholders for the purpose of winding up its affairs, the holders of the common shares will be entitled to receive the remaining property and assets of the Corporation.

There are no redemption provisions and no liability for further capital calls associated with the Corporation s common stock.

# Action Necessary To Change Rights Of Shareholders

In order to change the rights of our shareholders, we would need to amend our articles of incorporation to effect the change. Such an amendment would require the approval of holders of two-thirds of the shares cast at a duly called special meeting. For certain amendments such as those creating of a class of preferred shares, a shareholder is entitled to dissent in respect of such a resolution amending our articles and, if the resolution is adopted and the Corporation implements such changes, demand payment of the fair value of its shares.

# Meetings of Shareholders

An annual meeting of shareholders is held each year for the purpose of considering the financial statements and reports, electing directors, appointing auditors and for the transaction of other business as may be brought before the meeting. The board of directors has the power to call a special meeting of shareholders at any time.

Notice of the time and place of each meeting of shareholders must be given not less than 21 days, nor more than 60 days, before the date of each meeting to each director, to the auditor and to each shareholder who at the close of business on the record date for notice is entered in the securities register as the holder of one or more shares carrying the right to vote at the meeting. Notice of meeting of shareholders called for any other purpose other than consideration of the minutes of an earlier meeting, financial statements and auditor s report, election of directors and reappointment of the incumbent auditor, must state the nature of the business in sufficient detail to permit the shareholder to form a reasoned judgment on and must state the text of any special resolution or by-law to be submitted to the meeting.

The only persons entitled to be present at a meeting of shareholders are those entitled to vote, the directors of the Corporation and the auditor of the Corporation. Any other person may be admitted only on the invitation of the chairman of the meeting or with the consent of the meeting. In circumstances where a court orders a meeting of shareholders, the court may direct how the meeting may be held, including who may attend the meeting.

# Limitations On Right To Own Securities

Neither Canadian law nor our articles or by-laws limit the right of a nonresident to hold or vote our shares, other than as provided in the Investment Canada Act (the Investment Act ), as amended by the World Trade Organization Agreement Implementation Act. The Investment Act generally prohibits implementation of a direct reviewable investment by an individual, government or agency thereof, corporation, partnership, trust or joint venture that is not a Canadian, as defined in the Investment Act (a non-Canadian ), unless, after review, the minister responsible for the Investment Act is satisfied that the investment is likely to be of net benefit to Canada. An investment in our shares by a non-Canadian (other than a WTO Investor, as defined below) would be reviewable under the Investment Act if it were an investment to acquire direct control of our Corporation, and the value of the assets of our Corporation were CDN\$5.0 million or more (provided that immediately prior to the implementation of the investment the Corporation was not controlled by WTO Investors). An investment in our shares by a WTO Investor (or by a non-Canadian other than a WTO Investor if, immediately prior to the implementation of the investment the Corporation was controlled by WTO Investors) would be reviewable under the Investment Act if it were an investment to acquire direct control of the Corporation and the value of the assets of the Corporation equaled or exceeded a specified amount (the Review Threshold ). The Review Threshold in 2008 was CDN\$295 million, in 2009 was CDN\$312 million, in 2010 was CDN\$299 million and in 2011 is CDN\$312 million. A non-Canadian, whether a WTO Investor or otherwise, would be deemed to acquire control of the Corporation for purposes of the Investment Act if he or she acquired a majority of our shares. The acquisition of less than a majority, but at least one-third of our shares, would be presumed to be an acquisition of control of the Corporation, unless it could be established that we were not controlled in fact by the acquirer through the ownership of our shares. In general, an individual is a WTO Investor if he or she is a national of a country (other than Canada) that is a member of the World Trade Organization ( WTO Member ) or has a right of permanent residence in a WTO Member. A corporation or other entity will be a WTO Investor if it is a WTO investor-controlled entity, pursuant to detailed rules set out in the Investment Act. The United States is a WTO Member. Certain transactions involving our shares would be exempt from the Investment Act, including:

(a)

an acquisition of our shares if the acquisition were made in the ordinary course of that person s business as a trader or dealer in securities:

- (b) an acquisition of control of the Corporation in connection with the foreclosure of a security interest granted for a loan or other assistance and not for any purpose related to the provisions the Investment Act; and
- (c) an acquisition of control of the Corporation by reason of an amalgamation, consolidation or corporate reorganization, following which the direct or indirect control in fact of the Corporation, through ownership of voting interests, remains unchanged.

# **Change of Control**

There are no provisions of our bylaws or articles of incorporation that would have an effect of delaying, deferring or preventing a change in control of the Corporation and that would operate only with respect to a merger, acquisition or corporate restructuring involving the Corporation. Our bylaws do not contain a provision governing the ownership threshold above which shareholder ownership must be disclosed.

#### **Material Contracts**

The following is a summary of the material contracts to which the Corporation is a party, for the two years ended March 15, 2011.

- 1. The License and Collaboration Agreement between Nymox Pharmaceutical Corporation and Recordati Ireland Ltd., a subsidiary of Recordati, S.p.A. dated December 16, 2010, for the development and commercialization of NX-1207 in Europe including Russia and the CIS, the Middle East, the Maghreb area of North Africa and South Africa. The Agreement covers the use of NX-1207 for the treatment of BPH as the initial indication for development and commercialization. Under the Agreement, Recordati made an upfront payment to Nymox of 10 million and will make approval and sales milestones payments and tiered supply and royalty payments of a minimum of 26% to increase progressively up to 40% of total net sales in the case specific contractual conditions are achieved.
- 2. The Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated November 1, 2010. This agreement established a financing commitment for \$15 million over a twenty-four month period starting November 1, 2010. The terms and conditions of this commitment are further described in Liquidity and Capital Resources section in Item 5 of this report.
- 3. The Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated November 2, 2009. This agreement established a financing commitment for \$15 million over a twenty-four month period starting November 2, 2009. This agreement was replaced by the new agreement above on November 1, 2010.
- 4. The Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated November 10, 2008. This agreement established a financing commitment for \$15 million over a twenty-four month period starting November 10, 2008. This agreement was replaced by the new agreement above on November 2, 2009.

# **Exchange Controls**

Canada has no system of exchange controls. There are no exchange restrictions on borrowing from foreign countries or on the remittance of dividends, interest, royalties and similar payments, management fees, loan repayments, settlement of trade debts or the repatriation of capital.

There are no limitations on the rights of non-Canadians to exercise voting rights on their shares of Nymox.

## **Taxation**

#### U.S. Federal Income Tax Considerations for U.S. Persons

This section contains a summary of certain U.S. federal income tax considerations for U.S. Persons (as defined below) who hold common shares of Nymox. This summary is based upon the Internal Revenue Code of 1986, as amended (the Code ), Treasury regulations, rulings of the Internal Revenue Service (the IRS ), and judicial decisions in existence on the date hereof, all of which are subject to change. Any such change could apply retroactively and could have adverse consequences to Nymox and its shareholders. This summary is necessarily general and does not attempt to

summarize all aspects of the federal tax laws (and does not attempt to summarize any state or local laws) that may affect an investor s acquisition of an interest in Nymox. No ruling from the IRS will be requested and no assurance can be given that the IRS will agree with the tax consequences described in this summary.

For purposes of this discussion, the term U.S. Person means (a) an individual who is a citizen of the United States or who is resident in the United States for United States federal income tax purposes, (b) a corporation or a partnership that is organized under the laws of the United States or any state thereof, (c) an estate the income of which is subject to United States federal income taxation regardless of its source, or (d) a trust (i) that is subject to the supervision of a court within the United States and is subject to the control of one or more United States persons as described in the Code, or (ii) that has a valid election in effect under applicable Treasury regulations to be treated as a United States person. The term U.S. Holder means a shareholder of Nymox who is a U.S. Person. The term foreign corporation means an entity that is classified as a corporation for U.S. federal income tax purposes and that is not organized under the laws of the United States or any state thereof.

This summary does not discuss all United States federal income tax considerations that may be relevant to U.S. Holders in light of their particular circumstances or to certain holders that may be subject to special treatment under United States federal income tax law (for example, insurance companies, tax-exempt organizations, financial institutions, dealers in securities, persons who hold shares as part of a straddle, hedging, constructive sale, or conversion transaction, U.S. Holders whose functional currency is not the U.S. dollar, and U.S. Holders who acquired shares through exercise of employee stock options or otherwise as compensation for services). Furthermore, this summary does not address any aspects of state or local taxation.

The tax consequences of an investment in Nymox are complex and based on tax provisions that are subject to change. You are urged to consult with, and must depend upon, your own tax advisors with specific reference to your own tax situations as to the income and other tax consequences of an investment in Nymox.

Dividends and gains on sale. Except as described below with respect to the passive foreign investment corporation rules, dividends paid by Nymox to a U.S. Holder, without reduction for Canadian withholding taxes, will be included in the gross income of such U.S. Holder, as a dividend, to the extent paid out of current or accumulated earnings and profits, as determined under U.S. federal income tax. Such dividends will not be eligible for the dividend-received deduction generally allowed under the Code to dividend recipients that are U.S. corporations. The amount of any distribution in excess of Nymox s current and accumulated earnings and profits will first be applied to reduce the U.S. Holder s tax basis in its Nymox common shares, and any amount in excess of tax basis will be treated as gain from the sale or exchange of the common shares, A dividend paid by Nymox and received before January 1, 2013, generally will be taxed at the preferential tax rates applicable to long-term capital gains (where the maximum federal rate is currently 15%) if (a) Nymox is a qualified foreign corporation as defined in Section 1(h)(11) of the Code, (a QFC), (b) the U.S. Holder receiving such dividend is an individual, estate, or trust, and (c) such dividend is paid on common shares that have been held by such U.S. Holder for at least 61 days during the 121-day period beginning 60 days before the ex-dividend date (i.e., the first date that a purchaser of such common shares will not be entitled to receive such dividend). Nymox currently meets the definition of a QFC because its common shares are readily tradable on The Nasdaq Stock Market, an established securities market in the United States, provided that Nymox is not a passive foreign investment corporation (as described below) for the taxable year during which Nymox pays a dividend or for the preceding taxable year. If Nymox is not a QFC, a dividend paid by Nymox to a U.S. Holder that is an individual, estate, or trust generally will be taxed at ordinary income tax rates (and not at the preferential tax rates applicable to long-term capital gains). The dividend rules are complex, and each U.S. Holder should consult its own financial advisor, legal counsel, or accountant regarding the dividend rules.

Except as described below with respect to the passive foreign investment corporation rules, any gain recognized by a U.S. Holder on a sale or exchange of Nymox common shares (or on a distribution treated as a sale or exchange) generally will be treated as capital gain. Capital gains of corporations are taxable at the same rate as ordinary income. With respect to non-corporate taxpayers, the excess of net long-term capital gain over net short term capital loss may be taxed at a substantially lower rate than is ordinary income. A capital gain or loss is long-term if the asset has been held for more than one year and short-term if held for one year or less. In addition, the distinction between capital gain or loss and ordinary income or loss is relevant for purposes of limitations on the deductibility of capital losses.

A U.S. Holder generally may claim a credit against its U.S. federal income tax liability for Canadian income tax withheld from dividends received on Nymox common shares. The amount of this credit is subject to several limitations under the Code.

Controlled foreign corporation rules. A foreign corporation generally is classified as a controlled foreign corporation (a CFC) if more than 50% of the corporation s shares (by vote or value) are owned, directly or indirectly, by 10% U.S. Shareholders. For this purpose, a 10% U.S. Shareholder is a U.S. Person that owns, directly or indirectly, shares possessing 10% or more of the voting power in the foreign corporation. Nymox believes that it is not a CFC at the present time. If Nymox were a CFC, each 10% U.S. Shareholder that owns, directly or indirectly through foreign entities, an interest in Nymox generally would be required to include in its gross income for U.S. federal income tax purposes a pro-rata share of any Subpart F income earned by Nymox, whether or not such income is distributed by Nymox. Subpart F income generally includes interest, dividends, royalties, gain on the sale of stock or securities and certain other categories of income.

Passive foreign investment corporation rules. In general, a foreign corporation is a passive foreign investment corporation (a PFIC) during a taxable year if 75% or more of its gross income for the taxable year constitutes passive income or if 50% or more of its assets (by average fair market value) held during the taxable year produce, or are held for the production of, passive income. In general, any U.S. Person that owns, directly or indirectly, an interest in a foreign corporation will be subject to an interest charge (in addition to regular U.S. federal income tax) upon the disposition by the U.S. Person of, or receipt by the U.S. Person of excess distributions with respect to, any shares of the foreign corporation if: (i) the foreign corporation is a PFIC during the taxable year in which such income is realized by the U.S. Person; or (ii) the foreign corporation was a PFIC during any prior taxable year that is included in whole or in part in the U.S. Person s holding period (within the meaning of Section 1223 of the Code) with respect to its interest in the shares of the foreign corporation. Furthermore, the U.S. Person s share of such gain or excess distribution will be taxable as ordinary income. There exist several other adverse tax consequences that may apply to any U.S. Person that owns, directly or indirectly, an interest in a PFIC.

A U.S. Person that owns, directly or indirectly, an interest in a PFIC can elect to treat such PFIC as a qualified electing fund (a QEF) with respect to the U.S. Person. In general, the effect of a QEF election with respect to a PFIC is that, beginning with the first taxable year to which the election applies and in all succeeding taxable years during which the foreign corporation is a PFIC, the U.S. Person is required to include in its income its share of the ordinary earnings and net capital gains of the PFIC. The U.S. Person is not taxable with respect to any distribution by the PFIC from earnings that have been included previously in the U.S. Person s income under the QEF provisions. If the QEF election is made with respect to the first taxable year in which a U.S. Person owns, directly or indirectly, an interest in the particular PFIC, the adverse tax consequences described in the immediately preceding paragraph (including the interest charge and the treatment of gains as ordinary income) would not apply to the U.S. Person s interest in that PFIC. In order to make a QEF election, a U.S. Person is required to provide to the IRS certain information furnished by the PFIC.

Nymox believes that it has not been a PFIC during any taxable year ending on or before December 31, 2010 and, based on current business plans and financial expectations, Nymox does not believe that it will be a PFIC during its current taxable year. Because PFIC classification cannot be determined until the close of a taxable year, is determined annually, and depends on the application of complex rules which are subject to differing interpretations, there can be no assurance that Nymox has never been and will not become a PFIC for any taxable year during which U.S. Holders hold Nymox common stock. Nymox intends to notify its U.S. Holders within 45 days after the end of any taxable year for which Nymox believes it might be a PFIC. Nymox has further undertaken (i) to provide its U.S. Holders with timely and accurate information as to its status as a PFIC and the manner in which the QEF election can be made and (ii) to comply with all record-keeping, reporting and other requirements so that the U.S. Holders, at their option, may make a QEF election.

Each U.S. Person who owns, directly or indirectly, common shares of Nymox is urged to consult its own tax advisor with respect to the advantages and disadvantages of making a QEF election with respect to Nymox.

*Backup withholding*. Information reporting to the IRS may be required with respect to payments of dividends on the Nymox common shares to U.S. Holders, and with respect to proceeds received by U.S. Holders on the sale of Nymox common shares. A U.S. Holder may be subject to backup withholding at a 28% rate with respect to dividends received with respect to Nymox common shares, or proceeds received on the sale of Nymox common shares through a broker, unless the U.S. Holder (i) demonstrates that it qualifies for an applicable exemption (such as the exemption for holders that are corporations), or (ii) provides a taxpayer identification number and complies with certain other requirements. Any amount withheld from payment to a U.S. Holder under the backup withholding rules generally will be allowed as credit against the U.S. Holder s U.S. federal income tax liability, if any, and may entitle the U.S. Holder to a refund, provided that the required information is furnished to the IRS.

Recent Legislative Developments. Recently enacted legislation requires certain U.S. Holders who are individuals, estates or trusts to pay up to an additional 3.8% tax on, among other things, dividends and capital gains for taxable years beginning after December 31, 2012. In addition, for taxable years beginning after March 18, 2010, recently enacted legislation requires certain U.S. Holders who are individuals that hold certain foreign financial assets (which may include Nymox common shares) to report information relating to such assets, subject to certain exceptions. Each U.S. Holder should consult its own financial advisor, legal counsel, or accountant regarding the effect, if any, of this legislation on their ownership and disposition of Nymox common shares.

#### **Canadian Federal Income Taxation**

The following is, as of the date of this report, a summary of the principal Canadian federal income tax considerations generally applicable to shareholders who receive a dividend from Nymox and who, at all relevant times, for purposes of the Income Tax Act (Canada) the ( Tax Act ), hold and will hold Nymox common shares as capital property and deal with Nymox at arm s length.

Nymox s common shares will generally constitute capital property to a holder unless the holder holds such shares in the course of carrying on a business or the holder has acquired such shares in a transaction or transactions considered to be an adventure in the nature of trade. This summary is based on the current provisions of the Tax Act, the regulations under that act, counsel s understanding of current administrative and assessing policies of the Canada Customs and Revenue Agency and all specific proposals to amend the Tax Act publicly announced or released by or on behalf of the Minister of Finance (Canada) before the date of this report ( Tax Proposals ).

The Tax Act contains certain provisions relating to securities held by certain financial institutions (the Mark-to-Market Rules ). This summary does not take into account these Mark-to-Market Rules or any amendments to

them contained in the Tax Proposals and taxpayers that are financial institutions for purposes of those rules should consult their own tax advisors.

This summary is not exhaustive of all possible Canadian federal income tax considerations and, except for the Tax Proposals, does not take into account or anticipate any changes in law, whether by legislative, governmental or judicial action, nor does it take into account tax legislation of any province, territory or foreign jurisdiction. This summary is of a general nature only and is not intended to be, nor should it be construed as, legal or tax advice to any particular holder of Nymox common shares.

#### **Canadian Residents**

The following summary is relevant to a holder of Nymox common shares who, for purposes of the Tax Act and any applicable tax treaty or convention, is resident in Canada at all relevant times.

## Tax Treatment of Capital Gains and Capital Losses for Canadian Residents

On a disposition or deemed disposition of a Nymox common share, the holder will realize a capital gain (or capital loss) equal to the amount by which the proceeds of disposition for the Nymox common share exceed (or are less than) the aggregate of any costs of disposition and the adjusted cost base to the holder of the Nymox common share immediately before the disposition.

Pursuant to the Tax Act and subject to certain transitional rules which apply in certain circumstances, a holder of Nymox common shares will be required to include in income one-half of the amount of any capital gain (a Taxable capital gain ) and may deduct one-half of the amount of any capital loss (an Allowable capital loss ) against Taxable capital gains realized by the holder in the year of the disposition. Allowable capital losses in excess of Taxable capital gains may be carried back and deducted in any of the three preceding years or carried forward and deducted in any following year against taxable capital gains realized in such years to the extent and under the circumstances described in the Tax Act.

A capital loss realized by a holder of Nymox common shares that is a corporation, a partnership of which a corporation is a member or a trust of which a corporation is a beneficiary may be reduced by the amount of dividends received in certain circumstances. Capital gains realized by an individual may give rise to a liability for alternative minimum tax.

# Tax Treatment of Dividends Received by Canadian Residents

In the case of a holder of Nymox common shares who is an individual, any dividends received on the common shares will be included in computing his income and will be subject to the gross-up and dividend tax credit rules normally applicable to taxable dividends paid by taxable Canadian corporations. A holder that is a corporation may be liable to pay refundable tax under Part IV of the Tax Act. However, a public corporation which is not controlled, whether because of a beneficial interest in one or more trusts or otherwise, by or for the benefit of an individual (other than a trust) or a related group of individuals (other than trusts) will not be liable to pay refundable tax under Part IV of the Tax Act.

In the case of a holder of Nymox common shares that is a corporation, the amount of any capital loss otherwise determined resulting from the disposition of a Nymox common share may be reduced by the amount of dividends previously received or deemed to have been received thereon. Any such restriction will not occur where the corporate holder owned the Nymox common share for 365 days or longer and such holder (together with any persons with whom it did not deal at arm s length) did not own more than 5% of the shares of any class or series of Nymox at the time the relevant dividends were received or deemed to have been received. Analogous rules apply where a corporation is a member of a partnership or a beneficiary of a trust, which owns Nymox common shares.

#### Shareholders Who Are Not Residents of Canada

The following summary is relevant to a holder of Nymox common shares, who, at all relevant times, for purposes of the Tax Act and any applicable tax treaty or convention, is a non-resident or is deemed to be a non-resident of Canada and does not use and is not deemed to use or hold Nymox common shares in the course of carrying on a business in Canada. Special rules, which are not discussed below, may apply to a non-resident that is an insurer which carries on business in Canada and elsewhere.

#### Dividends Paid To Non-Residents of Canada

Under the Tax Act, dividends paid or credited to a non-resident are subject to withholding tax at the rate of 25% of the gross amount of the dividends. This withholding tax may be reduced or eliminated pursuant to the terms of an applicable tax treaty between Canada and the country of residence of the non-resident. For example, for persons who are resident in the United States for purposes of the Canada-United States Income Tax Convention (the Convention), the rate of withholding tax on dividends is reduced to 15% generally and 5% when the United States resident is a Corporation that beneficially owns at least 10% of the voting stock of the Corporation paying the dividends.

Under the Convention, dividends paid to certain religious, scientific, charitable and other similar tax-exempt organizations and certain organizations that are resident in, and exempt from tax in, the United States are exempt from Canadian non-resident withholding tax. Provided that certain administrative procedures designed to establish with the Canadian tax authorities the right of such entities to benefit from this withholding tax exemption are complied with by the tax-exempt entities prior to the distribution, Nymox would not be required to withhold such tax on such payment. Alternatively, the above-described tax-exempt entities may claim a refund of Canadian withholding tax otherwise withheld by Nymox on the distribution of dividends.

# Tax Treatment of Capital Gains of Non-Residents of Canada

On a disposition or deemed disposition of a Nymox common share, a non-resident holder will realize a capital gain (or capital loss) equal to the amount by which the proceeds of disposition for the Nymox common share exceed (or are less than) the aggregate of any costs of disposition and the adjusted cost base to the non-resident holder of the Nymox common share immediately before the disposition.

A non-resident of Canada is liable for Canadian income tax on a capital gain realized on the disposition of property only where that property constitutes taxable Canadian property . Pursuant to the Tax Act and subject to certain transitional rules which apply in certain circumstances, one-half of any capital gain from the disposition of taxable Canadian property is subject to Canadian tax.

Under the Tax Act, shares of Nymox will not constitute taxable Canadian property unless, at any time, in the five years immediately preceding the disposition, the non-resident holder, persons with whom the non-resident holder did not deal at arms length, or the non-resident holder together with all such persons owned (or had a right to acquire) 25% or more of the shares of any class of Nymox. Even in circumstances where shares of Nymox are taxable Canadian property to a non-resident holder, the non-resident holder may be entitled to relief from Canadian tax on any capital gain realized on the disposition thereof pursuant to the terms of an applicable tax treaty between Canada and the country of residence of the nonresident. For example, the Convention provides that gains realized by a resident of the United States on the disposition or deemed disposition of shares of a Corporation will generally not be subject to tax under the Tax Act, provided that the value of the shares is not derived principally from real property situated in Canada. Nymox believes that the value of its shares is not currently derived principally from real property situated in Canada and it does not expect this to change in the foreseeable future.

Provided that the Nymox common shares remain listed on a prescribed stock exchange, which includes the NASDAQ SmallCap Market System, a non-resident holder who disposes of Nymox common shares will not be required to comply with the Canadian notification procedures generally applicable to dispositions of taxable Canadian property.

### **Documents on Display**

Nymox is subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act ). In accordance with these requirements, the Corporation files reports and other information with the Securities and Exchange Commission. These materials, including this Annual Report on Form 20-F and the exhibits hereto, may be inspected and copied at the Commission s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Copies of the materials may be obtained from the Commission s Public Reference Room at prescribed rates. Information on the operation of the Public Reference Room may be obtained by calling the Commission at 1-800-SEC-0330. The Commission maintains an internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers, including Nymox, that file electronically with the Commission.

We are required to file reports and other information with the securities commissions in all provinces of Canada. You also are invited to read and copy any reports, statements or other information, other than confidential filings, that we file with the provincial securities commissions. These filings are also electronically available from the Canadian System for Electronic Document Analysis and Retrieval ("SEDAR") (http://www.sedar.com), the Canadian equivalent of the SEC's electronic document gathering and retrieval system. This material includes our Management Information Circular for the most recent annual meeting, which provides information including directors—and officers—, remuneration and indebtedness, principal holders of securities and securities authorized for issuance under equity compensation plans. Additional financial information is provided in our annual financial statements and our Management—s Discussion and Analysis relating to these statements. These documents are also accessible on SEDAR (www.sedar.com).

We will provide without charge to each person, including any beneficial owner, on the written or oral request of such person, a copy of any or all documents referred to above which have been or may be incorporated by reference in this Annual Report on Form 20-F (not including exhibits to such incorporated information that are not specifically incorporated by reference into such information). Requests for such copies should be directed to us at the following address: Nymox Pharmaceutical Corporation, 9900 Cavendish Blvd. Suite 306, St. Laurent, Quebec, Canada, H4M 2V2, Attention: Investor Relations. Telephone (800) 936-9669. Facsimile (514) 332-2227 EMAIL: info@nymox.com

# ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

# Capital disclosures

The Corporation's objective in managing capital is to ensure a sufficient liquidity position to finance its research and development activities, general and administrative expenses, working capital and overall capital expenditures, including those associated with patents. The Corporation makes every attempt to manage its liquidity to minimize shareholder dilution when possible.

The Corporation defines capital as total shareholders—equity. To fund its activities, the Corporation has followed an approach that relies almost exclusively on the issuance of common equity and most recently during 2010, entered into a collaboration agreement. Since inception, the Corporation has financed its liquidity needs primarily through private placements and since 2003 through a financing agreement with an investment Corporation that has been replaced annually by a new agreement with the same investor. The Corporation intends to access financing under this agreement when appropriate to fund its research and development activities. The recent financial crisis in the United States and the global economic environment has had a negative impact on the availability of liquidity in the market and may have an effect on the liquidity of the Purchaser to our Common Stock Private Purchase Agreement. Since 2003 through to December 2010, the Purchaser has always complied with the drawdowns made pursuant to the agreement. The Corporation believes that cash balances, funds from operations, as well as from existing financing agreements will be sufficient to meet the Corporation s cash requirements for the next twelve months.

The Corporation must comply with general covenants in order to draw on its facility including maintaining its stock exchange listing and registration requirements and having no material adverse effects, as defined in the agreement, with respect to the business and operations of the Corporation.

In October 2010, the Corporation was informed that it had been awarded a grant of \$244,479 from the U.S. Government under the Qualifying Therapeutic Discovery Project for its ongoing Phase III clinical trial program for NX-1207 for the treatment of BPH. The Corporation anticipates receiving the grant sometime in 2011. The Corporation will record this amount in its consolidated financial statement when it is received.

The capital management objectives remain the same as for the previous fiscal year. When possible, the Corporation tries to optimize its liquidity needs by non-dilutive sources, including sales, collaboration agreements, research tax credits and interest income. The Corporation's general policy on dividends is to retain cash to keep funds available to finance its research and development and operating expenses. The Corporation has no debt.

The Corporation is not subject to any capital requirements imposed by external parties.

### Financial risk management

#### Foreign currency risk

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

Approximately 78% of expenses that occurred during the year ended December 31, 2010 (2009 - 76%) were denominated in US dollars. Foreign exchange fluctuations had no meaningful impact on the Corporation s results in 2010, 2009 or 2008.

The following table provides significant items exposed to foreign exchange as at December 31, 2010 and 2009:

CA\$	2010	2009
Cash	\$ 26,736	\$ 71,224
Accounts, other receivables and research tax credits receivable	30,106	291,671
Accounts payable and accrued liabilities	(299,776)	(330,357)
	\$ (242,934)	\$ 32,538

The following exchange rates applied for the years ended December 31, 2010:

		Average rate		
		(twelve months)	Report	ing date December 31,
	2010	2009	2010	2009
US\$ - CA\$	1.0299	1.1419	.9946	1.0510

Based on the Corporation s foreign currency exposures noted above, varying the above foreign exchange rates to reflect a 5% strengthening of the US dollar would have reduced the net loss by less than \$15,000, assuming that all other variables remained constant.

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

#### Credit risk

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

The Corporation has a limited number of customers. Included in the accounts receivable on the consolidated balance sheet are trade receivables of \$11,278 (2009 - \$66,354), all of which were aged under 45 days. Four customers (2009 four customers) accounted for 100% (2009 88%) of the trade receivables balance at December 31, 2010. There was no amount recorded as bad debt expense for the year ended December 31, 2010 and a nominal amount was recorded for the year ended December 31, 2009).

As at December 31, 2010, the Corporation s maximum credit exposure corresponded to the carrying amount of cash, accounts receivable and other receivables.

#### Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. Cash bears interest at a variable rate. Accounts receivable, other receivables, accounts payable and accrued liabilities bear no interest. The Corporation has no other interest-bearing financial instruments.

#### Liquidity risk

Liquidity risk is the risk that the Corporation will not be able to meet its financial obligations as they fall due. The Corporation manages liquidity risk through the management of its capital structure, as outlined in note 12 to the consolidated financial statements ( Capital disclosures ). The Corporation does not have an operating credit facility and finances its activities through cash balances and an equity financing agreement with Lorros-Greyse, as described in note 8 (a) Common Stock Private Purchase Agreement. Furthermore, the Corporation has \$13 million of cash on hand at December 31, 2010, mainly as a result of receiving an upfront payment of \$13 million in December 2010 in connection with the license and collaboration agreement entered into with Recordati as referred to in Note 6 in the consolidated financial statements.

The following are the contractual maturities of financial liabilities as at December 31, 2010:

	Carrying amount		Less than 1 year		1 year to 5 years
Accounts payable and accrued liabilities	\$	2,577,903	\$	2,577,903	\$

# ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

None.

#### **PART II**

#### ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

# ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

#### ITEM 15. CONTROLS AND PROCEDURES

- (a) *Disclosure Controls and Procedures*. In accordance with Rule 13a-15(b) of the Exchange Act, the Corporation s management, including the Corporation s Chief Executive Officer and President, and the Chief Financial Officer and Secretary-Treasurer, evaluated the effectiveness of the design and operation of the Corporation s disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 20-F and the Chief Executive Officer and President, and the Chief Financial Officer and Secretary-Treasurer concluded that the disclosure controls and procedures were effective.
- (b) *Management s Annual Report on Internal Control over Financial Reporting*. Management is responsible for establishing and maintaining effective internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. The Corporation s internal control over financial reporting is designed to provide reasonable assurance to management and our board of directors regarding the preparation and fair presentation of published financial statements.

The Corporation s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Corporation; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Corporation are being made only in accordance with authorizations of management and directors of the Corporation; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Corporation s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting, as of December 31, 2010, based on the framework set forth in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its evaluation under this framework, management concluded that our internal control over financial reporting was effective as of December 31, 2010.

KPMG LLP (KPMG), the independent registered public accounting firm who also audited the Corporation s financial statements, issued an unqualified audit report on the effectiveness of our internal control over financial reporting as of December 31, 2010.

- (c) Attestation Report of the Registered Public Accounting Firm. KPMG s attestation report on the effectiveness of the Corporation s internal control over financial reporting is included in the financial statements which appear in this report.
- (d) Changes in Internal Controls over Financial Reporting. There have been no changes during the year ended December 31, 2010 in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Item 16. RESERVED**

#### Item 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Paul McDonald, the Chairman of our Audit Committee, is an audit committee financial expert and is an independent director under the applicable listing rules of the Nasdaq Stock Market.

## **Item 16B. CODE OF ETHICS**

We have adopted a code of ethics that is applicable to our officers, directors and employees in general and our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions in particular. The code of ethics can be found on our website, www.nymox.com.

#### Item 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our principal independent auditor is KPMG LLP.

#### **Fees and Services**

During the years ended December 31, 2010 and 2009, we paid the following fees for professional services to KPMG LLP:

	2010	2009
	(CAI	<b>N</b> \$)
Audit Fees	207,600	168,000
Audit-Related Fees	6,000	6,000
Tax Fees	23,300	20,900
Other Fees	0	0
Total	236,900	194,900

Audit Fees consisted of professional services rendered for the annual audit of the Corporation s consolidated financial statements and the quarterly reviews of the Corporation s interim financial statements, consultation concerning financial reporting and accounting standards, including assistance in preparing the Corporation for compliance with the requirements of International Financial Reporting Standards, and services provided in connection with statutory and regulatory filings or engagements. The fees for the annual audit of the Corporation s consolidated financial statements include fees relating to KPMG s audit of the effectiveness of the Corporation s internal control over financial reporting.

Audit-Related Fees consisted of translation services rendered in connection with the Corporation s financial documents.

*Tax Fees* consisted of services rendered in connection with the preparation of tax returns of the Corporation and its subsidiaries and general tax advice.

Other Fees there were no other professional services rendered during the years ended December 31, 2010 and 2009

#### Policy on Pre-Approval of Audit and Non-Audit Services of Independent Auditors

Our Audit Committee is responsible for the oversight of our independent auditor's work. Our Audit Committee's policy is to pre-approve all audit and non-audit services provided by KPMG. These services may include audit services, audit-related services, tax services and other services. The Audit Committee appoints the auditors and oversees and fixes the compensation for all such services. KPMG and our management report to the Audit Committee regarding the extent of services actually provided in accordance with the applicable pre-approval, and regarding the fees for the services performed. The Audit Committee approved 100% of the fees listed on the table above.

#### ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

# ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

# ITEM 16F. CHANGES IN REGISTRANT S CERTIFYING ACCOUNTANT

Not applicable.

#### ITEM 16G. CORPORATE GOVERNANCE

The Corporation complies with all the Nasdaq Stock Market corporate governance requirements.

#### **PART III**

#### ITEM 17. FINANCIAL STATEMENTS

Not applicable.

#### ITEM 18. FINANCIAL STATEMENTS

The financial statements for the three years ended December 31, 2010 are included in Item 8 of this report and are incorporated by reference in this item.

# ITEM 19. EXHIBITS

The following exhibits are included with or incorporated by reference into this report:

Exhibit No.	<u>Description</u>
1(a)	Articles of Incorporation, as amended. (incorporated by reference to Exhibit 3.1 to the Corporation s Form 20-F filed with the Commission December 9, 1996)
1(b)	Bylaws of the Corporation (incorporated by reference to Exhibit 3.2 to the Corporation s Form 20-F filed with the Commission December 9, 1996)
4(a)	Memorandum of Agreement between Paul Averback and the Corporation (incorporated by reference to Exhibit 10.1 to the Corporation s Form 20-F filed with the Commission December 9, 1996)
4(b)	Share Option Plan of the Corporation (incorporated by reference to Exhibit 10.2 to the Corporation s Form 20-F filed with the Commission December 9, 1996)
4(c)	Research and License Agreement between the Massachusetts General Hospital Corporation and the Corporation (incorporated by reference to Exhibit 10.3 to the Corporation s Form 20-F filed with the Commission December 9, 1996)
4(d)	Research and License Amendment between the Massachusetts General Hospital Corporation and the Corporation (incorporated by reference to Exhibit 10.5 to the Corporation s Form 20-F filed with the Commission February 21, 1997)
4(e)	Common Stock Purchase Agreement between Nymox Pharmaceutical Corporation and Jaspas Investments Limited dated November 1, 1999 (incorporated by reference to Exhibit 2.0 to the Corporation s Form F-1 Registration Statement filed with the Commission February 29, 2000)
4(f)	Registration Rights Agreement between Nymox Pharmaceutical Corporation and Jaspas Investments Limited dated November 1, 1999 (incorporated by reference to Exhibit 2.1 to the Corporation s Form F-1 Registration Statement filed with the Commission February 29, 2000)
4(g)	Escrow Agreement among Nymox Pharmaceutical Corporation, Jaspas Investments Limited and Epstein, Becker & Green, P.C. dated November 1, 1999 (incorporated by reference to Exhibit 2.2 to the Corporation s Form F-1 Registration Statement filed with the Commission February 29, 2000)
4(h)	Stock Purchase Warrant to purchase common shares issued to Jaspas Investments Limited dated November 1, 1999 (incorporated by reference to Exhibit 2.3 to the Corporation s Form F-1 Registration Statement filed with the Commission February 29, 2000)
4(i)	Research and License Agreement between the Rhode Island Hospital Corporation and the Corporation dated May 14, 1999 (incorporated by reference to Exhibit 10.10 to the Corporation s Form 20-F filed with the Commission May 15, 2000).
4(j)	Research and License Amendment between the Rhode Island Hospital Corporation and the Corporation dated November 19, 2001 (incorporated by reference to Exhibit 10.10 to the Corporation s Form 20-F filed with the Commission June 28, 2002).
4(k)	Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated January 27, 2003 (incorporated by reference to Exhibit 10.0 to the Corporation s F-3 Registration Statement filed with the Commission on March 12, 2003).
4(1)	Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated August 25, 2003 (incorporated by reference to Exhibit 10.1 to the Corporation s 6-K Report filed with the Commission on November 13, 2003).
4(m)	Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated October 6, 2004 (incorporated by reference to Exhibit 10.1 to

	the Corporation s 6-K Report filed with the Commission on November 15, 2004).
4(n)	Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated October 21, 2005. (incorporated by reference to Exhibit 10.1 to the Corporation s 20-F Report filed with the Commission on June 29, 2006).
4(o)	Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated November 13, 2006. (incorporated by reference to Exhibit 10.1 to the Corporation s 6-K Report filed with the Commission on March 15, 2007).
4(p)	Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated November 16, 2007. (incorporated by reference to Exhibit 99.1 to the Corporation s 6-K Report filed with the Commission on March 14, 2008).
4(q)	Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated November 10, 2008. (incorporated by reference to Exhibit 99.1 to the Corporation s 6-K Report filed with the Commission on March 13, 2009).
4(r)	Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated November 2, 2009. (incorporated by reference to Exhibit 99.1 to the Corporation s 6-K Report filed with the Commission on March 11, 2010).
4(s)	Common Stock Private Purchase Agreement between Nymox Pharmaceutical Corporation and Lorros-Greyse Investments Limited dated November 1, 2010. (filed herewith).
4(t)	License and Collaboration Agreement between Nymox Pharmaceutical Corporation and Recordati Ireland Ltd. dated December 16, 2010. (filed herewith).
8	List of Subsidiaries of Nymox Pharmaceutical Corporation (incorporated by reference to Exhibit 8 to the Corporation s Form 20-F filed with the Commission June 30, 2004)
11	Code of Business Conduct for the Officers, Directors and Employees of Nymox Pharmaceutical Corporation (incorporated by reference to Exhibit 11 to the Corporation s Form 20-F filed with the Commission June 30, 2004)
<u>12(a)</u>	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) or 15d-14(a)
<u>12(b)</u>	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) or 15d-14(a)
<u>13(a)</u>	Certification of Chief Executive Officer Pursuant to 18 U.S.C. 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
<u>13(b)</u>	Certification of Chief Financial Officer Pursuant to 18 U.S.C. 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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#### **SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

#### NYMOX PHARMACEUTICAL CORPORATION

(Registrant)

/s/ Paul Averback

Paul Averback

Title: President

Date: March 15, 2011

#### **EXHIBIT INDEX - NYMOX PHARMACEUTICAL CORPORATION**

Form 20-F Annual Report

4(m)

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#### **CERTIFICATION**

- I, Paul Averback, certify that:
- 1. I have reviewed this annual report on Form 20-F of Nymox Pharmaceutical Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Corporation as of, and for, the periods presented in this report;
- 4. The Corporation s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a 15(e) and 15d 15(e)), and internal control over financial reporting (as defined in the Exchange Act Rules 13a 15(f) and 15d 15(f)) for the Corporation and we have:
- a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Corporation, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) evaluated the effectiveness of the Corporation s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) disclosed in this report any change in the Corporation s internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Corporation s internal control over financial reporting; and
- 5. The Corporation s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Corporation s auditors and the audit committee of the Corporation s board of directors (or persons performing the equivalent function):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Corporation sability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Corporation s internal control over financial reporting.

Date: March 15, 2011

#### /s/ Paul Averback, MD

Paul Averback, MD President and Chief Executive Officer Nymox Pharmaceutical Corporation 98

#### **CERTIFICATION**

- I, Roy Wolvin, certify that:
- 1. I have reviewed this annual report on Form 20-F of Nymox Pharmaceutical Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Corporation as of, and for, the periods presented in this report;
- 4. The Corporation s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a 15(e) and 15d 15(e)), and internal control over financial reporting (as defined in the Exchange Act Rules 13a 15(f) and 15d 15(f)) for the Corporation and we have:
- a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Corporation, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) evaluated the effectiveness of the Corporation s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) disclosed in this report any change in the Corporation s internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Corporation s internal control over financial reporting; and
- 5. The Corporation s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Corporation s auditors and the audit committee of the Corporation s board of directors (or persons performing the equivalent function):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Corporation sability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Corporation s internal control over financial reporting.

Date: March 15, 2011

## /s/ Roy Wolvin

Roy Wolvin Chief Financial Officer Nymox Pharmaceutical Corporation 99

#### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul Averback, President and CEO of Nymox Pharmaceutical Corporation, do hereby certify that, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the information contained in the Annual Report on Form 20-F for the year ended December 31, 2010 of Nymox Pharmaceutical Corporation and filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934 and the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Nymox Pharmaceutical Corporation.

Date: March 15, 2011

/s/ Paul Averback, MD Paul Averback, MD

President and Chief Executive Officer

Nymox Pharmaceutical Corporation

#### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Roy Wolvin, CFO of Nymox Pharmaceutical Corporation, do hereby certify that, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the information contained in the Annual Report on Form 20-F for the year ended December 31, 2010 of Nymox Pharmaceutical Corporation and filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934 and the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Nymox Pharmaceutical Corporation.

Date: March 15, 2011

/s/ Roy Wolvin

Roy Wolvin Chief Financial Officer Nymox Pharmaceutical Corporation 101

#### **EXHIBIT 10.10**

#### COMMON STOCK PRIVATE PURCHASE AGREEMENT

This COMMON STOCK PRIVATE PURCHASE AGREEMENT (this Agreement ) is dated as of November 1, 2010 by and between Nymox Pharmaceutical Corporation, a Canadian corporation (the Company ), and Lorros-Greyse Investments, Ltd. (the Purchaser ). The parties hereto agree as follows:

#### **ARTICLE I**

#### **Definitions**

Section 1.1 Certain Definitions.

- a) Average Price shall be the average of the Closing Prices of the Company s Common Stock for each Trading Day in the Draw Down Period.
- b) Closing Price shall mean the price for the last reported trade as recorded by the Principal Market for the Trading Day.
- c) Current SEC Documents shall mean the Company's Annual Report, as amended, for the year ended December 31, 2009, including the accompanying financial statements, and the Company's latest Quarterly Report, as filed with the U.S. Securities and Exchange Commission (the SEC) and as available on the SEC s Electronic Data Gathering, Analysis, and Retrieval system (EDGAR).
- d) Draw Down shall have the meaning assigned to such term in Section 6.1(a) hereof.
- e) Draw Down Closing Date shall have the meaning assigned to such term in Section 6.1(b) hereof.
- f) Draw Down Pricing Period shall have the meaning assigned to such term in Section 6.1(a) hereof.
- g) Material Adverse Effect shall mean any adverse effect on the business, operations, properties or financial condition of the Company that materially impairs the ability of the Company and its subsidiaries and affiliates, taken as a whole, to perform any of its material obligations under this Agreement or to carry on its obligations, and shall include the loss for any reason to the Company of the services of Dr. Paul Averback.
- h) Principal Market shall mean initially the Nasdaq SmallCap Market, and shall include the Nasdaq National Market, the American Stock Exchange or the New York Stock Exchange if the Company is listed and trades on such market or exchange.
- i) SEC Documents—shall mean all reports, schedules, forms, statements and other documents or material that are available on the SEC s EDGAR system and that were filed by the Company with the SEC pursuant to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), including material filed pursuant to Section 13(a) or 15(d) of the Exchange Act and filings incorporated by reference.
- j) Shares shall mean, collectively, the shares of Common Stock of the Company being subscribed for hereunder, or, in the appropriate context, the shares of Common Stock of the Company issued with respect to a Draw Down.
- k) Trading Day shall mean any day on which the Principal Market is open for business.

#### **ARTICLE II**

#### **Purchase and Sale of Common Stock**

Section 2.1 *Purchase and Sale of Stock*. Subject to the terms and conditions of this Agreement, the Company shall issue and sell to the Purchaser and the Purchaser shall purchase from the Company up to Fifteen Million Dollars (\$15,000,000) of the Company s Common Stock, no par value per share (the Common Stock), based on Draw Downs requested under this Agreement. This Agreement replaces the earlier Common Stock Private Purchase Agreement between the Purchaser and the Company dated November 2, 2009.

Section 2.2 *The Shares*. The Company has authorized and has reserved and covenants to continue to reserve, free of preemptive rights and other similar contractual rights of stockholders, a sufficient number of its authorized but unissued shares of its Common Stock to cover the Shares to be issued in connection with all Draw Downs requested under this Agreement. At no time will the Company request a Draw Down which would result in the issuance of a number of shares of Common Stock pursuant to this Agreement which exceeds 19.9% of the number of shares of Common Stock issued and outstanding on the Closing Date without obtaining stockholder approval of such excess issuance.

Section 2.3 *Purchase Price and Closing*. The Company agrees to issue and sell to the Purchaser and the Purchaser agrees to purchase that number of the Shares to be issued in connection with each Draw Down. Each party shall deliver all documents, instruments and writings required to be delivered by such party pursuant to this Agreement.

#### **ARTICLE III**

#### **Representations and Warranties**

Section 3.1 Representation and Warranties of the Company. The Company hereby makes the following representations and warranties to the Purchaser: (a) Organization, Good Standing and Power. The Company is a corporation duly incorporated, validly existing and in good standing under the federal laws of Canada and has the requisite corporate power to own, lease and operate its properties and assets and to conduct its business as it is now being conducted. The Company does not have any subsidiaries except as set forth in the Current SEC Documents. The Company and each such subsidiary is duly qualified as a foreign corporation to do business and is in good standing in every jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary except for any jurisdiction in which the failure to be so qualified will not have a Material Adverse Effect on the Company s financial condition.

- (b) *Authorization, Enforcement*. The Company has the requisite corporate power and authority to enter into and perform this Agreement and to issue and sell the Shares in accordance with the terms hereof. The execution, delivery and performance of this Agreement by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary corporate action, and no further consent or authorization of the Company or its Board of Directors or stockholders is required. This Agreement has been duly executed and delivered, and constitutes a valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, liquidation, conservatorship, receivership or similar laws relating to, or affecting generally the enforcement of, creditor s rights and remedies or by other equitable principles of general application.
- (c) Capitalization. The Company currently has issued and outstanding 32,374,468 shares of its Common Stock, all of which have been duly and validly authorized and are fully-paid and non-assessable. Except as set forth in this Agreement and as set forth in the Current SEC Documents, no shares of Common Stock are entitled to preemptive rights or registration rights and there are no outstanding options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company. Furthermore, except as set forth in the SEC Documents, there are no contracts, commitments, understandings, or arrangements by which the Company is or may become bound to issue additional shares of the capital stock of the Company or options, securities or rights convertible into shares of capital stock of the Company. The Company is not a party to, and it has no knowledge of, any agreement restricting the voting or transfer of any shares of the capital stock of the Company. Except as set forth in the Current SEC Documents, the offer and sale of all capital stock, convertible securities, rights, warrants, or options of the Company issued prior to the Closing complied with all applicable United States Federal and state and Canadian and provincial securities laws, and no stockholder has a right of rescission or damages with respect thereto which would have a Material Adverse Effect on the Company s financial condition or operating results. The Company has made available to the Purchaser on request true and correct copies of the Company s Articles of Incorporation as in effect on the date hereof (the Articles ), and the Company s Bylaws as in effect on the date hereof (the Bylaws ). The Principal Market for the Common Stock in the United States is the Nasdaq Capital Market, and the Company has not received any notice from such market questioning or threatening the continued inclusion of the Common Stock on such market.
- (d) *Issuance of Shares*. The Shares to be issued under this Agreement have been duly authorized by all necessary corporate action and, when paid for or issued in accordance with the terms hereof, the Shares shall be validly issued and outstanding, fully paid and non-assessable, and the Purchaser shall be entitled to all rights accorded to a holder of Common Stock.

(e) No Conflicts. The execution, delivery and performance of this Agreement by the Company and the consummation by the Company of the transactions contemplated herein do not and will not (i) violate any provision of the Company's Articles or Bylaws, (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, mortgage, deed of trust, indenture, note, bond, license, lease agreement, instrument or obligation to which the Company is a party, (iii) create or impose a lien, charge or encumbrance on any property of the Company under any agreement or any commitment to which the Company is a party or by which the Company is bound or by which any of its respective properties or assets are bound, or (iv) result in a violation of any United States Federal, state, local or Canadian, provincial, or other foreign statute, rule, regulation, order, judgment or decree (including any United States Federal and state or Canadian or provincial securities laws and regulations) applicable to the Company or any of its subsidiaries or by which any property or asset of the Company or any of its subsidiaries are bound or affected, except, in all cases, for such conflicts, defaults, termination, amendments, accelerations, cancellations and violations as would not, individually or in the aggregate, have a Material Adverse Effect. The business of the Company and its subsidiaries is not being conducted in violation of any laws, ordinances or regulations of any governmental entity, except for possible violations which singularly or in the aggregate do not and will not have a Material Adverse Effect. The Company is not required under any United States Federal, state or local or Canadian or provincial law, rule or regulation to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency in order for it to execute, deliver or perform any of its obligations under this Agreement, or issue and sell the Shares in accordance with the terms hereof (other than any prior notification required to the Nasdaq Stock Market of the listing of additional shares and approval of the Autorité des Marchés Financiers (AMF) for a distribution of shares outside of Quebec and any filings subsequent to the Agreement Closing which may be required to be made by the Company with the SEC, the AMF, the Nasdaq Stock Market or state or provincial securities administrators and any registration statement, if any, which may be filed pursuant hereto); provided that, for purpose of the representation made in this sentence, the Company is assuming and relying upon the accuracy of the relevant representations and agreements of the Purchaser herein.

- (f) SEC Documents, Financial Statements. The Common Stock of the Company is registered pursuant to Section 12(g) of the Exchange Act, and, except as disclosed in the SEC Documents, the Company has timely filed all reports, schedules, forms, statements and other documents required to be filed by it with the SEC pursuant to the reporting requirements of the Exchange Act, including material filed pursuant to Section 13(a) or 15(d) of the Exchange Act. The Company has electronically filed true and complete copies of SEC Documents with the SEC s Electronic Data Gathering, Analysis, and Retrieval system (EDGAR) since August 8, 1996 and the Purchaser acknowledges having access to the EDGAR system and the SEC Documents. The Company has not provided to the Purchaser any information which, according to applicable law, rule or regulation, should have been disclosed publicly by the Company but which has not been so disclosed, other than with respect to the transactions contemplated by this Agreement. As of their filing dates, the Current SEC Documents complied in all material respects with the requirements of the Exchange Act and the rules and regulations of the SEC promulgated thereunder applicable to such documents, and, as of their filing dates, the Current SEC Documents did not contain any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Documents comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC or other applicable rules and regulations with respect thereto. Such financial statements have been prepared in accordance with Canadian generally accepted accounting principles (GAAP) applied on a consistent basis during the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto or (ii) in the case of unaudited interim statements, to the extent they may not include footnotes or may be condensed or summary statements), and fairly present in all material respects the financial position of the Company and its subsidiaries as of the dates thereof and the results of operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal year-end audit adjustments).
- (g) *Subsidiaries*. The Current SEC Documents hereto set forth each subsidiary of the Company, showing the jurisdiction of its incorporation or organization and showing the Company s ownership of the outstanding stock or other interests of such subsidiary. All of the outstanding shares of capital stock of each subsidiary have been duly authorized and validly issued, and are fully paid and non-assessable. Neither the Company nor any subsidiary is a party to, nor has any knowledge of, any agreement restricting the voting or transfer of any shares of the capital stock of any subsidiary.
- (h) *No Material Adverse Effect*. Since June 30, 2010, the date through which the most recent quarterly of the Company has been prepared and filed with the SEC, neither the Company nor its subsidiaries has experienced or suffered any Material Adverse Effect or incurred any liabilities, obligations, debts, claims or losses which, individually or in the aggregate, has had a Material Adverse Effect on the Company or its subsidiaries.
- (i) *No Undisclosed Events or Circumstances*. No event or circumstance has occurred or exists with respect to the Company or its subsidiaries or their respective businesses, properties, prospects, operations or financial condition, which, under applicable law, rule or regulation, requires public disclosure or announcement by the Company but which has not been so publicly announced or disclosed.
- (j) *Title to Assets*. Each of the Company and the subsidiaries has good and marketable title to all of its real and personal property reflected in the SEC Documents, free of any mortgages, pledges, charges, liens, security interests or other encumbrances, except for those indicated in the Current SEC Documents or such that do not cause a Material Adverse Effect on the Company s financial condition or operating results. All said leases of the Company and each of its subsidiaries are valid and subsisting and in full force and effect.

- (k) Actions Pending. There is no action, suit, claim, investigation or proceeding pending or, to the knowledge of the Company, threatened against the Company or any subsidiary which questions the validity of this Agreement or the transactions contemplated hereby or any action taken or to be taken pursuant hereto or thereto. Except as set forth in the Current SEC Documents or such that do not cause a Material Adverse Effect, there are no outstanding orders, judgments, injunctions, awards or decrees of any court, arbitrator or governmental or regulatory body against the Company or any subsidiary nor any actions, suits, claims, investigations or proceedings pending or, to the knowledge of the Company, threatened, against or involving the Company, any subsidiary or any of their respective properties or assets.
- (1) Compliance with Law. The business of the Company and its subsidiaries has been and is presently being conducted in accordance with all applicable United States Federal, state and local and Canadian and provincial governmental laws, rules, regulations and ordinances, except as set forth in the Current SEC Documents or such that do not cause a Material Adverse Effect. The Company and each of its subsidiaries have all franchises, permits, licenses, consents and other governmental or regulatory authorizations and approvals necessary for the conduct of their respective businesses as now being conducted by them unless the failure to possess such franchises, permits, licenses, consents and other governmental or regulatory authorizations and approvals, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect.
- (m) *Taxes*. Except as set forth in the Current SEC Documents, the Company and each of the subsidiaries has accurately prepared and filed all United States Federal and state and Canadian and provincial and other tax returns required by law to be filed by it, has paid or made provisions for the payment of all taxes shown to be due and all additional assessments, and adequate provision have been and are reflected in the financial statements of the Company and the subsidiaries for all current taxes and other charges to which the Company or any subsidiary is subject and which are not currently due and payable. The Company has no knowledge of any additional assessments, adjustments or contingent tax liability (whether federal, state or provincial) pending or threatened against the Company or any subsidiary for any period, nor of any basis for any such assessment, adjustment or contingency.

- (n) *Operation of Business*. The Company and each of the subsidiaries owns or possesses all patents, trademarks, service marks, trade names, copyrights, licenses and authorizations as set forth in the Current SEC Documents, and all rights with respect to the foregoing, which are necessary for the conduct of its business as now conducted without any conflict with the rights of others.
- (o) Regulatory Compliance. Except as disclosed in the Current SEC Documents or such that do not cause a Material Adverse Effect, the Company and each of its subsidiaries have obtained all material approvals, authorization, certificates, consents, licenses, orders and permits or other similar authorizations of all governmental authorities, or from any other person, that are required under any Food and Drug or Environmental Laws. Environmental Laws shall mean all applicable laws and regulations in the United States or Canada relating to the protection of the environment including, without limitation, all requirements pertaining to reporting, licensing, permitting, controlling, investigating or remediating emissions, discharges, releases or threatened releases of hazardous substances, chemical substances, pollutants, contaminants or toxic substances, materials or wastes, whether solid, liquid or gaseous in nature, into the air, surface water, groundwater or land, or relating to the manufacture, processing, distribution, use, treatment, storage, disposal transport or handling or hazardous substances, chemical substances, pollutants, contaminants or toxic substances, material or wastes, whether solid, liquid or gaseous in nature. Food and Drug Laws shall mean all applicable laws and regulations in the United States and Canada relating to the development, testing, manufacturing and distribution of pharmaceutical products. Except as set forth in the Current SEC Documents or such that do not cause a Material Adverse Effect, the Company has all necessary governmental approvals required under all Food and Drug and Environmental Laws and used in its business or in the business of any of its subsidiaries.
- (p) *Books and Records*. The records and documents of the Company and its subsidiaries accurately reflect in all material respects the information relating to the business of the Company and the subsidiaries, the location and collection of their assets, and the nature of all transactions giving rise to the obligations or accounts receivable of the Company or any subsidiary.
- (q) Securities Laws Compliance. The Company has complied and will comply with all applicable United States Federal and state and Canadian and provincial securities laws in connection with the offer, issuance and sale of the Shares hereunder. Neither the Company nor anyone acting on its behalf, directly or indirectly, has or will sell, offer to sell or solicit offers to buy the Shares or similar securities to, or solicit offers with respect thereto from, or enter into any preliminary conversations or negotiations relating thereto with, any person (other than the Purchaser), so as to bring the issuance and sale of the Shares under the registration provisions of the Securities Act and applicable state securities laws. Neither the Company nor any of its affiliates, nor any person acting on its or their behalf, has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D under the Securities Act) or directed selling efforts (within the meaning of Regulation S under the Securities Act) in connection with the offer or sale of the Shares. The Company is a foreign issuer within the meaning of Regulation S and Rule 405 under the Securities Act.
- (r) Governmental Approvals. Except as set forth in the Current SEC Documents, and except for the filing of any notice or the obtaining of any necessary approvals or exemptions prior or subsequent to the Closing that may be required under applicable United States Federal or state and Canadian or provincial securities laws (which if required, shall be filed on a timely basis), no authorization, consent, approval, license, exemption of, filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, is or will be necessary for, or in connection with, the execution or delivery of the Shares, or for the performance by the Company of its obligations under this Agreement.
- (s) *Employees*. Neither the Company nor any subsidiary has any collective bargaining arrangements or agreements covering any of its employees, except as set forth in the Current SEC Documents. Except as set forth in the Current

SEC Documents or such that do not cause a Material Adverse Effect, neither the Company nor any subsidiary is in breach of any employment contract, agreement regarding proprietary information, noncompetition agreement, nonsolicitation agreement, confidentiality agreement, or any other similar contract or restrictive covenant, relating to the right of any officer, employee or consultant to be employed or engaged by the Company or such subsidiary. Since the date of the latest Current SEC Document, no officer, consultant or key employee of the Company or any subsidiary whose termination, either individually or in the aggregate, could have a Material Adverse Effect, has terminated or, to the knowledge of the Company, has any present intention of terminating his or her employment or engagement with the Company or any subsidiary.

- (t) *Use of Proceeds*. The proceeds from the sale of the Shares will be used by the Company and its subsidiaries for general corporate purposes.
- (u) Acknowledgment Regarding Purchaser s Purchase of Shares. Company acknowledges and agrees that Purchaser is acting solely in the capacity of arm's length purchaser with respect to this Agreement and the transactions contemplated hereunder and that the Company's decision to enter into this Agreement has been based solely on the independent evaluation by the Company and its own representatives and counsel.

Section 3.2 Representations and Warranties of the Purchaser. The Purchaser hereby makes the following representations, acknowledgements and warranties to the Company: (a) Organization and Standing of the Purchaser. The Purchaser is a company duly incorporated, validly existing and in good standing under the laws of the Republic of Panama and maintains its principal place of business in Panama. The Purchaser does not maintain a place of business in the United States or Canada, is not a resident of the United States or Canada and is not beneficially owned by any U.S. person within the meaning of Regulation S promulgated under the Securities Act.

(b) *Authorization and Power*. The Purchaser has the requisite power and authority to enter into and perform this Agreement and to purchase the Shares being sold to it hereunder. The execution, delivery and performance of this Agreement by Purchaser and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action.

- (c) No Conflicts. The execution, delivery and performance of this Agreement and the consummation by the Purchaser of the transactions contemplated hereby or relating hereto do not and will not (i) result in a violation of such Purchaser's charter documents or bylaws or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of any agreement, indenture or instrument to which the Purchaser is a party, or result in a violation of any law, rule, or regulation, or any order, judgment or decree of any court or governmental agency applicable to the Purchaser or its properties (except for such conflicts, defaults and violations as would not, individually or in the aggregate, have a Material Adverse Effect on Purchaser).
- (d) *Financial Risks*. The Purchaser acknowledges that it is able to bear the financial risks associated with an investment in the Shares and that it has been given full access to such records of the Company and the subsidiaries and to the officers of the Company and the subsidiaries as it has deemed necessary or appropriate to conduct its due diligence investigation. The Purchaser is capable of evaluating the risks and merits of an investment in the Shares by virtue of its experience as an investor and its knowledge, experience, and sophistication in financial and business matters and the Purchaser is capable of bearing the entire loss of its investment in the Shares.
- (e) *Accredited Investor*. The Purchaser by itself or together with its adviser(s), is an "accredited investor", as such term is defined in Regulation D promulgated by the SEC under the Securities Act, is an accredited investor within the meaning of National Instrument 45-106, is experienced in investments and business matters, has made investments of a speculative nature and, with its representatives, has such knowledge and experience in financial, tax and other business matters as to enable the Purchaser to utilize the information made available by the Company to evaluate the merits and risks of and to make an informed investment decision with respect to the proposed purchase, which represents a speculative investment.
- (f) Reliance upon Regulation S The Purchaser acknowledges that it is purchasing the Shares pursuant to an exemption from registration under the United States securities laws in reliance upon Regulation S promulgated under the Securities Act of 1933, as amended (the Securities Act ). Accordingly, the Purchaser will not offer or sell any of the Shares to or for the benefit or account of a person resident in the United States or entity existing or incorporated under the laws of the United States or otherwise defined as a U.S. person under Regulation S for a period of at least forty (40) days from the date on which the Shares are purchased, unless such Shares are registered under the Securities Act or exempt from registration; (g) Access to Publicly Available Documents The Purchaser acknowledges that it or its advisors has access to all publicly-available documents or reports of the Company, including the SEC Documents and the Company s press releases, and that it or its advisors has reviewed and understands such documents or reports. The Purchaser acknowledges that the Company has not provided to the Purchaser any information which, according to applicable law, rule or regulation, should have been disclosed publicly by the Company but which has not been so disclosed, other than with respect to the transactions contemplated by this Agreement.
- (h) *Purchase for Investment*. The Purchaser is purchasing the Shares solely for investment, for its own account, and not with a present intent to resell or otherwise to distribute any of the Shares. The Purchaser further represents that the Purchaser has no present or contemplated agreement, undertaking, arrangement, obligation, indebtedness or commitment providing for or which is likely to compel a disposition in any manner of any of the Shares, that the Purchaser is not aware of any circumstances presently in existence which are likely to promote in the future any disposition by the Purchaser of the Shares and that the Purchaser does not presently contemplate any sale of any of the Shares upon the occurrence or nonoccurrence of any predetermined or undetermined event or circumstance.
- (i) *Not A U.S. Person*. The Purchaser is not a U.S. person or a person in the United States within the meaning of Regulation S promulgated under the Securities Act.

- (j) *No Prior Short Selling*. The Purchaser represents and warrants to the Company that at no time prior to the date of this Agreement has any of the Purchaser, its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any (i) "short sale" (as such term is defined in Rule 3b-3 of the Exchange Act) of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.
- (k) *General*. The Purchaser understands that the Company is relying upon the truth and accuracy of the representations, warranties, agreements, acknowledgments and understandings of the Purchaser set forth herein in order to determine the suitability of the Purchaser to acquire the Shares. The Purchaser represents that any information which the Purchaser is furnishing to the Company in this Agreement, including, without limitation, the information provided on the signature page hereof, is correct and complete, and if such information or responses should cease to be correct at any time following the date hereof, the Purchaser will immediately furnish fully revised or corrected information to the Company.
- (1) Survival. The foregoing representations, warranties and agreements of the Purchaser shall survive this Agreement.

#### **ARTICLE IV**

#### **Covenants**

Section 4.1 *The Company s Covenants*. The Company covenants with the Purchaser as follows:

(a) Securities Compliance. The Company shall notify The Nasdaq Stock Market, Inc., in accordance with their rules and regulations, of the transactions contemplated by this Agreement, and shall take all other necessary action and proceedings as may be required and permitted by applicable law, rule and regulation, for the legal and valid issuance of the Shares to the Purchaser or subsequent holders.

- (b) Registration and Listing. The Company will cause its Common Stock to continue to be registered under Sections 12(b) or 12(g) of the Exchange Act, will comply in all respects with its reporting and filing obligations under the Exchange Act, and will not take any action or file any document (whether or not permitted by the Securities Act or the rules promulgated thereunder) to terminate or suspend its reporting and filing obligations under the Exchange Act or Securities Act, except as permitted herein. The Company will take all action necessary to continue the listing or trading of its Common Stock on the Nasdaq SmallCap Market or another Principal Market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the NASD and The Nasdaq Stock Market.
- (c) *Compliance with Laws*. The Company shall comply, and cause each subsidiary to comply, with all applicable laws, rules, regulations and orders, noncompliance with which could have a Material Adverse Effect.
- (d) *Keeping of Records and Books of Account*. The Company shall keep and cause each subsidiary to keep adequate records and books of account, in which complete entries will be made in accordance with Canadian GAAP consistently applied, reflecting all financial transactions of the Company and its subsidiaries, and in which, for each fiscal year, all proper reserves for depreciation, depletion, obsolescence, amortization, taxes, bad debts and other purposes in connection with its business shall be made.
- (e) *Amendments*. The Company shall not amend or waive any provision the Articles of Incorporation, Bylaws of the Company in any way that would adversely affect the voting rights of the holders of the Shares.
- (f) *Other Agreements*. The Company shall not enter into any agreement the terms of which such agreement would restrict or impair the right to perform of the Company or any subsidiary under this Agreement or the Articles of Incorporation of the Company.
- (g) *Notice of Certain Events Affecting the Purchase or Sale.* The Company will immediately notify the Purchaser upon the occurrence of any of the following events in respect of the issuance, purchase, sale, trading or distribution of the Shares pursuant to this Agreement: (i) receipt of any notification by the SEC, any state or provincial securities commission or any other regulatory authority with respect to the suspension of the qualification or exemption from qualification of any of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (ii) issuance by the SEC, any state or provincial securities commission or any other regulatory authority of any stop order or of any order preventing or suspending any issuance, sale, purchase, trading or distribution of the Shares under this Agreement, or of the suspension of the qualification of the Shares for offering or sale in any jurisdiction, or the initiation or threatening of any proceeding for any such purpose.
- (h) *Consolidation; Merger*. The Company shall not, at any time after the date hereof, effect any merger or consolidation of the Company with or into, or a transfer of all or substantially all of the assets of the Company to, another entity (a Consolidation Event ) unless the resulting successor or acquiring entity (if not the Company) assumes by written instrument or by operation of law the obligation to deliver to the Purchaser such shares of stock and/or securities as the Purchaser is entitled to receive pursuant to this Agreement.
- (i) Compliance with Regulation S. The sale of the Shares shall be made in accordance with the provisions and requirements of Regulation S and any applicable federal, state or provincial securities law. The Company shall make any necessary SEC or other regulatory filings required to be made by the Company in connection with the sale of the Shares to the Purchaser as required by all applicable federal, state and provincial laws, and shall provide a copy thereof to the Purchaser upon request.

- (a) Limitation on Short Sales and Hedging Transactions. The Purchaser agrees that beginning on the date of this Agreement and ending on the date of termination or expiration of this Agreement, the Purchaser and its agents, representatives and affiliates shall not in any manner whatsoever enter into or effect, directly or indirectly, any (i) "short sale" (as such term is defined in Rule 3b-3 of the Exchange Act) of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.
- (b) *Compliance with Regulation S*. The purchase of the Shares shall be made in accordance with the provisions and requirements of Regulation S and any applicable federal, state or provincial securities law. The Purchaser s trading and distribution activities with respect to shares of the Company s Common Stock shall be in compliance with all applicable federal, state and provincial securities laws, rules and regulations and rules and regulations of the Principal Market on which the Company s Common Stock is listed including, without limitation, Regulation S.
- (c) *Notice of Certain Events Affecting The Purchase or Sale.* The Purchaser will immediately notify the Company upon the occurrence of any of the following events in respect of the issuance, purchase, sale, trading or distribution of the Shares pursuant to this Agreement: (i) receipt of any notification by the SEC, any state or provincial securities commission or any other regulatory authority with respect to the suspension of the qualification or exemption from qualification of any of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (ii) issuance by the SEC, any state or provincial securities commission or any other regulatory authority of any stop order or of any order preventing or suspending any issuance, sale, purchase, trading or distribution of the Shares under this Agreement, or of the suspension of the qualification of the Shares for offering or sale in any jurisdiction, or the initiation or threatening of any proceeding for any such purpose.

(d) *Material Changes in Purchaser s Status* The Purchaser will immediately notify the Company of any changes in circumstance that may reasonably affect the availability of the exemption from registration under the Securities Act and the rules and regulations promulgated thereunder, including, without limitation, any changes that may affect the Purchaser s status as an "accredited investor", as such term is defined in Regulation D or as a person or entity that is not a U.S. person or a person in the United States for the purposes of Regulation S.

#### ARTICLE V

#### **Conditions to Closing and Draw Downs**

- Section 5.1 Conditions Precedent to the Obligation of the Company to Sell the Shares. The obligation hereunder of the Company to issue and sell the Shares to the Purchaser is subject to the satisfaction or waiver, at or before the Agreement Closing or at or before each Draw Down Closing, of each of the conditions set forth below. These conditions are for the Company's sole benefit and may be waived by the Company at any time in its sole discretion.
- (a) Accuracy of the Purchaser's Representations and Warranties. The representations and warranties of the Purchaser shall be true and correct in all material respects as of the date when made and as of the Closing and as of each Draw Down Closing Date as though made at that time, except for representations and warranties that speak as of a particular date.
- (b) *Performance by the Purchaser*. The Purchaser shall have performed, satisfied and complied in all material respects with all material covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Purchaser at or prior to the Closing and as of each Draw Down Closing Date.
- (c) *No Injunction*. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction which prohibits the consummation of any of the transactions contemplated by this Agreement.
- Section 5.2 Conditions Precedent to the Obligation of the Purchaser to Close. The obligation hereunder of the Purchaser to enter this Agreement is subject to the satisfaction or waiver, at or before the Agreement Closing and at or before each Draw Down Closing, of each of the conditions set forth below. These conditions are for the Purchaser's sole benefit and may be waived by the Purchaser at any time in its sole discretion.
- (a) Accuracy of the Company's Representations and Warranties. Each of the representations and warranties of the Company shall be true and correct in all material respects as of the date when made and as of the Closing as though made at that time (except for representations and warranties that speak as of a particular date).
- (b) *Performance by the Company*. The Company shall have performed, satisfied and complied in all respects with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to the Closing.
- (c) *No Injunction*. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction which prohibits the consummation of any of the transactions contemplated by this Agreement.
- (d) *No Proceedings or Litigation*. No action, suit or proceeding before any arbitrator or any governmental authority shall have been commenced, and no investigation by any governmental authority shall have been threatened, against the Purchaser or the Company or any subsidiary, or any of the officers, directors or affiliates of the Company or any

subsidiary seeking to restrain, prevent or change the transactions contemplated by this Agreement, or seeking damages in connection with such transactions.

- (e) *No Suspension*. Trading in the Company's Common Stock shall not have been suspended by the SEC or The Nasdaq Stock Market, Inc. (except for any suspension of trading of limited duration agreed to by the Company, which suspension shall be terminated prior to each Draw Down request), and, at any time prior to such request, trading in securities generally as reported by Nasdaq shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by Nasdaq.
- (d) Material Adverse Effect. No Material Adverse Effect and no Consolidation Event shall have occurred.

#### **ARTICLE VI**

#### **Draw Down Terms**

Section 6.1 *Draw Down Terms*. Subject to the satisfaction of the conditions set forth in this Agreement, the parties agree as follows:

a) The Company may, in its sole discretion, issue and exercise a draw down (a Draw Down), which Draw Down the Purchaser will be obligated to accept. The Company shall issue the Draw Down by giving the Purchaser a Draw Down Notice specifying the total Draw Down amount and the date of the Draw Down Notice. The Draw Down Pricing Period shall be the five (5) Trading Days specified in the Draw Down Notice immediately preceding the date of the Draw Down Notice.

- b) Only one Draw Down shall be allowed for each Draw Down Pricing Period. The price per share paid by the Purchaser shall be based on the Average Daily Price on each separate Trading Day during the Draw Down Pricing Period. The number of shares of Common Stock purchased by the Purchaser with respect to each Draw Down shall be determined on the Draw Down Closing Date, which shall be the next Trading Day following the Draw Down date.
- c) The Company shall have the right to issue and exercise a Draw Down of up to \$500,000 of the Company s Common Stock per Draw Down, subject to the limitations set forth immediately below. The minimum Draw Down shall be \$100,000 unless otherwise agreed by Purchaser.
- d) The number of Shares of Common Stock to be issued in connection with each Draw Down shall be equal to the Draw Down amount divided by 97% of the Average Price of the Common Stock for the Draw Down Pricing Period.
- e) The Company must provide the Purchaser via facsimile transmission the Draw Down Notice. At no time shall the Purchaser be required to purchase more than the Draw Down amount specified for a given Draw Down Pricing Period.
- f) On or before three Trading Days after each Draw Down Closing Date, the Purchaser shall pay the specified Draw Down amount to the Company. Upon receipt of the Draw Down payment, the Company shall deliver the Shares to the Purchaser in accordance with any instructions from the Purchaser.

#### **ARTICLE VII**

#### **Legends; Transfer Agent Instructions**

Section 7.1 *Legends*. Unless otherwise provided below, each certificate representing Shares will bear the following legend or equivalent (the Legend):

THE SECURITIES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE SECURITIES ACT ), OR ANY OTHER APPLICABLE SECURITIES LAWS AND HAVE BEEN ISSUED IN RELIANCE UPON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT PROVIDED BY REGULATION S AND SUCH OTHER SECURITIES LAWS. NEITHER THIS SECURITY NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE SOLD, ASSIGNED, TRANSFERRED, PLEDGED, ENCUMBERED, OR OTHERWISE DISPOSED OF, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO A TRANSACTION THAT IS EXEMPT FROM SUCH REGISTRATION.

Section 7.2 *No Legend Required* The legend requirements in Section 7.1 above do not apply where, pursuant to instructions from the Purchaser, the Shares are not delivered to the Purchaser until after the expiration of all applicable holding periods restricting resale of the Shares as determined from the date of the settlement of the Draw Down.

Section 7.3 *Transfer Agent Instructions*. Upon the settlement of a Draw Down, the Company shall issue to the transfer agent for its Common Stock (and to any substitute or replacement transfer agent for its Common Stock upon the Company s appointment of any such substitute or replacement transfer agent) instructions substantially in the form of Exhibit E hereto. Such instructions shall be irrevocable by the Company from and after the date hereof or from and after the issuance thereof to any such substitute or replacement transfer agent, as the case may be.

Section 7.4 No Other Legend or Stock Transfer Restrictions. No legend other than the one specified in Section 7.1 shall be placed on the share certificates representing the Shares and no instructions or stop transfer orders, stock transfer restrictions, or other restrictions shall be given to the Company s transfer agent with respect thereto other than as expressly set forth in this Article VII, and the prohibition of transfers of the Shares except in compliance with the requirements of Regulation S, which the Investor hereby acknowledges.

Section 7.5 *Investor s Compliance*. Nothing in this Article shall affect in any way the Investor s obligations to comply with all applicable securities laws upon resale of the Common Stock.

#### **ARTICLE VIII**

#### **Termination**

Section 8.1 *Termination by Mutual Consent*. The term of this Agreement shall be twenty-four (24) months from the date of execution of this Agreement. This Agreement may be terminated at any time by mutual written consent of the parties.

Section 8.2 Other Termination.

(a) The Purchaser may terminate this Agreement upon ten (10) Trading Days notice if (i) an event resulting in a Material Adverse Effect has occurred, (ii) the Common Stock is de-listed from the Nasdaq SmallCap Market unless such de-listing is in connection with the listing of the Common Stock on the Nasdaq National Market, the New York or American Stock Exchanges, (iii) the Company files for protection from creditors under any applicable law, or (iv) the Company fails to deliver the Shares to the Purchaser in accordance with the instructions from the Purchaser.

(b) The Company may terminate this Agreement upon ten (10) Trading Days notice if (i) the Company has completed Draw Downs of at least Eight Million Dollars (\$8,000,000) or (ii) the Purchaser shall fail to fund a properly noticed Draw Down within ten (10) Trading Days of the date payment for such Draw Down is due.

Section 8.3 *Effect of Termination*. In the event of termination by the Company or the Purchaser, written notice thereof shall forthwith be given to the other party and the transactions contemplated by this Agreement shall be terminated without further action by either party. If this Agreement is terminated as provided in Section 8.1 or 8.2 herein, this Agreement shall become void and of no further force and effect, except for Articles IX and XI herein. Nothing in this Section 8.3 shall be deemed to release the Company or the Purchaser from any liability for any breach under this Agreement, or to impair the rights to the Company and the Purchaser to compel specific performance by the other party of its obligations under this Agreement.

#### **ARTICLE IX**

#### Indemnification

Section 9.1 *General Indemnity*. The Company agrees to indemnify and hold harmless the Purchaser (and its directors, officers, affiliates, agents, successors and assigns) from and against any and all losses, liabilities, deficiencies, costs, damages and expenses (including, without limitation, reasonable attorney's fees, charges and disbursements) incurred by the Purchaser as a result of any inaccuracy in or breach of the representations, warranties or covenants made by the Company herein. The Purchaser agrees to indemnify and hold harmless the Company and its directors, officers, affiliates, agents, successors and assigns from and against any and all losses, liabilities, deficiencies, costs, damages and expenses (including, without limitation, reasonable attorneys fees, charges and disbursements) incurred by the Company as result of any inaccuracy in or breach of the representations, warranties or covenants made by the Purchaser herein.

Section 9.2 Indemnification Procedure. Any party entitled to indemnification under this Article IX (an "indemnified party") will give written notice to the indemnifying party of any matters giving rise to a claim for indemnification; provided, that the failure of any party entitled to indemnification hereunder to give notice as provided herein shall not relieve the indemnifying party of its obligations under this Article IX except to the extent that the indemnifying party is actually prejudiced by such failure to give notice. In case any action, proceeding or claim is brought against an indemnified party in respect of which indemnification is sought hereunder, the indemnifying party shall be entitled to participate in and, unless in the reasonable judgment of counsel to the indemnified party a conflict of interest between it and the indemnifying party may exist with respect of such action, proceeding or claim, to assume the defense thereof with counsel reasonably satisfactory to the indemnified party. In the event that the indemnifying party advises an indemnified party that it will contest such a claim for indemnification hereunder, or fails, within thirty (30) days of receipt of any indemnification notice to notify, in writing, such person of its election to defend, settle or compromise, at its sole cost and expense, any action, proceeding or claim (or discontinues its defense at any time after it commences such defense), then the indemnified party may, at its option, defend, settle or otherwise compromise or pay such action or claim. In any event, unless and until the indemnifying party elects in writing to assume and does so assume the defense of any such claim, proceeding or action, the indemnified party's costs and expenses arising out of the defense, settlement or compromise of any such action, claim or proceeding shall be losses subject to indemnification hereunder. The indemnified party shall cooperate fully with the indemnifying party in connection with any settlement negotiations or defense of any such action or claim by the indemnifying party and shall furnish to the indemnifying party all information reasonably available to the indemnified party which relates to such action or claim. The indemnifying party shall keep the indemnified party fully apprised at all times as to the status of the defense or any settlement negotiations with respect thereto. If the indemnifying party elects to defend any such action or claim, then the indemnified party shall be entitled to participate in such defense with counsel of its choice at its sole

cost and expense. The indemnifying party shall not be liable for any settlement of any action, claim or proceeding effected without its prior written consent. Notwithstanding anything in this Article IX to the contrary, the indemnifying party shall not, without the indemnified party s prior written consent, settle or compromise any claim or consent to entry of any judgment in respect thereof which imposes any future obligation on the indemnified party or which does not include, as an unconditional term thereof, the giving by the claimant or the plaintiff to the indemnified party of a release from all liability in respect of such claim. The indemnification required by this Article IX shall be made by periodic payments of the amount thereof during the course of investigation or defense, as and when bills are received or expense, loss, damage or liability is incurred, so long as the indemnified party irrevocably agrees to refund such moneys if it is ultimately determined by a court of competent jurisdiction that such party was not entitled to indemnification. The indemnity agreements contained herein shall be in addition to (a) any cause of action or similar rights of the indemnified party against the indemnifying party or others, and (b) any liabilities the indemnifying party may be subject to.

#### **ARTICLE X**

#### **Assignment**

Section 10.1 *Assignment*. Neither this Agreement nor any rights of the Purchaser or the Company hereunder may be assigned by either party to any other person.

#### **ARTICLE XI**

#### **Notices**

Section 11.1 *Notices*. All notices, demands, requests, consents, approvals, and other communications required or permitted hereunder shall be in writing and, unless otherwise specified herein, shall be (i) hand delivered, (ii) deposited in the mail, registered or certified, return receipt requested, postage prepaid, (iii) delivered by reputable air courier service with charges prepaid, or (iv) transmitted by facsimile, addressed as set forth below or to such other address as such party shall have specified most recently by written notice. Any notice or other communication required or permitted to be given hereunder shall be deemed effective (a) upon hand delivery or delivery by facsimile, with accurate confirmation generated by the transmitting facsimile machine, at the address or number designated below (if delivered on a business day during normal business hours where such notice is to be received), or the first business day following such delivery (if delivered other than on a business day during normal business hours where such notice is to be received) or (b) on the first business day following the date of sending by reputable courier service, fully prepaid, addressed to such address, or (c) upon actual receipt of such mailing, if mailed. The addresses for such communications shall be:

If to the Company: Nymox Pharmaceutical Corporation

9900 Cavendish Blvd., Suite 306

St. Laurent, Quebec, Canada H4M 2V2

Telephone Number: (800) 936-9669 - Fax: (514) 332-9167

Attention: Dr. Paul Averback, President

if to the Investor: As set forth on the signature pages hereto

Either party hereto may from time to time change its address or facsimile number for notices under this Section 11.1 by giving written notice of such changed address or facsimile number to the other party hereto as provided in this Section 11.1.

#### **ARTICLE XII**

#### Miscellaneous

Section 12.1 *Fees and Expenses*. The Company shall pay all fees and expenses related to the transactions contemplated by this Agreement; provided, that the Company shall pay, at the Closing of the Agreement, all attorneys fees and expenses (exclusive of disbursements and out-of-pocket expenses) incurred by the Purchaser in connection with the preparation, negotiation, execution and delivery of this Agreement and the transactions contemplated hereunder. In addition, the Company shall pay all reasonable fees and expenses incurred by the Purchaser in connection with any amendments, modifications or waivers of this Agreement or incurred in connection with the enforcement of this Agreement, including, without limitation, all reasonable attorneys fees and expenses. The Company shall pay all stamp or other similar taxes and duties levied in connection with issuance of the Shares pursuant hereto.

Section 12.2 Specific Enforcement, Consent to Jurisdiction.

- (a) *Injunctive Relief*. The Company and the Purchaser acknowledge and agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent or cure breaches of the provisions of this Agreement and to enforce specifically the terms and provisions hereof or thereof, this being in addition to any other remedy to which any of them may be entitled by law or equity.
- (b) *Governing Law*. This Agreement shall be governed by and construed in accordance with the laws of Canada applicable to contracts made in Quebec by persons domiciled in Montreal and without regard to its principles of conflicts of laws.
- (c) *Jurisdiction* Each of the Company and the Purchaser (i) hereby irrevocably submits to the jurisdiction of the Quebec Superior Court and other courts of the Province of Quebec sitting in the District of Montreal for the purposes of any suit, action or proceeding arising out of or relating to this Agreement and (ii) hereby waives, and agrees not to assert in any such suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such court, that the suit, action or proceeding is brought in an inconvenient forum or that the venue of the suit, action or proceeding is improper. Each of the Company and the Purchaser consents to process being served in any such suit, action or proceeding by mailing a copy thereof by certified mail, return receipt requested, to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing in this Section shall affect or limit any right to serve process in any other

manner permitted by law.

Section 12.3 *Entire Agreement; Amendment*. This Agreement contains the entire understanding of the parties with respect to the matters covered hereby and, except as specifically set forth herein, neither the Company nor the Purchaser makes any representations, warranty, covenant or undertaking with respect to such matters. No provision of this Agreement may be waived or amended other than by a written instrument signed by the party against whom enforcement of any such amendment or waiver is sought.

Section 12.4 *Waivers*. No waiver by either party of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any other provisions, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right accruing to it thereafter.

Section 12.5 *Headings*. The article, section and subsection headings in this Agreement are for convenience only and shall not constitute a part of this Agreement for any other purpose and shall not be deemed to limit or affect any of the provisions hereof.

Section 12.6 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and assigns. The parties hereto may not amend this Agreement or any rights or obligations hereunder without the prior written consent of the Company and each Purchaser to be affected by the amendment. After Closing, the assignment by a party to this Agreement of any rights hereunder shall not affect the obligations of such party under this Agreement.

Section 12.7 No Third Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other person.

Section 12.8 *Counterparts*. This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and shall become effective when counterparts have been signed by each party and delivered to the other parties hereto, it being understood that all parties need not sign the same counterpart. Execution may be made by delivery by facsimile.

Section 12.9 *Publicity*. Prior to the Closing, neither the Company nor the Purchaser shall issue any press release or otherwise make any public statement or announcement with respect to this Agreement or the transactions contemplated hereby or the existence of this Agreement. After the Closing, the Company may issue a press release or otherwise make a public statement or announcement with respect to this Agreement or the transactions contemplated hereby or the existence of this Agreement; provided, that prior to issuing any such press release, making any such public statement or announcement, the Company obtains the prior consent of the Purchaser, which consent shall not be unreasonably withheld or delayed.

Section 12.10 Severability. The provisions of this Agreement are severable and, in the event that any court of competent jurisdiction shall determine that any one or more of the provisions or part of the provisions contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision or part of a provision of this Agreement and this Agreement shall be reformed and construed as if such invalid or illegal or unenforceable provision, or part of such provision, had never been contained herein, so that such provisions would be valid, legal and enforceable to the maximum extent possible.

Section 12.11 Further Assurances. From and after the date of this Agreement, upon the request of the Purchaser or the Company, each of the Company and the Purchaser shall execute and deliver such instruments, documents and other writings as may be reasonably necessary or desirable to confirm and carry out and to effectuate fully the intent and purposes of this Agreement. Section 12.12 Currencies. Unless otherwise specified, all references herein to dollars means United States dollars.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorize officer as of the date first above written.

#### NYMOX PHARMACEUTICAL CORPORATION

By: /s/ Paul Averback, MD

Name: Dr. Paul Averback

Title: President

#### LORROS-GREYSE INVESTMENTS, LTD.

By: /s/ Dr. Stephan Eschmann

Name: Dr. Stephan Eschmann

Title: President

EXHIBIT E
TREASURY DIRECTIVE
To: Computershare Investor Services
Re: Issuance of common shares of
NYMOX PHARMACEUTICAL CORPORATION
By resolution adopted by the Board of Directors of Nymox Pharmaceutical Corporation (the Company) dated, you are hereby authorized to issue common shares (the Shares) in consideration for \$
As transfer agent and registrar for the Company, we request that you issue a certificate for the shares in question as follows:
Lorros-Greyse Investments, Ltd.
We have received a legal opinion that in order to permit the Company to comply with the requirements of the United States Securities Act of 1933, before the certificate for the Shares is issued to the Investor, the following legend should be typed on the certificate:
THE SECURITIES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE SECURITIES ACT ), OR ANY OTHER APPLICABLE SECURITIES LAWS AND HAVE BEEN ISSUED IN RELIANCE UPON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT PROVIDED BY REGULATION S AND SUCH OTHER SECURITIES LAWS. NEITHER THIS SECURITY NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE SOLD, ASSIGNED, TRANSFERRED, PLEDGED, ENCUMBERED, OR OTHERWISE DISPOSED OF, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO A TRANSACTION THAT IS EXEMPT FROM SUCH REGISTRATION.
Please deliver the certificate to:
Nymox Pharmaceutical Corporation 9900 Cavendish Blvd., Suite 306 St. Laurent, QC H4M 2V2 Attn: Roy Wolvin, C.F.O.
Signed this day of, 2010

## NYMOX PHARMACEUTICAL CORPORATION

By:	
	Roy Wolvin
	Secretary-Treasurer

LICENSE AND COLLABORATION AGREEMENT		
between		
Nymox Pharmaceutical Corp.		
and		
Recordati Ireland Ltd.		
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This License and Collaboration Agreement (hereinafter referred to as the **Agreement**) is made and entered into as of the 16th of December 2010 (the **Effective Date**) between Nymox Pharmaceutical Corp., a corporation organized and existing under the laws of Canada, with its principal business office located at 9900 Cavendish Blvd., Suite 306, St. Laurent, Quebec, Canada, H4M 2V2 (hereinafter referred to as **Nymox**), and Recordati Ireland Ltd., a limited liability company organized and existing under the laws of Ireland, with a principal business office located at Raheens East, Ringaskiddy, Co Cork, Ireland (hereinafter referred to as **Recordati**). Each of Nymox and Recordati may be referred to in this Agreement as a **Party** and together as the **Parties**.

#### WITNESSETH

WHEREAS, Nymox owns certain Know-How and Patent rights relating to the Development and Commercialization of the Compound and Product (each as defined below) and is actively developing the Compound and the Product, currently through Phase III Clinical Trials with a goal to submit an NDA and to obtain regulatory approval in USA;

WHEREAS, Recordati is engaged in the research, development, marketing, manufacture and distribution of pharmaceutical compounds used in treating or preventing human diseases and conditions;

WHEREAS, Nymox wishes to out-license certain rights to the Compound and Product to Recordati for certain uses in the Field and the Territory (each as defined below);

WHEREAS, Recordati now desires to obtain such rights on the terms and conditions set forth herein;

NOW THEREFORE, in consideration of the foregoing premises, the Parties agree as follows:

# ARTICLE I. DEFINITIONS

For the purposes of this Agreement, the following terms, whether used in singular or plural form, shall have the respective meanings set forth below: **1.1** Accounting Standards shall mean records and books of accounts in accordance with IFRS and USGAAP (each as defined below), as applicable.

- **1.2 Affiliate** shall mean any individual, corporation, partnership, firm, joint venture or other entity, which, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, Recordati or Nymox, as the case may be, including any entity controlled, directly or indirectly, by the entity having the ultimate control of a Party. An entity will be regarded as in control of another entity for purposes of this definition, only if it owns or controls more than fifty per cent (50%) of the shares of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority) or otherwise possesses the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of the outstanding voting securities or by contract or otherwise.
- **1.3 Agreed Indications** means the Initial Indication and any other Indications in the Field that the Parties agree in writing are suitable for inclusion in the Development Plan and in respect of which Recordati shall thereafter be permitted to conduct Development and Commercialization activities.
- **1.4 Applicable Law** shall mean applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities that may be in effect from time to time.

1.5 [\*\*\*]

- **1.6 Business Day** shall mean a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York, USA or Cork, Ireland, are authorized or obligated by Applicable Law to close.
- **1.7** Calendar Quarter shall mean the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.
- **1.8** Clinical Data shall mean all information made, collected or otherwise generated under or in connection with Clinical Trials, including any Data, reports and results with respect to any of the foregoing.
- **1.9** Clinical Supplies shall mean the drug products containing the Compound (whether in the form of active pharmaceutical ingredient (API) or otherwise) intended to be utilized for Development, in particular for administration to humans during Clinical Trials and where applicable conforming to the IMPD.
- **1.10 Clinical Trials** shall mean those clinical studies, which are carried out in humans by a Party or its respective Affiliates and Sublicensees, to advance Development of the Compound in the Field for an Agreed Indication.

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- **1.11 Commercialize** or **Commercialization** shall mean all activities conducted by either Party, an Affiliate or, to the extent permitted herein, through a Sublicensee (each if applicable, as defined below), performed to advertise, market, promote, distribute, package, label, import, export, offer for sale and sell the Product for use for an Agreed Indication in the Field, including, without limitation, the performance of pre-launch market preparation activities and distribution of Product samples and the conduct of Non-Regulatory Clinical Trials. When used as a verb, Commercialize means to engage in Commercialization.
- **1.12** Commercialization Plan shall mean an annual plan developed by Recordati and submitted to Nymox, describing the Commercialization strategy and implementation plan for the Product in the Territory, as further specified herein.
- **1.13 Commercialization Program** shall mean the activities conducted hereunder in the Commercialization of the Product.
- 1.14 Commercially Reasonable Efforts shall mean the level, type and quality of efforts that would be applied by a pharmaceutical company having resources and expertise similar to the applicable Party, to perform its obligations hereunder, with respect to a compound or product developed by such company, including its obligation to Develop, seek and obtain Regulatory Approvals for, manufacture and Commercialize the Product, all to the extent consistent with reasonable business practices, for example, in light of the reasonable commercial potential of the Product in the Territory. Without limiting the foregoing, Commercially Reasonable Efforts shall require that such Party devote appropriate resources and personnel with an appropriate level of education and experience similar to what the Party usually devotes to products in comparable markets having similar commercial potential to the Product in the Territory. Commercially Reasonable Efforts are meant to apply to the Territory as a whole, rather than to any part of it separately, recognizing that obtaining Regulatory Approval (including, e.g., by accepting Product Labelling different from the Product Labelling approved by the EMA, or by setting maximum prices or reimbursement value with potential negative cross reference pricing impact) or effecting Commercialization of the Product in one or more specific countries of the Territory, may impact in an adverse manner on the economic success of the Product in the Territory as a whole for the applicable Party.
- **1.15** Committee shall have the meaning assigned to it in Section 7.2.
- **1.16 Competitive Product** shall mean any product or compound administered by intraprostatic injection or other means of local administration in order to effect cell destruction or tissue atrophy for the Initial Indication or any Agreed Indication.
- **1.17 Compound** shall mean the chemical compound known as NX-1207, as further defined <u>on Annex</u> A attached hereto, including both acid and salt forms as well as optical isomers, hydrates and solvates thereof.
- **1.18 Confidentiality Agreement** shall mean that certain Confidential Disclosure Agreement entered into by and between Nymox and Recordati S.p.A. on or about December 10, 2009.
- **1.19 Controlled** or **Controls** shall mean, when used with respect to any Intellectual Property (as defined below), the legal authority or right of a Party or its Affiliate to grant a license or Sublicense or other right to such Intellectual Property rights to the other Party hereto as provided herein, or to otherwise disclose proprietary or trade secret information to the other Party as provided herein, without incurring payment obligations to a Third Party, breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

- **1.20 Cost of Goods** shall mean the cost invoiced by Nymox to Recordati to manufacture and supply Product as provided for in the Supply Agreement.
- **1.21 Current Good Clinical Practice** or **cGCP** shall mean clinical practices that conform with the current Good Clinical Practices as established by the International Conference on Harmonization (CPMP/ICH/135/95), as such regulations may be amended from time to time, and in conformity with equivalent regulations in regulatory jurisdictions in the Territory, including for the EU, regulations based on Directive 2001/20/EC and related guidelines.
- 1.22 Current Good Laboratory Practice or cGLP shall mean the framework within which: (i) laboratory studies are planned, performed, monitored, recorded, reported and archived as defined under OECD Principles on Good Laboratory Practice (ENV/MC/Chem (98)17) and rules in force in the European Union relating to Good Laboratory Practice including EC Directives 2004/10/EC, 87/18 EEC, and 1999/11/EC and equivalent regulations in regulatory jurisdictions within the Territory; and (iii) Good Laboratory Practice is inspected and verified, as set out in EC Directives 2004/9/EC and 88/320/EEC and equivalent regulations in regulatory jurisdictions within the Territory, in all cases as amended from time to time.
- **1.23** Current Good Manufacturing Practice or cGMP shall mean in the EU the rules and Guidelines for Good Manufacturing Practice for medicinal products for human use as defined under (i) Directive 2003/94/EC and (ii) Volume 4 GMP Guidelines in The Rules Governing Medicinal Products in the EU, Part I and II, in each case, as amended from time to time, and in conformity with equivalent regulations in regulatory jurisdictions in the Territory.

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- **1.24 Data** shall mean all data and information generated, collected or filed, in relation to research, Development and/or manufacturing activities relating to the Compound or Product for Agreed Indications in the Field, including but not limited to toxicology data, pharmacological data, non-clinical reports, clinical reports, single patient clinical report forms (CRFs), data points and the databases, and stability data, chemical data and quality control data (excluding the closed portion of any DMF).
- **1.25 Data Exclusivity** shall mean the Data Exclusivity and the Market Exclusivity obtained through the protection for a certain period of time of non-clinical and clinical results on which the initial Marketing Authorization is based, during which Generic Product applicants cannot rely on the dossier of the original reference product for the purposes of submitting an application ( Data Exclusivity ), obtaining a Marketing Authorization and placing on the market ( Market Exclusivity ) a Generic Product or similar product as exemplified in the EU by Article 10 of Directive 2001/83/EC as amended by Directive 2004/27/EC and Article 14 of Regulation (EC) No 726/2004, and any further amendments, or by other equivalent legislation, regulations or directives in the EU or in other jurisdiction or country in the Territory.
- **1.26 Data Packages** shall have the meaning set out in Section 2.3.1.
- **1.27 Develop** or **Development** shall mean all activities conducted by either Party, an Affiliate or Sublicensee, either by itself or through a Third Party, performed to advance development of the Compound or Product for an Agreed Indication within the Field, including without limitation, the planning, implementation, conduct, evaluation and reporting of non-clinical development activities, and the performance of non-clinical safety studies, CMC (chemistry, manufacturing and controls) activities, Regulatory Clinical Trials, and such other activities as are necessary to obtain and maintain Regulatory Approval for the Product by a governmental Regulatory Authority. When used as a verb Develop means to engage in Development.
- **1.28 Development Plan** shall mean an estimated (subject to, among others, advice from EMA or any other Regulatory Authority in the Territory) plan prepared by Recordati describing the Development activities to be undertaken by Recordati or its Affiliates or its Sublicensees for the Compound and Product to be Commercialized in the Territory, and the obligations of Nymox precedent to or otherwise in connection therewith, as further specified herein.
- **1.29 Development Program** shall mean the activities conducted with respect to the Development of the Product pursuant to the Development Plans.
- **1.30** Effective Date of this Agreement shall mean the date set forth in the first paragraph of this Agreement.
- **1.31 EMA** shall mean the European Medicines Agency and the respective deciding body (European Commission), or respective successor agencies in case the EMA no longer exists.
- **1.32** EU for the purpose of this Agreement shall mean the member states of the European Union at any given time.
- **1.33 EURO**, EUR or shall mean Euros, the currency of the European Union.
- **1.34 FDA** shall mean the United States Food and Drug Administration or any successor agency thereto.
- **1.35** Field shall mean the treatment of diseases or conditions of (i) the prostate gland in humans and (ii) any other human tissues (e.g. liver).

- **1.36 First Commercial Sale** shall mean the first sale of Product by Recordati or an Affiliate or Sublicensee of Recordati to a Third Party in a given country following Marketing Authorisation of the Product in that country.
- **1.37 Generic Product** shall mean a generic or biosimilar product that contains the Compound that is approved for marketing for the same indication and for the same route of administration as the Product.
- **1.38 IFRS** shall mean International Financial Reporting Standards including the International Accounting Standards (IAS), the Interpretation of the International Financial Reporting Interpretations Committee (IFRIC) and the Interpretation of the Standing Interpretations Committee (SIC).
- **1.39 IMPD** shall mean Investigational Medicinal Product Dossier for the Product and the Compound (whether in the form of API or otherwise) manufactured according to Volume 4 of cGMP Guidelines and in particular to Annex 13 of such Guidelines.
- **1.40** Improvements and Enhancements shall mean and include any and all changes, modifications and amendments relating to the administration, formulation or use of the Compound or Product in the Field which: (i) improve the performance or efficacy of Product and/or Compound; (ii) reduce any side effects, drug interactions or other adverse effects of Product and/or Compound; (iii) reduce the cost and/or increase the efficiency or productivity of the manufacturing and production processes for Product and/or Compound; or (iv) otherwise modify, alter or enhance the Product and/or Compound in the Field.

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- **1.41 Indication** shall mean a recognized disease or condition, a sign or symptom of a disease or condition, or a symptom associated with a disease or condition that may be diagnosed, prevented, treated, mitigated or cured by the Product.
- **1.42** Initial Indication means treatment of benign prostatic hyperplasia.
- **1.43** In-License shall have the meaning assigned to it in Section 8.12(a).
- **1.44** In-Licensed Rights shall have the meaning assigned to it in Section 8.12(a).
- **1.45** Intellectual Property shall mean Patents, Trademarks and Know-How.
- **1.46** Invention shall mean any and all Improvements and Enhancements, methods of making and/or using the Products and/or Compound, or other discoveries or inventions that (i) are conceived, discovered, reduced to practice or developed by Recordati or one of its Affiliates or its Sublicensees, in each case, in connection with activities performed under this Agreement during the Term, or (ii) are conceived, discovered, reduced to practice or developed by Nymox or one of its Affiliates or Sublicensees either in connection with the activities performed under this Agreement during the Term or in the conduct of any research, Development, manufacturing or Commercialization relating to the Product in the Field for an Agreed Indication.
- **1.47 Investigational Medicinal Product** shall mean a formulated and/or packaged pharmaceutical form of an active substance (including a Compound or comparator) or placebo being tested or used as a reference in a Clinical Trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form.
- **1.48 Investigation New Drug Application** or **IND** shall mean an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act, as amended, and any equivalent applications filed with Regulatory Authorities outside of the United States, including any clinical trial authorization (**CTA**) in the EU.
- **1.49** Joint Steering Committee or JSC shall have the meaning assigned to it in Section 7.1.
- **1.50 Jointly Owned Know-How** shall mean Know-How conceived, discovered, reduced to practice or otherwise developed jointly by a Party, or any of its Affiliates or its Sublicensees and the other Party or any of its Affiliates and its Sublicensees, in each case in connection with activities performed under this Agreement during the Term.
- **1.51 Jointly Owned Patents** shall mean Patents claiming Jointly Owned Know-How.
- **1.52** Key Countries [\*\*\*]
- **1.53 Know-How** shall mean proprietary material and information, including but not limited to, Data, technical information (including analytical test methods to control the Compound), Inventions, compositions of matter, Specifications and information relating to formulation, production, quality control, manufacture, packaging, design, Regulatory Approval, sale and/or use of Product or Compounds for an Agreed Indication in the Field, or as required for regulatory purposes, in each case whether currently existing or developed or obtained during the Term, and whether or not patentable or confidential.

1.54	Knowledge	shall mean, with respect to a given Party, the actual knowledge of any officer or director of such
Party	(or any of its	Affiliates), with respect to a specific topic, after reasonable inquiry of the person(s) employed or
contra	cted by such	Party (or any of its Affiliates) that have operational responsibility for the business function that is
most 1	relevant to the	specific topic.

1.55 [\*\*\*] 1.56 [\*\*\*]

1.57 [\*\*\*]

- **1.58** Manufacturing Recall shall have the meaning ascribed to it in Section 6.8.1.
- **1.59 Marketing Authorisation** or **MA** shall mean the approval granted by the EMA, or other relevant Regulatory Authorities as the case may be, as a result of the Marketing Authorisation Application.
- **1.60 Marketing Authorisation Application** or **MAA** shall mean an application for the authorisation for marketing of a Product in the Territory for an Agreed Indication, filed with the EMA or the relevant Regulatory Authority in a country in the Territory, as applicable.

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**1.61 Marketing Materials** shall mean any Promotional Materials, Product Labeling, marketing studies, and other similar information or material used to Commercialize or assist in the Commercialization of the Product. For the avoidance of doubt, particulars of persons are not Marketing Materials.

1.62 [\*\*\*]

- **1.63** Non-Regulatory Clinical Trial shall mean Clinical Trials that are intended to support Commercialization of a product, excluding Regulatory Clinical Trials, but including Phase IV Clinical Trials (to the extent not included as a Regulatory Clinical Trial) and pharmacoeconomic studies.
- 1.64 Net Sales shall mean the gross amount invoiced by Recordati, an Affiliate or a Sublicensee on sales of Products to a Third Party less deductions for (i) trade, cash and quantity discounts (including early payment cash discounts), (ii) returns, rejections and recalled Product, (iii) rebates and allowances, chargebacks, retroactive price reductions actually allowed or granted to any public or private purchaser or reimburser including managed care organizations, (iv) rebates, paybacks and discounts imposed by the competent authorities as well as rebates, paybacks and discounts imposed by the competent authorities as an effect or a condition for maintaining the reimbursement status of the Product, (v) excise, sales or use taxes, value added taxes and other tariffs or duties levied on the sale, transportation or delivery of Products to the extent reflected in the gross amount invoiced, and (vi) freight, insurance and other transportation charges. All of such foregoing deductions shall be calculated in accordance with International Financial Reporting Standards (IFRS) or other similar accounting methods as mutually agreed upon by the Parties, and on an accrual basis of accounting. Net Sales shall not include the distribution of a Product for promotional samples, clinical studies, compassionate use, named patient programs, test marketing, or any similar instance. In the case of any sale or other disposal of a Product between or among Recordati and its Affiliates or its Sublicensees, for resale, Net Sales shall be calculated only on the value charged or invoiced on the first arm s-length sale thereafter to a Third Party.
- **1.65** Nymox Intellectual Property shall mean all Nymox Patents, Nymox Know-How and Nymox Trademarks (as defined below).
- **1.66 Nymox Know-How** shall mean all Know-How (including Nymox s right, title and interest in and to any Jointly Owned Know-How) that is (i) an Invention conceived, discovered, reduced to practice or developed by Nymox or any of its Affiliates or its Sublicensees during the Term or (ii) otherwise Controlled by Nymox or one of its Affiliates as of the Effective Date or during the Term; and in each case of (i) and (ii) that relates to the research, Development, Commercialization, manufacture, use or sale of the Compound or the Product for an Agreed Indication in the Field.
- **1.67 Nymox Patents** shall mean all Patents (including Nymox s right, title and interest in and to any Jointly Owned Patents) that (i) claim an Invention conceived, discovered, reduced to practice or developed by Nymox or any of its Affiliates or its Sublicensees during the Term or (ii) are otherwise Controlled by Nymox or one of its Affiliates as of the Effective Date or during the Term; in each case of (i) and (ii) that relate to the research, Development, Commercialization, manufacture, use or sale of the Compound or the Product for an Agreed Indication in the Field. A list of Nymox Patents as of the Effective Date is appended hereto as <u>Annex C</u> and will be updated periodically to reflect additions thereto during the Term.
- **1.68** Nymox Trademarks shall mean any trademark owned by Nymox and used in connection with the Product.
- **1.69** Patent(s) shall mean: (i) any patents and patent applications, (ii) all divisionals, continuations, continuations-in-part thereof, and any other patent application claiming priority directly or indirectly to: (a) any patents or patent applications in the foregoing clause (i) or (b) any patent or patent application from which the patents or patent applications in the foregoing clause (i) claim direct or indirect priority, (iii) all patents issuing on any of the

foregoing applications, (iv) any foreign counterparts or equivalents to any of the foregoing, and (v) all registrations, reissues, re-examinations, renewals, supplemental protection certificates, or extensions of any of the foregoing, and any foreign counterparts thereof.

- **1.70 Platform Patent** shall have the meaning assigned to it in Section 8.12(g).
- **1.71 Product** shall mean a product in finished dosage form and packaging containing the Compound as an active ingredient, regardless of dosage or formulation.
- **1.72 Product Labelling** shall mean, with respect to the Product in a given country or other regulatory jurisdiction, all labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for the Product as approved by the applicable Regulatory Authority (to the extent necessary).
- **1.73 Product Trademark(s)** shall have the meaning set forth in Section 8.15.
- **1.74 Promotional Materials** shall mean all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, direct mail, medical information/education monographs, direct-to-consumer advertising, internet postings, broadcast advertisements and sales reminder aids (e.g., scratch pads, pens and other such items) intended for use or used in connection with any promotion of the Product (but excluding Product Labelling).

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1.75 [\*\*\*]

- **1.76** Recordati Intellectual Property shall mean all Recordati Patents (as defined below), Recordati Trademarks and Logos (as defined below) and Recordati Know-How (as defined below).
- 1.77 Recordati Know-How shall mean all Know-How (including Recordati s right, title and interest in and to any Jointly Owned Know-How) that is (i) an Invention conceived, discovered, reduced to practice or developed by Recordati or any of its Affiliates or its Sublicensees during the Term, or (ii) otherwise Controlled by Recordati or one of its Affiliates as of the Effective Date or during the Term and that is actually used by Recordati, its Affiliates or its Sublicensees in the Development, Commercialization or manufacture of the Compound or Product in the Territory; and in each case of (i) and (ii) that relates to the research, Development, Commercialization, manufacture, use or sale of the Compound or the Product in the Field.
- **1.78 Recordati Patents** shall mean all Patents (including Recordati s right, title and interest in and to any Jointly Owned Patents) that (i) claim an Invention conceived, discovered, reduced to practice or developed by Recordati or any of its Affiliates or its Sublicensees during the Term or (ii) are otherwise Controlled by Recordati or one of its Affiliates as of the Effective Date or during the Term and that claim an Invention or technology actually used in the research, Development, Commercialization, manufacture, use or sale of the Compound or Product as conducted by Recordati, its Affiliates and its Sublicensees in the Territory; and in each case of (i) and (ii) that relate to the research, Development, Commercialization, manufacture, use or sale of the Compound or the Product in the Field.
- **1.79** Recordati Trademarks and Logos shall mean any trademark and logo owned or used by Recordati in connection with the Product.

1.80 [\*\*\*]

- **1.81 Regulatory Approval** shall mean the grant of a Marketing Authorisation, and any pricing approval, reimbursement approval, or any other approval required to market and sell a Product in any country or other regulatory jurisdiction for an Agreed Indication in the Field.
- **1.82 Regulatory Authority** shall mean the appropriate governmental entity or entities having the authority to grant Regulatory Approval for the marketing and sale of Product in a country or other regulatory jurisdiction, including but not limited to the EMA.
- **1.83 Regulatory Clinical Trials** shall mean Clinical Trials intended to support a Regulatory Approval, including a Regulatory Approval for an Additional Indication, and any Clinical Trial required by a Regulatory Authority as a condition to, or in connection with the grant or maintenance of, a Regulatory Approval.
- **1.84 Regulatory Data** shall mean Data that is included, or is intended to be included, in Regulatory Documentation (as defined below).
- **1.85 Regulatory Documentation** shall mean all applications, registrations, licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents in connection therewith, and all non-clinical and clinical studies and tests (including any Regulatory Clinical Studies and Non-Regulatory Clinical Studies), relating to the use of the Product for Agreed Indications in the Field, or as required for regulatory purposes and all Data contained in any of the foregoing, including all INDs, IMPDs, MAA s, regulatory drug lists, advertising and promotion documents, manufacturing data,

drug master files, Clinical Data, adverse event files and complaint files, in each case related to the Product and Agreed Indications in the Field, or as required for regulatory purposes.

- **1.86 Rejected Indication** shall have the meaning assigned to it in Section 4.1.1.
- **1.87 Royalty Term** shall have the meaning assigned to it in Section 3.4.4.
- **1.88** Sales Report shall mean a written report or reports showing each of (i) gross sales (expressed in total gross invoice amount and in number of units of Product sold), a listing of permitted deductions by category (as described in the definition of Net Sales ) and the calculation of Net Sales in each country in the Territory, for each Calendar Quarter, by Recordati and each of its Affiliates and its Sublicensees; (ii) the royalties which shall have accrued hereunder in respect of such sales, and a reasonable description of information that form the basis of calculating those royalties; (iii) withholding taxes, if any, required by law to be deducted and paid to a taxing authority from such royalties; and (iv) the exchange rate used for converting currency from the currencies in which sales were made into the currency in which payment is to be made hereunder.

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- **1.89** SPC shall mean a Supplementary Protection Certificate for medicinal products issued pursuant to Regulation (EC) No. 1768/92 as amended from time to time and includes any certificate, order, provision, or process issued pursuant to or provided by Applicable Law, rules, regulations, or directives of a jurisdiction in the Territory that has the effect of extending the basic Patent rights to the Product or conferring rights equivalent or similar to those Patent rights for a period following the end of the term of the basic Patent.
- **1.90 Specifications** shall mean the specifications for the Product, the Compound and the Investigational Medicinal Product, in each case as attached hereto as <u>Annex D</u>, and as amended from time-to-time.
- **1.91 Sublicense** shall mean, (i) with respect to Recordati, any sublicense of any of the rights granted under Section 2.1.1 below (whether such right is pursuant to a sublicense agreement, or any other agreement or understanding, including any co-development, co-promotion or similar arrangement expressly granting such rights) granted to a Third Party in any or all countries in the Territory and (ii) with respect to Nymox, a grant by Nymox or any of its Affiliates of a license or other right to a Third Party outside the Territory, under any Patents or Know-How Controlled by Nymox (or such Affiliates) with respect to the research, Development, Commercialization, manufacture, use or sale of the Compound or the Product. For purposes of clarity, this Agreement shall not be considered a Sublicense .
- **1.92** Sublicensee(s) shall mean, (i) with respect to Recordati any Third Party to whom Recordati (or any of its Affiliates) grants a Sublicense and (ii) with respect to Nymox any Third Party to whom Nymox (or any of its Affiliates) grants a Sublicense outside the Territory.
- **1.93 Supply Agreement** shall mean the agreement that Recordati and Nymox will sign upon signature of this Agreement for the purpose of regulating the terms and condition of the supply of the Product by Nymox to Recordati as amended from time to time. The Supply Agreement will be attached as <u>Annex H</u>.
- **1.94 Term** shall mean the Term of this Agreement as specified in Section 12.1.
- **1.95** Territory shall mean the countries listed in Annex E.
- **1.96** Third Party shall mean any person or entity, which is not a Party or an Affiliate of any Party to this Agreement.
- **1.97** Third Party Licensor shall have the meaning assigned to it in Section 8.12(a).
- **1.98 Trading Day** shall mean the last day of the month where the local currency versus USD or EURO, as applicable, is traded on public exchanges or in case a currency is not traded on a public exchange, Trading Day shall mean the last day of the month for which an exchange rate is published on www.oanda.com or another comparable independent source.
- **1.99** U.S. shall mean the United States of America and its possessions and territories.
- 1.100 USD shall mean U.S. dollars.
- **1.101** USGAAP shall mean generally accepted accounting principles in the United States of America.
- **1.102** Valid Claim shall mean a claim of (i) an issued and unexpired Patent or an unexpired supplementary protection certificate, which claim has not been abandoned, disclaimed, revoked or held invalid or unenforceable by a court or other government agency of competent jurisdiction from which no appeal has been taken, and has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, reissue, opposition procedure, nullity

suit or otherwise, or (ii) a Patent application that has been pending for three (3) or fewer years and has not been cancelled, withdrawn or abandoned.

**1.103** Value Added Tax (VAT) & Indirect Taxes means the tax imposed by the Sixth Council Directive of the European Community (77/388/EEC) and any national legislation implementing that directive together with legislation supplemental thereto or other tax of a similar nature, including sales taxes, and excise duties imposed elsewhere instead of or in addition to value added tax.

The Annexes attached to this Agreement shall form an integral part of this Agreement. However in the event of any conflict between the operative terms of this Agreement and the Annexes, the operative terms of this Agreement shall prevail.

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## ARTICLE II. LICENSE GRANTS

#### 2.1 Recordati s License.

- **2.1.1 License.** Subject to the terms and conditions of this Agreement, Nymox and its Affiliates hereby grants to Recordati an exclusive (even as to Nymox and its Affiliates), royalty-bearing, license, under the Nymox Intellectual Property to Develop, to file for and hold the Regulatory Approvals and Commercialize the Product in the Field solely for the Agreed Indications in the Territory. Recordati shall have the right to grant Sublicenses of the foregoing rights solely as provided in Section 2.1.2 below.
- **2.1.2 Sublicenses.** Recordati shall have the right to grant Sublicenses in the Territory without the approval of Nymox to (i) Third Parties outside of the Key Countries and (ii) to its Affiliates. In all other cases, Recordati shall have the right to grant Sublicenses in the Territory to Third Parties, subject to the prior written approval of Nymox (such approval not to be unreasonably withheld). Any such Sublicenses shall be granted and governed by written agreements and shall be subject to the terms and conditions of this Agreement. Recordati shall be and remain responsible for ensuring its Sublicensees compliance with this Agreement and shall be and remain liable for any breaches hereof by any such Sublicensee. Where the prior written approval of Nymox is required, Recordati shall supply a copy (where economic provisions and terms will be redacted) of all proposed Sublicenses to Nymox no later than ten (10) Business Days prior to execution of same.
- **2.2 Nymox s Rights and License.** Subject to the terms and conditions of this Agreement and with respect to Recordati Inventions set forth in Section 8.2, Recordati and its Affiliates hereby grant to Nymox a royalty-free, non-exclusive, license and Sublicense (as applicable), with a right to grant Sublicenses, under Recordati Intellectual Property to (i) Develop the Compound and Product anywhere in the world for Commercialization in the Field outside the Territory and (ii) Commercialize the Product in the Field outside the Territory. If Nymox exercises the foregoing license (or Sublicense, as applicable), and Recordati is obligated to pay a royalty or other amount to a Third Party for such use by Nymox, its Affiliates and its Sublicensees, then Recordati shall notify Nymox in advance as to the existence and scope of such obligation and Nymox shall bear such royalty (and other amounts) payable to such Third Party.

#### 2.3 Transfer of Information, Data, Marketing Materials and Support.

- **2.3.1 Transfer of Information.** In furtherance of the rights and license granted by Nymox to Recordati under this Agreement, (i) within [\*\*\*] after the Effective Date of this Agreement, and (ii) promptly following the completion of subsequent Clinical Trials of the Product that are and will be conducted by Nymox during the Term, Nymox shall furnish to Recordati a data package that shall include all or substantially all of the Nymox Know-How, and at least all material Nymox Know-How, existing in tangible and/or electronic form as of the Effective Date or such future date, as applicable, which has not been previously delivered or made available to Recordati and which is related to the Compound or Product, including any such Data that is useful or required for the purpose of obtaining Regulatory Approvals in the Territory, or complying with all Applicable Laws, with respect to the Product (including manufacturing data, non-clinical data, Clinical Data, CMC and quality control data) (such initial and updated data packages are the **Data Packages**).
- **2.3.2 Updates.** Recordati shall, from time to time upon request of Nymox during the Term, disclose or provide to Nymox, and cause its Affiliates, and Sublicensees to disclose or provide to Nymox, complete copies of all (i) Recordati Know-How, including electronic files and recordings in Common Technical Document (CTD) format and adhering to ICH requirements as well as any other pre-agreed format, and (ii) any Marketing Materials Controlled by them at the Effective Date and during the Term that relate to the Product. Nymox shall, from time to time upon

request of Recordati during the Term, disclose or provide to Recordati, and cause its Affiliates, and Sublicensees to disclose or provide to Recordati, complete copies of all Nymox Know-How, including electronic files and recordings in CTD format and adhering to ICH requirements as well as any other pre-agreed format, as well as Marketing Materials Controlled by them at the Effective Date and during the Term that relate to the Product in the Field.

**2.3.3** Expenses and Use. The disclosing Party under Section 2.3.1 or 2.3.2, as applicable, shall carry its own costs of such disclosure or transfer. The receiving Party under Section 2.3.1 or 2.3.2, as applicable, shall use the information and materials disclosed or transferred only in connection with the Compound or the Product, and during the Term, unless the receiving Party has a right deriving from this Agreement to use such information after the Term. Without limiting the generality of the foregoing, with respect to Marketing Materials, (i) the receiving Party under Section 2.3.1 or 2.3.2 shall only have the right to use such Marketing Materials to the extent that such materials are in compliance with the Applicable Laws for the given country where such materials are intended to be used, (ii) the Recordati name and Recordati Trademarks and Logos shall not be used by Nymox or any Sublicensee outside the Territory with respect to any Marketing Materials for the Product and (iii) the name, trademarks, and company logos of any Sublicensee of Nymox (other than a Sublicensee manufacturing the Compound or Product) shall not be used by Recordati with respect to any Marketing Materials for the Product, without the approval of the Sublicensee and/or Nymox.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

## ARTICLE III. PAYMENTS

- **A. Initial, Milestone and Royalty Payments.** In consideration of the rights conferred on Recordati herein, including the licenses and Sublicenses granted to Intellectual Property owned or Controlled by Nymox, and for research and development costs incurred by Nymox, Recordati shall make the payments provided for herein.
- **3.1 Initial Payment.** Recordati will pay to Nymox a non-refundable payment of ten million Euros ( 10,000,000). Such amount shall be paid by Recordati, in immediately available funds, no later than [\*\*\*] after the Effective Date, by wire transfer in accordance with the instruction indicated in Section 3.7 below.
- **3.2 Milestone Payments by Recordati.** Recordati will make the following non-refundable payments (subject to Section 3.3) to Nymox upon the first achievement of the following milestone events with respect to the Product (whether such event is achieved by Recordati, its Affiliates or Sublicensees, acting together or separately) and will make such payment within [\*\*\*] of it achieving the triggering event, subject to issuance of an invoice by Nymox:

#### 3.2.1 Milestones.

Triggering Event	<b>MILESTONE</b>				
1. Obtaining Marketing Authorisation for the Product for					
the Initial Indication by EMA or by a Regulatory	[***]				
Authority in a Key Country (the <b>Regulatory Approval</b>	[]				
Milestone )					
2. First achieving [***] Net Sales of Products in a	[***]				
calendar year (the Commercial Milestone )	[]				
3. First achieving a successive incremental increase of					
[***] in Net Sales (above[***]) in a calendar year (the	[***]				
Incremental Commercial Milestones as further defined	[]				
below)					
4. Obtaining Marketing Authorisation for the Product by					
EMA or by a Regulatory Authority in a Key Country for	[***]				
an Agreed Indication [***]other than the Initial Indication					
5. Obtaining Marketing Authorization for a new Agreed					
Indication [***] for the Product by EMA or by a	[***]				
Regulatory Authority in a Key Country					

Each Incremental Commercial Milestone shall be payable upon the Net Sales in a calendar year first reaching its respective tier in Net Sales above [\*\*\*] as follows:

Annual Net Sales of Product First Achieved	One-Time Incremental Commercial Milestone Payable
Annual Net Sales of Product First Achieved	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Each Incremental Commercial Milestone shall be payable only one-time upon the first achieving of its respective Net Sales level. If two or more Incremental Commercial Milestones are first achieved in a given calendar year, then all those two or more Incremental Commercial Milestones first achieved shall be payable at the end of that calendar year.

- 3.3 [\*\*\*]
  3.3.1 [\*\*\*]
  3.3.2 [\*\*\*]
- 3.3.3 [\*\*\*]
- 3.3.4 [\*\*\*]

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

#### 3.4 Running Royalties.

**3.4.1 Royalty Rate.** Recordati shall pay to Nymox, for the rights granted to Recordati herein, the following royalty on total annual (calculated on a calendar year basis) Net Sales of all Products:

ANNUAL NET SALES IN THE TERRITORY	ROYALTY PERCENTAGE OF ANNUAL NET SALES
For the portion that is less than[***]	[***]
For the portion that is equal to or greater than [***] but less than [***]	[***]
For the portion that is equal to or greater than [***] but less than [***]	[***]
For the portion that is equal to or greater than [***]	[***]

- **3.4.2 Payment Conduct for Running Royalties.** Recordati shall, within [\*\*\*] after the issuance of an invoice by Nymox with the amount to be paid by Recordati, which amount shall be communicated by Recordati to Nymox together with each Sales Report, transfer to the bank account indicated by Nymox the royalty covering the Net Sales of Product in the previous Calendar Quarter. Recordati shall obligate any Affiliate or Sublicensee to account for and report its Net Sales of Products in the same manner, specifically including an itemization of quantities of Products sold. For clarity, Recordati shall pay royalty payments to Nymox as if the Net Sales of its Sublicensees and Affiliates were Net Sales of Recordati (but without duplication). Payments shall be made in accordance with Section 3.7.
- **3.4.3 Sales Report.** During the Term and after the First Commercial Sale of Product, Recordati shall furnish or cause to be furnished to Nymox on a quarterly basis (i.e. for each Calendar Quarter) a Sales Report. Such Sales Report shall be finalized and delivered to Nymox within [\*\*\*] of the end of each respective Calendar Quarter.
- **3.4.4 Royalty Term.** Royalties will be payable by Recordati to Nymox on Net Sales of the Product until the last to occur of the following events with respect to each country in the Territory (i) the last to expire, if any, of the last Nymox Patent with a Valid Claim that covers the manufacture, use, or sale of the Product within, or the importation of the Product into, such country, (ii) the end of any period of Data Exclusivity applicable to the Product in such country, (iii) the end of any period of an SPC applicable to the Product in such country, and (iv) the Publication of the last part of the Nymox Know-How that (A) was previously confidential and that (B) is used by Nymox, or its designee, to manufacture the Compound or Product for Recordati, its Affiliates or Sublicensees, or (C) that is used by Recordati, its Affiliates or Sublicensees in the Commercialization of the Product (the foregoing period is the **Royalty Term**); provided however, that if and to the extent the Royalty Term is extended beyond the period described in the foregoing clauses (i), (ii), and (iii) by application of the foregoing clause (iv) then the royalties otherwise payable for the relevant Product and relevant country under Section 3.4 for such period shall be payable at the rates indicated in Section 3.4 but reduced by [\*\*\*] unless and until the foregoing clause (i), (ii), or (iii) becomes applicable to such Product and such country again (for example, due to the issuance of another Nymox Patent or SPC applicable to the Product) at which point the full royalties shall again become due and payable. For avoidance of doubt, the Royalty Term shall be determined on a country by country basis. For purposes of this Section, Publication means to be made publicly known by means other than by Recordati, its Affiliates or Sublicensees in breach of this Agreement. Notwithstanding the above, and for the avoidance of doubt, the Royalty Term shall expire on a country by country basis upon the successful launch of a Generic Product and in any case the Royalty Term shall expire for all the Territory upon the expiry of the [\*\*\*] period from the date EMA approves the first MA, after which the license will be considered fully paid up and perpetual as per Section 12.6.4 and Recordati will be able to Commercialize the Product with no further payments to Nymox and will be able to manufacture or have manufactured the Product at its choice. For purposes of this Section, the phrase successful launch of a Generic Product means that the total sales (measured in number of units) of products which are generic to a Product by Third Parties (not working with

Recordati, directly or indirectly) in a given country for a six (6) month period exceed [\*\*\*] of the total sales (measured in number of units) of the Product in such country for such period.

**3.4.5 Patent Challenges.** In the event Recordati or an Affiliate initiates any proceeding or otherwise asserts any claim challenging the validity or enforceability of any Nymox Patent in any court, administrative agency or other forum (Challenge), Nymox shall have the right to terminate this Agreement. In the event a Sublicensee of Recordati (other than an Affiliate) initiates a Challenge, Nymox shall have the right to terminate this Agreement limited to the country or countries for which the Sublicensee holds a licence.

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#### **B.** Other Payment Related Issues

- 3.5 Withholding Tax. In the event that Recordati is required to withhold any tax regarding any payment to Nymox due to the Applicable Laws of any country, such amount will be deducted from the payment to be made by Recordati and remitted to the appropriate taxing authority for the benefit of Nymox. Recordati will withhold only such amounts as are required to be withheld by Applicable Law. Recordati shall submit to Nymox originals or certified copies of the remittance voucher and the official receipt evidencing the payment of the corresponding taxes with the applicable royalty report, if possible, or within ten (10) Business Days after Recordati receives such documents, if later. Recordati will make all Commercially Reasonable Efforts, and will fully cooperate with Nymox, to provide such information and records as Nymox may require in connection with any respective application by Nymox to the tax authorities in any country including the obtaining of an exemption or of a credit for any withholding tax paid in any country from which royalty payments and any other payments are being made by Recordati to Nymox pursuant to this Agreement. Nymox shall provide the appropriate tax exemption documentation, if any, to Recordati in a timely manner before the payment of any initial payment, milestone payment or royalty.
- **3.6 No Bartering; Non-Monetary Consideration.** Without the prior written consent of Nymox (such consent not to be unreasonably withheld), Recordati and its Affiliates and its Sublicensees shall not: (i) enter into any bartering arrangement with respect to the sale of the Product, or (ii) accept or solicit any non-monetary consideration of the sale of the Product to Third Parties other than as would be reflected in Net Sales. The use by Recordati and its Affiliates and its Sublicensees of a commercially reasonable amount of Product for promotional free sampling, clinical studies, compassionate use, named patient programs, test marketing or any similar instance shall not violate this Agreement.
- 3.7 Currencies. The initial payment set forth in Section 3.1 shall be made in Euro. All other milestone payments shall be paid by Recordati to Nymox in U.S. Dollars, by wire transfer of immediately available funds in accordance with instructions set forth below, provided that amounts denominated in Euro shall be converted into U.S. Dollars at the daily reference conversion rate reported by the European Central Bank on the day preceding the day of payment. All other payments under this Agreement shall be paid by Recordati to Nymox in U.S. Dollars by wire transfer of immediately available funds in accordance with instructions set forth below. Amounts expressed in currencies other than the Euro shall be converted into Euro following Recordati s normal process for the preparation of group consolidated accounts and amounts expressed in Euro shall be converted into U.S. Dollars at the average of the daily reference conversion rate reported by the European Central Bank (ECB) for the last Trading Day of each month during the applicable Calendar Quarter. To the extent any milestone payment is payable based on achieving certain sales levels calculated in Euros, amounts expressed in currencies other than Euros shall be converted into Euros following Recordati s normal process for the preparation of group consolidated accounts during the applicable Calendar Quarter or year. Following are the wire transfer instructions for Nymox. Nymox may designate new wire transfer instructions to bank accounts in Canada, the EU or the USA from time to time during the Term by written notice to Recordati.

All payments to Nymox shall be made to: [\*\*\*]

**3.8 Sales Records.** Recordati will maintain, and contractually require that its Affiliates and its Sublicensees maintain, complete and accurate books and financial records pertaining to total sales of the Product, Net Sales, the royalty calculation and any costs or income needed to audit the accuracy of amounts included in the Sales Statements. Such books and records will be kept until five (5) years after the end of the period to which such books and records pertain, or such longer period as Applicable Law may require.

**3.9** Audits. Recordati shall permit, and shall obligate each of its respective Affiliates and Sublicensees to permit a leading Big 4 (PWC, E&Y, KPMG, Deloitte) certified public accountant or other certified public accounting firm designated by Nymox and acceptable to Recordati, at Nymox s expense, to visit and inspect and to examine the books and records of Recordati, Affiliate or Sublicensee, during regular business hours and on prior written notice, no more than once per calendar year (except to the extent Nymox has a reasonable basis to believe that a particular amount reported by Recordati is inaccurate), and support Nymox with any explanation or information relevant for the audit, for the sole purpose of verifying for Nymox the correctness of the amounts reported to Nymox hereunder. All results and the basis for such results of such accountant s audit shall be deemed Confidential Information of the entity under audit. Such accountant shall have executed and delivered to the entity under audit a confidentiality agreement as reasonably requested by such entity, which agreement shall include provisions limiting such accountant s disclosures to Nymox to the results of the audit and the basis for such results of such audit. Nymox shall not use any information learned by it or disclosed to it pursuant to this Section for any purpose other than to enforce its rights under this Agreement. Any error detected in such audit shall be reported to the CFOs of the Parties or respective person in charge of the financials of the Agreement and any underpaying or overcharging shall be remitted within sixty (60) days of receiving the audit report (or the final determination if the amount is disputed) and the corresponding invoice or credit note. Further, if the audit for an annual period shows an error for that period of in excess of five per cent (5%), Recordati shall reimburse Nymox for its audit fees and reasonable out of pocket expenses in connection with said audit within sixty (60) days from an invoice. Any agreement pursuant to which Recordati grants a Sublicense to a Sublicensee shall provide that Nymox shall have audit rights described in this Section on the same basis as if such Sublicensee were a Party to this Agreement.

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3.9.1 [\*\*\*]

3.10 VAT & Indirect Taxes. The recipient of any transfer under this Agreement of Nymox Patents, Nymox Know-How, Recordati Patents, Recordati Know-How, Compounds or Products, as the case may be, shall be solely responsible for any sales, use, value added, excise or other taxes applicable to such transfer. All amounts relating to sales or transfers under this Agreement and any other documents related to this Agreement, of Nymox Patents, Nymox Know-How, Recordati Patents, Recordati Know-How, Compounds or Products, as the case may be, are stated exclusive of VAT & Indirect Taxes. The payor is responsible for the payment of all such appropriately levied taxes to the payee. The payee will provide to the payor, within 30 days (or alternative territory specific time period as set out in the local legislation) of the receipt of any consideration under this Agreement, a valid VAT invoice if appropriate. Should such amounts of VAT be refunded subsequently by the fiscal authorities to the payee, the payee will refund these monies to the payor within thirty (30) days of receipt. Where local laws mean the recipient of services under this Agreement is required to self-account for VAT, the recipient undertakes to so account. Furthermore, where local laws require the recipient to pay import VAT and duties to the fiscal authorities relating to Product shipped, the recipient undertakes so to do. However, if the assignment of this Agreement or a part thereof causes unfavourable consequences in respect of any sales, use, value added, excise or other taxes as compared to the situation prevailing before such assignment, then the Party effecting such assignment shall bear such unfavourable consequences.

## ARTICLE IV. DEVELOPMENT AND REGULATORY MATTERS

## 4.1 Development of the Product.

**4.1.1 Agreed Indication and Rejected Indications.** Either Party may propose, at anytime during the Term, that Recordati pursue the Development and Commercialization of additional Indications (that is, in addition to the Initial Indication and any previously Agreed Indications) within the Field. If Recordati desires to pursue the Development and Commercialization of additional Indications within the Field, it shall [\*\*\*] provide a draft development plan to Nymox describing the efforts Recordati proposes to make to Develop the Compound and Product in such Indication. If Nymox reasonably determines that such draft development plan is satisfactory in terms of the type and amount of effort to be expended by Recordati, then Nymox shall approve such draft development plan and [\*\*\*] such development plan shall become part of the Development Plan for all purposes under this Agreement and such Indication shall become an Agreed Indication for all purposes under this Agreement. If Nymox does not so approve the draft development plan, the Parties shall meet to negotiate changes to the draft development plan so that it includes efforts that Nymox reasonably determines to be satisfactory. The procedure above detailed in this Section 4.1.1 shall apply also in case of proposals from Nymox. [\*\*\*] For avoidance of doubt, if there are no Agreed Indications (for example because no new Indication became Agreed Indications and Recordati decides, at any time and at its discretion, to abandon Development or Commercialization of the Initial Indication), then this Agreement shall automatically terminate with the effects indicated in Section 12.6.1.

**4.1.2 On-going Development and Information Transfer.** During the Term of this Agreement, each Party will deliver to the other Party copies of all of its (and any of its Affiliate s and Sublicensee s) material Data and Regulatory Documentation as and when such Data and Regulatory Documentation become available to the Party, specifically (i) all non-clinical and Clinical Trial results and resultant data analyses, (ii) all material regulatory submissions made to the FDA or to the EMA by or on behalf of such Party with respect to the Compound or the Product and an Agreed Indication and (iii) protocols for any ongoing Clinical Trials and proposed designs for any anticipated Clinical Trials with respect to the Compound or the Product, in each case related to the Product anywhere in the world. For avoidance of doubt, a Party shall only be required to deliver any particular document to the other Party one time under this Agreement.

- (a) Recordati Right of Reference. Nymox hereby grants Recordati, its Affiliates and Sublicensees, a right of reference to all Data and Regulatory Documentation (including all Regulatory Approvals and INDs) for all uses in connection with the Product for sale in the Territory for use in the Agreed Indications, including the research, Development (including obtaining and maintaining Regulatory Approvals), manufacturing and Commercialization thereof.
- **(b) Nymox Right of Reference.** Recordati hereby grants Nymox, its Affiliates and Sublicensees, a right of reference to all Data and Regulatory Documentation (including all Regulatory Approvals and IMPDs) for all uses in connection with the Product for sale outside the Territory for use in the Field, including the research, Development (including obtaining and maintaining Regulatory Approvals), manufacturing and Commercialization thereof.

### 4.1.3 Roles; Compliance and Diligence.

- (a) Roles; Compliance. Recordati shall have the primary responsibility, at its own expense (except as otherwise expressly set forth herein, including in Section 3.3) for implementing the Development Plan and seeking Regulatory Approval for the Product in the Territory. All such Development activities shall be conducted in accordance with this Agreement and in compliance with Applicable Law and cGCPs. For clarity, neither Recordati (nor any of its Affiliates or Sublicensees) shall engage in any Development with respect to the Product except pursuant to the Development Plan.
- (b) General Diligence. Recordati, either directly or through one or more of its Affiliates or its Sublicensees, shall use Commercially Reasonable Efforts to perform the activities described in the Development Plan and this Agreement, expeditiously and efficiently. Without limiting the foregoing, Recordati (and such other entities, as applicable) shall use Commercially Reasonable Efforts (a) to Develop the Product in the Territory in accordance with the terms and conditions of this Agreement, and (b) to seek and maintain Regulatory Approval(s) with respect to the Product in the Territory, in each case for the Initial Indication and each Agreed Indication (if any).

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- **(c) Cooperation.** Each Party shall provide reasonable cooperation to the other Party as necessary to enable such other Party to respond to inquiries relating to the Compound or the Product received from Regulatory Authorities in the Territory, in the case of Recordati, or outside the Territory, in the case of Nymox.
- **4.1.4 Development Plan.** Attached hereto as <u>Annex B</u> is a copy of the initial Development Plan. During the Term, Recordati may propose updates, additions and amendments thereto to the JSC for its approval with respect to the incremental Development of the Compound and Product for Commercialization in the Territory. For the avoidance of doubt and notwithstanding anything to the contrary contained herein, in all cases Recordati shall have the right to conduct such Regulatory Clinical Trials and other Development activities in the Territory that are required by Applicable Law, or are otherwise required by Regulatory Authorities and/or useful to obtain or maintain Regulatory Approval for the Product for the Initial Indication or any Agreed Indication.
- **4.1.5 Development Costs.** As between the Parties (except as otherwise expressly set forth herein), all costs incurred by Recordati or its Affiliates with respect to any Development activities under the Development Plan shall be borne solely by Recordati, subject to Section 3.3.

#### 4.2 Regulatory Matters.

- **4.2.1 Regulatory Responsibilities.** Subject to Section 4.2.3, Section 4.2.4, and Section 5.2, as between the Parties, Recordati shall have sole responsibility for preparing, submitting and maintaining all Regulatory Documentation with respect to Regulatory Approvals, including MAAs, for the Product in the Territory, being understood that Recordati may seek one or more MAs in one or more countries of the Territory under different Recordati Trademarks and Logos if so deemed advisable for the Commercialisation of the Product. Subject to Article XII, all Regulatory Approvals and related Regulatory Documentation within the Territory relating to the Product shall be held in the name of Recordati, its Affiliates or its Sublicensees.
- **4.2.2 Clinical Data and Regulatory Data.** Without limiting the provisions of Section 4.1.2, each Party shall promptly provide the other Party with copies of all Clinical Data, non-clinical data and other Regulatory Data specified in Section 4.1.2 Developed by or on behalf of such Party from any Development activities with respect to the Compound or Product during the Term, when and as such Clinical Data, non-clinical data or other Regulatory Data becomes available to such Party. Each Party shall have the right to use such Clinical Data and Regulatory Data, provided that Nymox and/or Nymox s Affiliates and/or Nymox s licensees shall not use such Clinical Data, non-clinical data and Regulatory Data for commercial purposes within the Territory, and shall support the other, as may be reasonably necessary, in obtaining Regulatory Approvals for the Product, including providing necessary documents or other materials (to the extent controlled by such Party) required by Applicable Law to obtain Regulatory Approvals for the Product, in each case in accordance with the terms and conditions of this Agreement (provided, however that for clarity, such support obligation shall not obligate either Party to conduct any additional Clinical Trials, except as otherwise expressly set forth in this Agreement, and shall be limited to the types of activities such as providing available information and reports to the other Party).
- **4.2.3 Preparation of Regulatory Submissions.** The JSC shall have the right to review the content and subject matter of the MAA submitted to the EMA and other material filing for Regulatory Approval and material correspondence submitted to EMA related to the design of Regulatory Clinical Trials, and to the proposed and final Product Labeling for the Product and any changes thereto. Notwithstanding the foregoing, Recordati shall not be required to delay a regulatory submission in a manner that affects Recordati s ability to comply with Applicable Law nor to submit the above materials, correspondence, communications to the JSC or request related decisions of the JSC in advance of Recordati s submissions or decisions. Nymox shall be responsible for preparing and delivering to Recordati in a timely manner a complete CMC package and a complete initial draft of any CMC non-clinical and clinical section (and any

similar sections) of any Marketing Authorisation Application or other Regulatory Documentation for Recordati s review, amendment and use in connection with any MAAs or other Regulatory Documentation or correspondence with respect to the Product in the Territory. Such CMC section and CMC package shall be delivered to Recordati in e-CTD format (or such other format as may be reasonably requested by Recordati).

- (a) Regulatory Information Sharing in Territory. Recordati shall promptly provide to Nymox copies of material written or electronic communications received by Recordati or its Affiliates, or Sublicensees from, or forwarded by Recordati or its Affiliates or its Sublicensees to, the EMA with respect to (A) obtaining or maintaining Regulatory Approvals in the Territory or (B) any other activities relating to the Compound or the Product in the Territory and (C) copies of all contact reports of a material nature that are produced by Recordati, its Affiliates or its Sublicensees, provided that it shall also supply Nymox at least once a year with a report describing other material regulatory Developments in the Territory. Recordati shall have the right to redact any portions of the foregoing to the extent not related to the Compound or Product.
- (b) Regulatory Information Sharing Inside and Outside Territory. Nymox shall promptly provide to Recordati (1) copies of material written or electronic communications received by Nymox or its Affiliates, or Sublicensees from, or forwarded by Nymox or its Affiliates or its Sublicensees to, the FDA with respect to (A) obtaining or maintaining any Regulatory Approvals in the U.S. or (B) any other activities relating to the Compound or the Product regarding the F.D.A. and (2) copies of all contact reports of a material nature that are produced by Nymox or its Affiliates or its Sublicensees, provided that it shall also supply Recordati twice a year with a report describing other material regulatory Developments outside the Territory. Nymox shall have the right to redact any portions of the foregoing to the extent not related to the Compound or Product.

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- **4.2.4 Communications with Regulatory Authorities in the Territory.** Subject to Section 4.2.3 and Section 5.2, as between the Parties, Recordati shall be responsible for communicating with, and responding to communications with, the Regulatory Authorities in the Territory during the Term relating to the Product; provided that Nymox shall be primarily responsible for such communications to the extent relating to the closed portion of the DMF as set forth in Section 5.2 or relating to other clinical and non-clinical studies Nymox is conducting in the Territory. Notwithstanding the foregoing, except in the case of exigent circumstances (in which case the applicable Party shall notify the other Party of any following as promptly as reasonably practical) or to the extent not permitted by Applicable Law, (a) each Party shall notify the other Party as early as reasonably practicable in advance of all material meetings and material communications with representatives of the EMA concerning the Product in the Territory or of the FDA concerning the Product, (b) such other Party shall be permitted to participate (subject to EMA consent and practice) in any such material meetings and to review and comment on such material communications, (c) each Party shall ensure that all such material communications are consistent with the Development Plan and (d) each Party shall keep the other Party informed of all meetings and material written communications with the EMA or with the FDA relating to the Product; provided, in all such cases Recordati shall be the lead party except to the extent the foregoing is related to the closed portion of the DMF as set forth in Section 5.2 or related to other clinical and non-clinical studies Nymox is conducting in the Territory. Notwithstanding the foregoing, neither Party shall be required to delay a regulatory submission in a manner that affects such Party s ability to comply with Applicable Law.
- **4.2.5 Regulatory Records.** Each Party shall maintain, or cause to be maintained, records of its Development activities with respect to the Product in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall be reasonably complete and accurate and shall properly reflect all work done and results achieved in the performance of such Development activities, and which shall be retained by such Party for at least three (3) years after the termination of this Agreement, or for such longer period as may be required by Applicable Law. Each Party shall have the right, once a year, during normal business hours and upon reasonable notice, to inspect and copy any such records of the other Party.
- **4.3 Transfer of Product Documentation.** Promptly after the Effective Date, Nymox shall assign and/or transfer to Recordati its entire right, title, and interest in and to any and all Regulatory Approvals, including if relevant IMPDs, relating to the Compound or the Product in the Territory and shall execute and deliver to the EMA (and any other Regulatory Authority in the Territory as reasonably requested by Recordati in writing) a letter in a form approved by Recordati transferring ownership to Recordati of any such Regulatory Approvals, including IMPDs, filed with such Regulatory Authorities in the Territory; provided, however that Nymox shall not be required to assign to Recordati any IMPDs for any Clinical Trials then being conducted by Nymox in the Territory. Nymox shall provide Recordati with complete and accurate copies of all such assigned Regulatory Approvals, as soon as reasonably practicable after Recordati s written request therefor, but in any event within forty-five (45) days of such request.
- **4.4 Disclosures.** Recordati shall disclose to Nymox in writing any and all Recordati Know-How, Recordati Patents and Regulatory Documentation Developed or prepared or otherwise Controlled by Recordati or any of its Affiliates or its Sublicensees in respect to Recordati Inventions set forth in Section 8.2, promptly after the Development or preparation or acquisition thereof, in each case as reasonably necessary or useful for Nymox to exercise the license granted to it pursuant to Section 2. Nymox shall disclose to Recordati in writing any and all Nymox Know-How, Nymox Patents and Regulatory Documentation Developed or prepared or otherwise Controlled by Nymox or any of its Affiliates or its Sublicensees, promptly after the Development or preparation or acquisition thereof, in each case as reasonably necessary or useful for Recordati to exercise the license granted to it pursuant to Section 2.2.

ARTICLE V. MANUFACTURING

- **5.1 Nymox s Supply of Drug.** Nymox shall supply Recordati with all of Recordati s requirements for the Product in accordance with the terms and conditions set forth in the Supply Agreement entered into by and between Nymox and Recordati on the Effective Date. Save as otherwise expressly set forth in Section 5.1 or elsewhere in this Agreement, the Supply Agreement shall contain provisions as customary in the industry for agreements of a similar nature. For avoidance of doubt, and despite the licenses granted to Recordati herein, Recordati, its Affiliates and Sublicensees shall all be prohibited from manufacturing Compound or Product and from purchasing or receiving Compound or Product from any person or entity other than Nymox or its designee during the term of the Supply Agreement save as provided for therein. The Supply Agreement shall require that [\*\*\*] The Supply Agreement shall also provide that the [\*\*\*] supply price to be paid by Recordati for each unit of the Product under the Supply Agreement [\*\*\*] shall be [\*\*\*] The Supply Agreement shall also provide that (i) [\*\*\*] and that, (ii) [\*\*\*]. The Supply Agreement shall provide further for the manufacturing and supply of Clinical Supplies, including specific planning, delivery and economic conditions therefor.
- **5.2 Drug Master File.** Nymox, either directly or through a Third Party supplier or designee, shall submit and maintain a Drug Master File (DMF) for the Product to the applicable Regulatory Authorities in all countries in the Territory where Recordati (or any of its Affiliates or its Sublicensees) submits, or intends to submit, a Marketing Authorization Application, as well as all other countries in the Territory where the Compound or Product is manufactured or as otherwise required by Applicable Law. Prior to any such submission, Nymox shall provide a copy of the open portion of such Drug Master File to Recordati for its review and comment (which comments shall be considered by Nymox in good faith). Any communications from the Regulatory Authorities to Recordati relating to the DMF shall promptly be referred to Nymox, and, subject to the provisions of Section 4.2.4, Nymox shall be solely responsible for responding to any such communications and resolving any issues with the Regulatory Authorities, in each case to the extent permitted by Applicable Law. Nymox, either directly or through a Third Party supplier, shall file and maintain the DMF in compliance with all Applicable Laws as well as any Regulatory Approval for the Product, and will notify Recordati of any significant communications with the Regulatory Authorities relating to the potential discontinuance and/or withdrawal of the DMF or any Regulatory Approval for the Product, or any safety, efficacy or potency concern relating to the Compound or Product. Recordati will cooperate with Nymox as reasonably necessary to support Nymox s performance of its obligations under this Section 5.2. During the Term, Nymox shall permit Recordati to cross reference said DMF in its Regulatory Approvals for the Product and will cooperate with Recordati as reasonably necessary to affect such cross reference.

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**5.3 Changes to Specifications.** To the extent a change to the then-current Specifications for the Product would require the filing of an application for Regulatory Approval (or an amendment or supplement to an existing Regulatory Approval), then except to the extent such changes are required by Applicable Law or Regulatory Authorities, neither Party shall make any such changes to the Specifications, either inside or outside the Territory, without the prior written consent of the other Party, such consent not to be unreasonably withheld.

## ARTICLE VI. COMMERCIALIZATION

#### 6.1 Commercialization of the Product.

- **6.1.1 General.** Recordati shall have the sole right, at its own expense, to Commercialize the Product in the Territory solely for the Initial Indication and all Agreed Indications (if any). Recordati shall use Commercially Reasonable Efforts to Commercialize the Product throughout the Territory for the Initial Indication and all Agreed Indications (if any) in accordance with this Agreement, provided however that Recordati may elect not to Commercialize or to discontinue Commercialization of the Product in any part of the Territory if in its opinion Commercialization in such part of the Territory is likely to be detrimental to the overall Commercialization in the Territory as a whole (including because of reference pricing or other commercial grounds).
- **6.1.2 Covenant.** During the Term, Recordati, its Affiliate and Sublicensees, shall not market, detail, promote or otherwise sell, directly or indirectly, a Competitive Product for the Initial Indication or any Agreed Indications in the Territory. For purposes of this Agreement, [\*\*\*] is not considered a Competitive Product.
- **6.2** Commercialization Plan and Implementation. Recordati may review and amend the Commercialization Plan, from time to time during the Term as Recordati desires, with respect to the Commercialization of the Product, as necessary or desirable to Commercialize the Product throughout the Territory, and shall submit such amendments to Nymox. Recordati will consider in good faith any suggestion from Nymox in relation thereto.

#### 6.3 Promotional Materials and Activities.

- **6.3.1 In General.** Recordati shall be responsible, at its sole expense, for preparing all Promotional Materials used to support the Commercialization of the Product for the Initial Indication and all Agreed Indications (if any) in the Territory. Recordati shall ensure that all its Promotional Materials shall be consistent with Applicable Law and with the approved Product Labeling for the Product in the Territory. Recordati shall be responsible for obtaining any Regulatory Approvals from the Regulatory Authorities required for the use of any Promotional Materials for the Initial Indication and all Agreed Indications (if any) in the Territory and shall submit all applicable Promotional Materials to such Regulatory Authorities as required by Applicable Law.
- **6.3.2 Markings.** Subject to Applicable Law, all Promotional Materials, packaging and Product Labeling for the Product used by Recordati, its Affiliates and its Sublicensees in connection with the Product for the Initial Indication and all Agreed Indications (if any) in the Territory shall contain (i) the applicable Trademark for use in Commercialization of the Product in the Territory, (ii) the corporate name and/or logo of Recordati and of Nymox, in a reasonably prominent manner, (iii) the corporate name of the manufacturer, and (iv) if appropriate, the applicable Patent numbers.

#### 6.4 Statements and Compliance with Applicable Law.

**6.4.1 Public Statements Regarding Product.** In exercising its rights pursuant to this Article VI, Recordati shall use Commercially Reasonable Efforts to prevent claims or representations in respect of the Product or the characteristics of the Product (e.g., safety or efficacy) being made by or on behalf of it or its Affiliates or its Sublicensees (by members of its or their sales force or otherwise) that do not materially represent an accurate or fairly balanced summary or explanation of the Product Labeling for the Product in the country in the Territory in question.

**6.4.2 Sales Force Compliance.** Recordati, directly or through one or more of its Affiliates or its Sublicensees, shall use Commercially Reasonable Efforts to train and monitor its sales representatives to (i) use only Promotional Materials (without any material addition, deletion or other modification) that are compliant with the requirements of Section 6.3.1 for the promotion of the Product in the Territory, (ii) limit claims of efficacy and safety for the Product to those that are consistent with Applicable Law and with approved (by the appropriate Regulatory Authority, if and to the extent so required by Applicable Law) promotional claims in Product Labeling and Promotional Materials for the Product, and (iii) Commercialize the Product in compliance in all material respects with Applicable Law.

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- **6.4.3 Medical and Other Inquiries.** Recordati (directly or through one or more of its Affiliates or its Sublicensees) shall be responsible with Nymox s reasonable support for responding to all medical questions or inquiries relating to the Product sold for use in the Field in Territory. Recordati (and such other entities, as applicable) shall keep such records and make such reports as are reasonably necessary to document such communications in compliance with all Applicable Law.
- **6.4.4 Compliance with Laws.** Recordati shall, in all material respects, conform its practices and procedures relating to educating the medical community in the Territory with respect to the Product to the regulations, policies and guidelines of any pharmaceutical industry association of which Recordati is a member, as amended from time to time, and Applicable Law.
- **6.4.5 Non-Regulatory Clinical Trials.** Except as set forth in this Section 6.4.5, Recordati (and its Affiliates) shall only be permitted to sponsor, or participate in (for example, through providing financial support or free Product) Non-Regulatory Clinical Trials of the Compound or Product with Nymox s prior written consent, not to be unreasonably withheld or delayed. Recordati may sponsor, or may participate in (for example, through providing financial support or free Product) Non-Regulatory Clinical Trials of the Product, without the consent of Nymox, to the extent that such Non-Regulatory Clinical Trials are conducted in the Territory and (i) [\*\*\*] (ii) [\*\*\*] (iii) provide for dosing that is within the approved dosing parameters from the Regulatory Approval for the Product in the country or jurisdiction in which the trial is being conducted and (iv) is for the treatment of an approved Indication. In furtherance of the provisions of Section 4.1.2, each Party shall keep the other Party informed with respect to any Non-Regulatory Clinical Trials to be performed by or on behalf of such Party with respect to the Product and shall provide copies of all Data generated thereby to the other Party as and when such Data becomes available.
- **6.5** Sales and Distribution in the Territory. As between the Parties, Recordati shall have the sole right to, and shall be solely responsible for, invoicing and booking sales of the Product in the Territory, contracting and establishing all terms of such sales (including pricing and discounts), and warehousing and distributing the Product in the Territory, and performing all related services, in each case in a manner consistent with the terms and conditions of this Agreement. As between the Parties, Recordati shall also have the sole right to, and shall be solely responsible for, handling all returns, recalls or withdrawals, order processing, invoicing and collection, distribution and inventory and receivables with respect to the Product in the Territory.
- **6.6 Adverse Event Reporting.** Each Party shall provide the other Party with all information available to such Party that such other Party may reasonably require to comply with its pharmacovigilance responsibilities under Applicable Law with respect to the Product in accordance with the terms and conditions set forth in the Pharmacovigilance Agreement entered into by and between Nymox and Recordati as soon as practicable after the Effective Date.
- **6.7 Pharmacovigilance Costs.** Recordati shall bear all costs incurred in connection with receiving, recording, reviewing, communicating, reporting and responding to adverse events with respect to the Product in the Field in the Territory and Nymox shall bear all costs incurred in connection with the same outside the Territory.

#### 6.8 Recalls.

**6.8.1 Notification and Recall.** In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with the Product anywhere in the world, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, the Party notified of or desiring such recall or similar action shall, immediately (but no later than within twenty-four (24) hours), advise the other Party thereof by telephone (and confirmed by email or facsimile), email or facsimile. As between the Parties, Recordati shall have the sole right to initiate a recall of the Product in the Territory; provided, however that Nymox

shall have the right to cause Recordati to initiate a recall with respect to a particular batch of Product in the Territory to the extent such recall is necessary for safety or efficacy reasons as a result of a manufacturing issue with respect to any Product supplied by Nymox pursuant to the Supply Agreement (a **Manufacturing Recall**). If Nymox reasonably believes that a Manufacturing Recall is necessary, Nymox shall notify Recordati thereof in writing and the Parties shall meet or communicate to determine the manner in which any such Manufacturing Recall shall be conducted. Recordati shall conduct any recall of Product in the Field within the Territory and shall have the sole right to determine the manner in which any such recall shall be conducted. Nymox shall have the sole right to decide, in its discretion, whether to conduct a recall, at its expense, of the Product outside the Territory, and the manner in which any such recall shall be conducted.

**6.8.2 Expenses.** Except as provided in this Section 6.8.2 or in the Supply Agreement, Nymox shall bear the expenses of a recall of the Product outside the Territory (including the Cost of Goods for the Product actually returned or destroyed, the cost of shipping and destruction of same and reasonable administrative costs) and Recordati shall bear the expenses of a recall of the Product inside the Territory (including the Cost of Goods for the Product actually returned or destroyed, the cost of shipping and destruction of same and reasonable administrative costs). If a recall of Product in the Territory is required due to a breach by Nymox of this Agreement, or the negligence or intentional misconduct of Nymox, its Sublicensees, or any of their respective Affiliates or agents, or the failure of the Product to meet Specifications, then Nymox shall bear the expenses of the recall of the Product (including the Cost of Goods for the Product actually returned or destroyed, the cost of shipping and destruction of same and reasonable administrative costs). If a recall outside of the Territory is required due to a breach by Recordati of this Agreement, or the negligence or intentional misconduct of Recordati, a Sublicensee, or any of their respective Affiliates or agents, then Recordati shall bear the expenses of the recall of the Product (including the Cost of Goods for the Product actually returned or destroyed, the cost of shipping and destruction of same and reasonable administrative costs).

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#### 6.9 Unauthorized Sales.

- **6.9.1 Unauthorized Sales by Recordati.** Recordati (a) shall, and shall cause its Affiliates and its Sublicensees to, distribute, market, promote, offer for sale and sell the Product only in the Territory and only for Agreed Indications that have received Regulatory Approval and, to the extent consistent with Applicable Law, (b) shall not, and shall not permit its Affiliates and shall use Commercially Reasonable Efforts to not permit Sublicensees to, distribute, market, promote, offer for sale or sell the Product (i) to any person outside the Territory or (ii) to any person inside the Territory that Recordati, or its Affiliates, or Sublicensees, as applicable, knows is reasonably likely to distribute, market, promote, offer for sale or sell such Product outside the Territory or assist another person to do so. Such Commercially Reasonable Efforts with respect to Sublicensees shall include obtaining their written agreement to an undertaking at least as restrictive with respect to such Sublicensees as the preceding sentence is with respect to Recordati and its Affiliates. [\*\*\*]
- **6.9.2 Unauthorized Sales by Nymox.** Nymox (a) shall, and shall cause its Affiliates and its Sublicensees to, distribute, market, promote, offer for sale and sell the Product only outside of the Territory or in the Territory for Rejected Indications (subject to Recordati's Right of First Refusal) and, to the extent consistent with Applicable Law, (b) shall not, and shall not permit its Affiliates and shall use Commercially Reasonable Efforts to not permit Sublicensees to, distribute, market, promote, offer for sale or sell the Product (i) to any person inside the Territory except for Rejected Indications (subject to Recordati's Right of First Refusal) or (ii) to any person outside of the Territory that Nymox, or its Affiliates, or Sublicensees, as applicable, knows is reasonably likely to distribute, market, promote, offer for sale or sell such Product inside the Territory or assist another person to do so for an Agreed Indication. Such Commercially Reasonable Efforts with respect to Sublicensees shall include obtaining their written agreement to an undertaking at least as restrictive with respect to such Sublicensees as the preceding sentence is with respect to Nymox and its Affiliates. If Nymox or any of its Affiliates or its Sublicensees receives any orders for the Product for the Territory, it shall refer such orders to Recordati.
- **6.9.3 Mitigation.** To the extent that sales referred to in Section 6.9.1 or Section 6.9.2 have a material negative effect on the sales of the Product by Party in its territory, and if such effect cannot be mitigated, for example due to legal or practical considerations, then the Parties agree to negotiate in good faith towards an agreement pursuant to which the Parties will share the benefits and burdens of such cross territorial transactions in a manner that allows both to substantially preserve and enjoy the benefits of the transaction as reflected in this Agreement.
- **6.10 Reporting.** Recordati shall prepare and maintain reasonably complete and accurate records regarding Commercialization of the Product in the Territory and shall provide to Nymox a detailed report regarding such Commercialization at least [\*\*\*]. Such report shall contain sufficient detail to enable Nymox to assess Recordati s compliance with its Commercialization obligations hereunder during the preceding [\*\*\*] period, including a general description of the following, in each case with respect to the Product, at a minimum in the Key Countries: (i) Recordati s material activities with respect to promoting, detailing and marketing of the Product in such country(ies); (ii) material pre-launch Commercialization activities; (iii) sales force size and allocation by country; (iv) the nature of promotional activities and Product sampling activities conducted, if any; (v) market and Sales Reports for the Product; and (vi) the conduct of advertising, public relations and other promotional programs, including notable professional symposia and speaker and peer to peer activity programs (which at a minimum shall include such activities when conducted in international congresses) used in the Commercialization of the Product. Subject to any applicable Third Party confidentiality obligations, Recordati shall provide Nymox with such additional information regarding the Commercialization of the Product in the Territory as Nymox may reasonably request from time to time.
- **6.11 Sales Activities Audit Right.** [\*\*\*], Nymox shall have the right to appoint an independent auditor to review Recordati s sales force activity in the Key Countries (e.g. by electronic territory management system or other sales

force activity monitoring tool) during ordinary business hours and upon reasonable prior written notice (and in a manner so as to not unduly interrupt Recordati s ongoing business activities) to evaluate performance for the Product and to otherwise audit compliance by Recordati with its Commercialization obligations hereunder. Recordati will collaborate with such audit and Nymox will bear the costs of the external auditor. Recordati shall ensure that all its Affiliates, and shall contractually require that all its Sublicensees that qualify as auditees, will be obliged under similar conditions to allow Nymox, through an independent auditor, to inspect and audit such Affiliates—and Sublicensees sales force activity and relevant Commercialization information solely with respect to the Product. Information disclosed to Nymox or its representation during such audit may not be used for any other purpose than said audit, unless otherwise agreed.

## ARTICLE VII. COLLABORATION MANAGEMENT

#### 7.1 Joint Steering Committee.

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- **7.1.1 Formation and Purpose.** The Parties shall form a Joint Steering Committee (the **Joint Steering Committee** or **JSC**), which shall meet [\*\*\*] (unless both Parties agree otherwise), to monitor and review the implementation of, and results achieved under, the Development Program. The JSC shall also facilitate the flow of information between the Parties with respect to Development activities being conducted for the Compound or the Product. Except as provided in this Section 7.1, the JSC shall have the membership and shall operate by the procedures set forth in Section 7.2.
- **7.1.2 Specific Responsibilities of the JSC.** In support of its responsibility for overseeing, coordinating and expediting the Development of, and regulatory filings for, the Compound or the Product, the JSC shall have the responsibility to: (i) review and approve the Development Plan (including any updates and amendments thereto), (ii) facilitate the exchange of all information and Data relating to all Clinical Trials, Non-Regulatory Clinical Trials and other Development activities including non-clinical activities in respect of the Compound or the Product; and (iii) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement. Any decision taken by the JSC shall be submitted for written approval to each Parties Board of Directors or manager delegated by it.
- **7.1.3 Membership of the JSC.** The JSC shall be composed of [\*\*\*] representatives appointed by each Party. Each of the Parties shall notify the other Party in writing of the names of each of its initial JSC members within [\*\*\*] after the Effective Date. A designee of Nymox shall serve as the Chair of the JSC.
- **7.2 General Provisions Governing the JSC.** The following provisions shall govern the conduct of the JSC and such other committees as the JSC may establish from time to time under this Agreement (each, a **Committee**), except as otherwise expressly provided elsewhere in this Agreement or as agreed to by the Parties in writing.
- **7.2.1 Membership.** Each Committee shall include an equal number of representatives of each of the Parties, each with the requisite experience and seniority to enable him or her to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of such Committee. From time to time, each Party may change one or more of its representatives on a Committee upon written notice to the other Party.
- **7.2.2 Meetings and Minutes.** Each Committee shall meet at locations designated alternately by Nymox and by Recordati, with the first location to be designated by Nymox. Committees may also conduct meetings by conference call, videoconference or other means provided that all participants are able to hear and be heard throughout the meeting. The chairperson of the Committee shall be responsible for calling meetings, provided that the chairperson shall call a meeting of the Committee promptly upon the reasonable request of either Party. The requesting Party shall disclose to the other Party the proposed agenda for a meeting along with appropriate information within a reasonable period of time in advance of such meeting of the applicable Committee. The Chair shall prepare and circulate, for review and approval by the Committee members, minutes of such meeting within [\*\*\*] after such meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than [\*\*\*] from the date of the meeting.
- **7.2.3 Procedural Rules.** A Committee shall have the right to adopt such standing rules as shall be necessary for its work to the extent that such rules are not inconsistent with this Agreement. A quorum of a Committee shall exist whenever there is present at a meeting at least one representative appointed by each Party. Members of a Committee may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed. A Committee shall take action by consensus of the members present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance or by a written resolution signed by a representative of each of the members of the Committee. Employees or consultants of either Party that are not members of a Committee may attend any meeting of such Committee; provided, however, that such

attendees (a) shall not vote or otherwise participate in the decision-making process of such Committee and (b) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in Article X.

- **7.2.4 Dispute Resolution.** The JSC and all other Committees shall endeavour to decide all matters and resolve all disputes by consensus. If a Committee (other than the JSC) cannot, or does not, reach consensus on an issue as set forth in Section 7.2.3 within [\*\*\*] after such issue is first presented to such Committee, then the dispute shall be referred to the JSC for resolution and a special meeting of the JSC may be called for such purpose. If the JSC cannot, or does not, reach consensus on an issue as set forth in Section 7.2.3 within [\*\*\*] after such issue is first presented to the JSC for resolution, including any dispute arising in another Committee, then the provisions set forth in Section 11.2.1 shall apply.
- **7.2.5 Limitations on Authority.** Each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No Committee shall have the power to amend, modify or waive compliance with this Agreement.
- **7.2.6 Decision-making Standard.** All decisions and other actions of the JSC shall be made in good faith and with due care, after consideration of the reasonably available information with the intention that the resulting decision or actions will conform to, or be consistent with, the provisions and requirements of this Agreement.

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**7.2.7 Interactions Between Committees and Internal Teams.** The Parties recognize that each Party possesses an internal structure (including various committees, teams and review boards) that will be involved in administering such Party s activities under this Agreement. Each Committee shall establish procedures to facilitate communications between such Committee and the relevant internal committee, team or board of each of the Parties in order to maximize the efficiency of the Committees and the performance of the Parties of their obligations under this Agreement, including by requiring appropriate members of such Committee to be available at reasonable times and places and upon reasonable prior notice for making appropriate oral reports to, and responding to reasonable inquiries from, the relevant internal committee, team or board.

# ARTICLE VIII. INTELLECTUAL PROPERTY, KNOW HOW

#### A. INVENTIONS

- **8.1 Nymox Inventions.** In the event that during the Term, Nymox, its Affiliates or its Sublicensees Develops any Inventions in the Field with respect to the Product or the Compound that are Controlled-by Nymox or its Affiliates, Nymox shall furnish Recordati with timely written notice of such Inventions. As to such Inventions that are Improvements and Enhancements, Nymox shall furnish Recordati with a complete written disclosure of any such Improvements and Enhancements promptly after conception of such Improvements and Enhancements, with the goal of making such disclosure within a [\*\*\*] period. When Data has been produced relating to such Improvements and Enhancements in the Field, Nymox shall furnish Recordati with a Data package which, in Nymox s reasonable opinion, contains all material information, Know-How and other Data available to Nymox that would be useful for Recordati to obtain Regulatory Approvals in the Territory for such Improvements and Enhancements, and to implement such Improvements and Enhancements in Recordati s manufacture, production, research, Development, packaging, marketing, promotion, distribution, sale and/or use of Product in the Field in the Territory. All such information, Know-How and other Data with respect to any such Improvements and Enhancements shall be deemed to constitute Nymox Know-How, and Recordati shall have the right to use such Nymox Know-How, at no additional charge in accordance with Section 2.1 and the other terms and conditions, and subject to the limitations, of this Agreement. As to Inventions in the Field Controlled by Nymox that are not Improvements and Enhancements and relate to the Product or the Compound, Nymox shall furnish Recordati with a complete written disclosure of any Inventions promptly after the conception of such Inventions. Recordati shall have the right to use any such Inventions in the Field at no additional charge, in accordance with Section 2.1 and the other terms and conditions, and subject to the limitations, of this Agreement.
- 8.2 Recordati Inventions. In the event that during the Term Recordati, its Affiliates or its Sublicensees Develops any Inventions in the Field with respect to the Product or the Compound that are Controlled by Recordati or its Affiliates, Recordati shall furnish Nymox with timely written notice of such Recordati Inventions. As to such Inventions that are Improvements and Enhancements, Recordati shall furnish Nymox with a complete written disclosure of any such Improvements and Enhancements promptly after conception of such Improvements and Enhancements, with the goal of making such disclosure within [\*\*\*] period. When Data has been produced relating to such Improvements and Enhancements in the Field, Recordati shall furnish Nymox with a Data package which, in Recordati s reasonable opinion, contains all material information, Know-How and other Data available to Recordati that would be useful for Nymox to obtain Regulatory Approvals outside the Territory for such Improvements and Enhancements, and to implement such Improvements and Enhancements in Nymox s manufacture, production, research, Development, marketing, distribution, sale and/or use of Product in the Field outside the Territory. All such information, Know-How and other Data with respect to any such Improvements and Enhancements shall be deemed to constitute Recordati Know-How, and Nymox shall have the right to use such Recordati Know-How in accordance with Section 2.2 and the other terms and conditions, and subject to the limitations, of this Agreement. As to Recordati Inventions in the Field

Controlled by Recordati that are not Improvements and Enhancements and relate to the Product or the Compound, Recordati shall furnish Nymox with a complete written disclosure of any Inventions promptly after the conception of such Inventions. Nymox shall have the right to use any such Inventions in the Field in accordance with Section 2.2 and the other terms and conditions, and subject to the limitations, of this Agreement.

#### **B. OWNERSHIP AND MAINTENANCE**

- **8.3 Ownership of Intellectual Property Rights.** Recordati hereby acknowledges that all of the Nymox Intellectual Property is owned or Controlled by Nymox. Nymox hereby acknowledges that all of the Recordati Intellectual Property is owned or Controlled by Recordati. Neither Party shall acquire any rights, title or interest whatsoever in or to any Intellectual Property rights of the other Party hereunder, except as specifically provided in the Agreement. Without limiting the generality of this provision, a Party shall not utilize any intellectual property rights, trademarks, patents, copyrights or know-how belonging to the other Party for any purpose whatsoever, except as specifically authorized in this Agreement or by separate agreement.
- **8.4 Ownership of Inventions.** In the event that a Party conceives, Develops, discovers or acquires any Inventions with respect to the use of the Product and/or Compound, subject to the provisions of Section 8.1 or Section 8.2, as the case may be, that Party shall be the sole owner of all Intellectual Property rights in and to such Invention and shall have the sole right, and shall be solely responsible, for applying for, obtaining, and bearing all costs and expenses associated with, all Patents and other Intellectual Property rights with respect to such Invention, as that Party determines to be necessary or appropriate, in its sole discretion, subject in all cases to the provisions of this Section VIII. Each Party will require all of its and its Affiliates employees to assign all Inventions that are Developed, made or conceived by such employees according to the ownership principles described in this Section 8.4. Each Party will require its Affiliates, agents or independent contractors performing any Development activity pursuant to this Agreement to assign to such Party all Inventions that are Developed, made or conceived by such agents or independent contractors according to the ownership principles described in Section 8.4 and shall impose such assignment requirements on its Sublicensees that perform any Development activity pursuant to this Agreement.

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8.5 Prosecution and Maintenance of Patents for Nymox Inventions and Recordati Inventions. Recordati shall prepare all Patents for Recordati Inventions. Recordati shall at its own expense and subject to good business judgment be responsible for filing, prosecuting, and maintaining Patents for Recordati Inventions in countries within or outside the Territory (at Recordati s choice) subject to the following provisions. Recordati shall be responsible for filing, prosecuting and maintaining Recordati Patents for Recordati Inventions outside the Territory in countries selected by Nymox. All reasonable costs associated with filing, prosecuting and maintaining Recordati Patents in countries selected by Nymox shall be borne by Nymox. Nymox shall prepare all Patents for Nymox Inventions. Nymox shall at its own expense and subject to good business judgment be responsible for filing, prosecuting, and maintaining Patents for Nymox Inventions in countries outside the Territory (at Nymox s choice) and within the Territory. Each Party hereto shall keep the other Party informed about the existence and status of any Patent filings pertaining to a Recordati Invention or a Nymox Invention, respectively. The Party responsible for prosecution and maintenance will in due time make information available to the other Party that is relevant for material issues of filing, prosecuting or maintaining such Patents and Patent applications and will consider in good faith advice or lawful suggestions furnished by such other Party. In the event that Recordati decides not to apply for Patent protection in a jurisdiction of interest to Nymox outside the Territory as set forth above for a Recordati Invention it will inform Nymox of such decision and offer to assign to Nymox, at no cost to Nymox, the right to file Patent applications claiming such Inventions in such jurisdictions of interest to Nymox, in Nymox s own name and Nymox shall own all right, title and interest in and to such Patent applications and any Patents issuing therefrom in such jurisdictions. In the event that Nymox decides not to apply for patent protection in a jurisdiction of interest to Recordati within the Territory as set forth above for a Nymox Invention it will inform Recordati of such decision and offer to assign to Recordati, at no cost to Recordati, the right to file patent applications claiming such Inventions in such jurisdictions of interest to Recordati, in Recordati s own name and Recordati shall own all right, title and interest in and to such patent applications and any patents issuing therefrom in such jurisdictions. Nymox will provide Recordati with an annually-updated Patent status report that includes in detail the identification and status of each Patent in Nymox Intellectual Property including information on annuity payment status. Recordati will provide Nymox with an annually-updated Patent status report that includes in detail the identification and status of each Patent in Recordati Intellectual Property including information on annuity payment status.

**8.6 Joint Ownership.** The Parties will jointly own within the Territory any Intellectual Property made or acquired jointly.

**8.7 Prosecution of Patents for Jointly Owned Inventions.** Promptly after conception of jointly owned Inventions, the Parties shall confer to determine whether to seek Jointly Owned Patents for such Inventions. As to those Inventions selected for filing of Jointly Owned Patents, the Parties shall jointly be responsible for preparing, filing, prosecuting, and maintaining Jointly Owned Patents in countries within or outside the Territory (as the Parties may agree) all in accordance with the Parties overall prosecution and maintenance strategy; provided that Nymox shall take the lead in determining and implementing such strategy in jurisdictions outside of the Territory and Recordati shall take the lead in determining and implementing such strategy in jurisdictions within the Territory. All reasonable out of pocket expenses associated with preparing, filing, prosecuting and maintaining Jointly Owned Patents shall be equally shared by the Parties, provided that if either Party does not desire to file or maintain such a Patent application or Patent, it shall notify the other Party of that desire and it shall, at such other Party s request, assign to such other Party the right to file Patent applications claiming such Inventions in such jurisdictions, in such other Party s own name, and such other Party shall own all right, title and interest in and to such Patent applications and any Patents issuing therefrom in such jurisdictions and such Patent applications and any Patents issuing therefrom shall no longer by subject to the licenses granted herein (and the assigning Party shall thereafter not be obligated to share in any costs thereof). To the extent filing and prosecution is conducted through an external patent law firm this will be a mutually acceptable law firm. Nymox s interest in Jointly Owned Patents shall be deemed included in the license granted to Recordati under Section 2.1 hereabove and Recordati s interest in such Jointly Owned Patents shall be deemed

included in the license granted to Nymox under Section 2.2 hereabove.

**8.8 Offer of Assignment.** The Party receiving an offer hereunder of assignment of any Patent or application therefore, shall accept or decline the offer in writing within [\*\*\*] after receipt of such offer. The failure to respond in writing to any such offer shall be construed as declining the offer and as authority for the offering Party to abandon and/or discontinue maintaining any Patents or Patent applications covered by such offer. If such an offer of assignment is accepted, the assigning Party shall at no cost to the other Party execute all lawful documents required to assign such Patent or prosecute and maintain such Patents and applications, and to transfer ownership of such Patents or applications to the Party requesting an assignment in response to an offer to assign as set forth herein, and such Patent applications and any Patents issuing therefrom shall no longer be subject to the licenses granted herein.

**8.9 Failure to Maintain Nymox Patents.** In no event will Nymox permit any of the Nymox Patents that are owned by Nymox or any of its Affiliates to be abandoned in any country in the Territory without Recordati first being given an opportunity to assume full responsibility for the continued prosecution and maintenance of such Nymox Patents. In the event that Nymox decides not to continue the prosecution or maintenance of such a Patent application or Patent within the Nymox Patents in any country in the Territory, Nymox shall provide Recordati with written notice of this decision at least[\*\*\*] prior to any pending lapse or abandonment thereof. In such event, Nymox shall provide Recordati with an opportunity to assume responsibility for the further prosecution and maintenance of such Patent application and any Patent issuing thereon, at its own cost. In the event that Recordati provides notice of its desire to assume responsibility for such prosecution and maintenance, Nymox shall promptly transfer the responsibility for such prosecution and maintenance of such Patent applications and Patents to patent counsel selected and directed by Recordati, at Recordati s sole expense. With respect to Nymox Patents that are not owned by Nymox, Nymox shall do the following: (a) if Nymox has a contractual right to assign to Recordati control over prosecution and maintenance of such Patent applications and Patents in the Territory if they are otherwise to be abandoned, Nymox will provide notice to Recordati of such pending abandonment and, if Recordati provides notice of its desire to assume responsibility for such prosecution and maintenance, then Nymox shall promptly transfer the responsibility for such prosecution and maintenance of such Patent applications and Patents to patent counsel selected, and directed, by Recordati, at Recordati s sole expense or (b) if Nymox does not have the contractual right to assign to Recordati control over prosecution and maintenance, then Nymox shall prosecute and maintain such Patent applications and Patents in the Territory.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

**8.10 Failure to Maintain Recordati Patents.** In no event will Recordati permit any of the Recordati Patents that are owned by Recordati or any of its Affiliates to be abandoned in any country outside the Territory without Nymox first being given an opportunity to assume full responsibility for the continued prosecution and maintenance of such Recordati Patents. In the event that Recordati decides not to continue the prosecution or maintenance of such a Patent application or Patent within the Recordati Patents in any country outside the Territory, Recordati shall provide Nymox with written notice of this decision at least [\*\*\*] prior to any pending lapse or abandonment thereof. In such event, Recordati shall provide Nymox with an opportunity to assume responsibility for the further prosecution and maintenance of such Patent application and any Patent issuing thereon, at its own cost. In the event that Nymox provides notice of its desire to assume responsibility for such prosecution and maintenance, Recordati shall promptly transfer the responsibility for such prosecution and maintenance of such Patent applications and Patents to patent counsel selected and directed by Nymox, at Nymox s sole expense. With respect to Recordati Patents that are not owned by Recordati, Recordati shall do the following: (a) if Recordati has a contractual right to assign to Nymox control over prosecution and maintenance of such Patent applications and Patents outside the Territory if they are otherwise to be abandoned, Recordati will provide notice to Nymox of such pending abandonment and, if Nymox provides notice of its desire to assume responsibility for such prosecution and maintenance, then Recordati shall promptly transfer the responsibility for such prosecution and maintenance of such Patent applications and Patents to patent counsel selected, and directed, by Nymox, at Nymox s sole expense or (b) if Recordati does not have the contractual right to assign to Nymox control over prosecution and maintenance, then Recordati shall prosecute and maintain such Patent applications and Patents outside the Territory.

**8.11 Defence of Data Exclusivity.** Recordati, in good faith consultation with Nymox, will determine a strategy to obtain and defend Data Exclusivity for the Product in the Territory. Each Party will promptly make available to the other Party any available information that is relevant for any material issue of obtaining or defending the Data Exclusivity for the Product in the Territory. Each Party will provide any lawful formal support, signatures, evidence or other documents relevant to the defending Party with respect to such Data Exclusivity. The out of pocket expenses relating to obtaining or defending Data Exclusivity in the Territory will be the sole responsibility of Recordati. Nymox s interest in the Data Exclusivity shall be deemed included in the license granted to Recordati hereunder and Recordati s interest in such Data Exclusivity shall be deemed included in the license granted to Nymox under Section 2.2 hereinabove.

#### C. INFRINGEMENT

**8.12 Infringement by Third Parties within the Territory.** If, during the Term of this Agreement either Party becomes aware of any Third Party infringement or threatened infringement of any of the Nymox Intellectual Property or Recordati Intellectual Property or any unauthorized use thereof, the following provisions shall apply:

(a) To the extent a Party Controls (for purposes of this Agreement) Intellectual Property of a Third Party (a **Third Party Licensor**) as a result of a license or other grant of rights to such Intellectual Property from such Third Party (such Intellectual Property, the **In-LicensedRights**, and the agreement granting such rights to such Intellectual Property, the **In-License**), the terms of such In-License shall govern efforts to prevent, prohibit or terminate any actual or threatened infringement or unauthorized use of the In-Licensed Rights granted pursuant to such In-License; provided that, the Party Controlling the In-Licensed Rights shall use Commercially Reasonable Efforts to obtain from the Third Party Licensor the right to respond to such infringement or unauthorized usage as provided in this Section 8.12. Moreover, each Party and its Affiliates and its Sublicensees shall be required to take such measures as may be reasonably necessary or convenient to enable such Party to fulfil its obligations hereunder pertaining to the prosecution, maintenance and enforcement of any In-Licensed Rights as provided in any In-License. The remaining provisions of this Section 8.12 are subject to this Section 8.12(a). Notwithstanding the foregoing, (i) Annex F sets forth a list of all Nymox Intellectual Property which is an In-Licensed Right, together with the applicable In-Licenses,

as of the Effective Date, (ii) with respect to Intellectual Property (under an In-License) licensed by Nymox to Recordati hereunder as of the Effective Date, the rights granted to Recordati pursuant to this Section 8.12 and Section 8.13 with respect to such Intellectual Property shall only be subject to the rights of a Third Party Licensor to the extent set forth on Annex F and (iii) with respect to new Intellectual Property (under an In-License) licensed by Nymox to Recordati hereunder as a result of Nymox (or any of its Affiliates) entering into a new In-License after the Effective Date, the rights granted to Recordati pursuant to this Section 8.12 and Section 8.13 with respect to such new Intellectual Property shall be subject to the rights of such Third Party Licensor as set forth in such new In-License.

(b) The Party having such Knowledge shall promptly give notice to the other Party, with all available details of such infringement. For purposes of this Section 8.12 only, Jointly Owned Patents will be treated as Nymox Patents (and not Recordati Patents) for all purposes outside the Territory and will be treated as Recordati Patents (and not Nymox Patents) for all purposes in the Territory.

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- (c) Recordati shall have the first right, but not the obligation, to bring suit for infringement in the Territory in its name, or in the name of Nymox if necessary, at its own expense, to restrain such infringement or unauthorized use and to recover profits and damages, or to otherwise halt the infringement. Nymox agrees to being joined as a Party plaintiff in any such suit and to cooperate in the prosecution thereof as is reasonably necessary, at the expense of Recordati. If Recordati decides to undertake such suit, then Recordati shall have the sole right to control prosecution, and the right to settle such action, provided, however that to the extent such infringement relates to Nymox Intellectual Property, any such settlement shall require the prior written consent of Nymox, which consent shall not be unreasonably withheld. Nymox shall provide Recordati with such assistance as Recordati shall reasonably request in connection with any action to prevent or enjoin any such infringement or unauthorized use of the Nymox Intellectual Property or Recordati Intellectual Property.
- (d) If Recordati fails to initiate suit or otherwise halt such infringement or unauthorized use of the Nymox Intellectual Property or Recordati Intellectual Property in the Territory within [\*\*\*] after becoming aware of any such infringement, in the first instance or by notice from Nymox, then Nymox, at any time prior to Recordati thereafter filing an action for infringement, shall have the right but not the obligation, at its own expense, to take such action in its own name as it deems necessary or appropriate. Recordati shall cooperate with Nymox as is reasonably necessary in any such action brought by Nymox and at no expense to Nymox. Recordati may elect to join or intervene in any such action brought by Nymox in its own name, at the expense of Recordati, and be represented by its own counsel. If Nymox brings legal action for Patent infringement or to otherwise halt unauthorized use of the Nymox Intellectual Property or Recordati Intellectual Property, Nymox shall have the sole right to control prosecution, and the right to settle such action with the prior written consent of Recordati, which consent shall not be unreasonably withheld.
- (e) Nymox shall have the first right, but not the obligation, to bring suit for infringement outside the Territory in its name, or in the name of Recordati if necessary, at its own expense, to restrain such infringement or unauthorized use and to recover profits and damages, or to otherwise halt the infringement. Recordati agrees to being joined as a Party plaintiff in any such suit and to cooperate in the prosecution thereof as is reasonably necessary, at the expense of Nymox. If Nymox decides to undertake such suit, then Nymox shall have the sole right to control prosecution, and the right to settle such action, provided, however that to the extent such infringement relates to Recordati Intellectual Property, any such settlement shall require the prior written consent of Recordati, which consent shall not be unreasonably withheld. Recordati shall provide Nymox with such assistance as Nymox shall reasonably request in connection with any action to prevent or enjoin any such infringement or unauthorized use of the Recordati Intellectual Property or Nymox Intellectual Property.
- (f) If Nymox fails to initiate suit or otherwise halt infringement or unauthorized use of the Recordati Intellectual Property outside the Territory within [\*\*\*] after becoming aware of any such infringement, in the first instance or by notice from Recordati, then Recordati, at any time prior to Nymox thereafter filing an action for infringement, shall have the right but not the obligation, at its own expense, to take such action in its own name as it deems necessary or appropriate. Nymox shall cooperate with Recordati as is reasonably necessary in any such action brought by Recordati and at no expense to Recordati. Nymox may elect to join or intervene in any such action brought by Recordati in its own name, at the expense of Nymox, and be represented by its own counsel. If Recordati brings legal action for Patent infringement or to otherwise halt unauthorized use of the Recordati Intellectual Property, Recordati shall have the sole right to control prosecution, and the right to settle such action with the prior written consent of Nymox, which consent shall not be unreasonably withheld.
- (g) The Parties hereby agree and acknowledge that, notwithstanding the provisions of this Section 8.12, a Party shall not have the right to bring a suit or other action against a Third Party for infringement or unauthorized use of any Platform Patent (as defined below) owned or Controlled by the other Party to the extent that the Party owning or Controlling such Platform Patent determines (in its sole discretion) that taking action against a Third Party would put

such Platform Patent at risk of being rendered invalid or unenforceable in connection with such suit or other action. As used herein, the term **Platform Patent** means a Patent that claims a technology that is used in the Product and which is also used in another product, including, for example, a patented formulation technology.

- (h) In the event any monetary recovery is obtained in connection with any action taken pursuant to Section 8.12(c), (d), (e) or (f) above, such recovery shall be applied in the following priority: first, to reimburse Nymox and Recordati by the proportion and up to the extent of their out-of-pocket expenses (including reasonable attorneys fees) in prosecuting such action; and second, the remainder (if any) to be shared equally between Recordati and Nymox (including sharing equally any recoveries that Nymox is entitled to receive in connection with the enforcement of In-Licensed Rights pursuant to an In-License after Nymox recovers any out-of-pocket expenses incurred in connection with such activities).
- **8.13 Claimed Infringement of Third Party Rights in the Territory.** Each of the Parties will notify the other promptly in writing in the event that it becomes aware of or suspects any claim, threat of, or suit for infringement by any Third Party directed against the manufacture, packaging, use, sale, offer to sell or import of Product in the Territory. The Parties will support each other with advice or any statements or documents to support the defence of any such claims or suits.
- **8.14 Updates.** Unless otherwise agreed, each Party will provide and update free of cost during the Term, copies of any physical embodiment of Know-How subject to a license granted hereunder, and complete copies of any Patents claiming Intellectual Property subject to a license granted hereunder and applied for or granted after the Effective Date, including any relevant prosecution information thereof. The Parties will provide and update free of cost during the Term and at least on an annual basis complete copies of any Patents granted from the Nymox Intellectual Property or Recordati Intellectual Property, and information about Data Exclusivity, after the Effective Date, including any relevant prosecution information thereof.

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#### D. TRADEMARKS

**8.15 Trademarks.** The JSC will be responsible for selecting a trademark(s) for the use on or in connection with the Product in the Territory (the **Product Trademark(s)** ). Nymox will be responsible for registration and defence of such Product Trademark(s) outside of the Territory and will be the sole owner of such Product Trademark outside of the Territory. Recordati will be responsible for registration and defence of such Product Trademark(s) in the Territory and will be the sole owner of such Product Trademark in the Territory. The JSC will aim to select trademark(s) that are suitable as global trademarks, provided, however, that Recordati may determine to seek unique trademarks or additional trademarks, different from the Product Trademark(s) for inside the Territory or a part thereof if it determines that a global trademark would negatively affect Commercialization of the Product in the Territory or a part thereof or if Recordati considers to co-market the Product in some of the countries of the Territory. Each Party shall use Commercially Reasonable Efforts to ensure that the nature and quality of their use of the Product Trademarks do not detract from the goodwill associated with such Product Trademarks. Neither Party shall file any application to register any mark that is confusingly similar to the Product Trademark at any time during the Term or thereafter. Neither Party shall challenge the other Party stitle to or rights in such Product Trademarks. Each Party shall ensure that the Product Trademarks are (a) used in conjunction with the ® or designations as applicable; (b) not modified by in any manner without the prior written consent of the other Party (such consent not to be unreasonably withheld); (c) not combined with any other terms or designs as a composite mark or otherwise used with any other terms or designs in a manner that materially tarnish or dilute such Product Trademarks without the other Party's prior written consent.

**8.16 Product Trade Dress.** The Product will be supplied by Nymox in accordance with the Supply Agreement and presented in packaging and trade dress selected and owned by Recordati in the Territory.

**8.17 Marking.** In conjunction with the Commercialization of Product, Recordati, its Affiliates and its Sublicensees shall, to the extent required by Applicable Law and Regulatory Authorities approvals, explicitly refer to any relevant Nymox Patents and the Nymox license. All Product shipped, marketed, or sold by Recordati, its Affiliates and its Sublicensees shall be marked on the package, on the package insert, or as otherwise required by Applicable Law, with all relevant patent numbers of the Nymox Patents as reasonably requested by Nymox to preserve all rights with respect to such Patents under Applicable Law, provided that such marking obtains approval by the relevant Regulatory Authorities in the Territory. All Product shall be marked to indicate that it is sold under license by Nymox as required by law or required by Nymox. To the extent any Nymox Trademarks are used, such use shall be consistent with guidelines to be supplied by Nymox, which guidelines shall be reasonable and consistent with prevailing industry standards and Applicable Law.

#### E. DOMAIN NAMES

**8.18 Domain Names.** Recordati shall use Commercially Reasonable Efforts to register and maintain in the Key Countries of the Territory, at its sole cost, and to the extent allowed by Applicable Law, the ccTlds ( **Country Code Top Level Domain** ), including the ccTld .eu, of the Product Trademark(s) used in the Key Countries of the Territory. Recordati may do so at its discretion in the other countries of the Territory. Recordati will be responsible for registration and defence of such ccTlds names and will be their sole owner in the Territory. Nymox shall be responsible for registration and defence of the gTld .com ( **Generic Top Level Domain** ) of the Product Trademark(s) within and outside the Territory and shall be responsible for registration and defence and will be the sole owner of such ccTlds names outside of the Territory. Each Party shall use Commercially Reasonable Efforts to operate such sites in accordance with Applicable Law.

#### F. COOPERATION

- **8.19** Coordination of Intellectual Property. The Parties shall cooperate in good faith on strategic issues with respect to the Intellectual Property related to the Compound or Product on a global basis, including:
- (a) Preparing a global Patent strategy for the Compound and/or Product and/or any Inventions.
- **(b)** Discuss upcoming actions needed to be taken with respect to Nymox Patents, Recordati Patents, Joint Owned Patents or Inventions, that is in compliance with the global Patent and freedom to operate strategy.
- (c) Discuss any Third Party rights of potential relevance to the Development or Commercialization of the Product inside the Territory and define a strategy for dealing with such rights.
- (d) The Parties shall endeavour to promptly resolve any disagreement regarding such Intellectual Property through communication between Chief Patent Counsel (or equivalent) of each Party, or his/her delegate.

#### ARTICLE IX.

#### REPRESENTATIONS, WARRANTIES AND COVENANTS

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- 9.1 Mutual Representations and Warranties and Covenants.
- **9.1.1 Mutual Representations and Warranties.** Each Party represents and warrants to the other that, as of the Effective Date:
- (a) **Power.** It is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation, and has all requisite power and authority, corporate or otherwise, to conduct its business and to enter into this Agreement and to carry out the provisions hereof.
- **(b) Due Authorization.** The execution, delivery and performance by it of this Agreement has been duly authorized by all necessary corporate action and does not and will not (i) require any consent or approval of its stockholders, (ii) violate any provision of any law, rule, regulation, order, writ, judgment, injunction, decree, determination or award presently in effect having applicability to it or any provision of its charter or by-laws, or (iii) result in a breach of or constitute a default under any agreement, mortgage, lease, license, permit, patent or other instrument or obligation, written or oral, to which it (or any of its Affiliates) is a party or by which it (or any of its Affiliates) or its (or any of its Affiliate s) assets may be bound or affected. No authorization, consent, approval, license, exemption of, or filing or registration with, any court or governmental authority or regulatory body is required for the due execution, delivery or performance by it of this Agreement.
- (c) Binding Agreement. This Agreement is legally binding upon it, enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it (i) does not conflict with any agreement, instrument or understanding, oral or written, to which it (or any of its Affiliates) is a party or by which it (or any of its Affiliates) may be bound, and (ii), to its Knowledge, does not violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.
- **9.1.2 Mutual Covenants.** Each Party hereby covenants to the other Party that:
- (a) Grant of Rights; Maintenance of Agreements. It (and its Affiliates) will not during the Term, grant any right to any Third Party that would conflict with the obligations or rights granted to the other Party hereunder. It (and its Affiliates) has (or will have at the time performance is due) maintained and will maintain and keep in full force and effect all agreements (including license agreements) and filings (including Patent filings) necessary to perform its obligations hereunder, including by making all required payments thereunder.
- **(b)** Compliance with Standards and Guidelines. Any Development, manufacturing, marketing and sale of Product shall be conducted by it (and its Affiliates) in compliance with cGLP, cGCP and cGMP standard, as applicable to such activities, and all other Applicable Laws.
- 9.2 Representations, Warranties and Covenants of Nymox to Recordati.
- **9.2.1 Representations and Warranties of Nymox.** Except as otherwise disclosed on <u>Schedule 9.1</u> (the **Nymox Disclosure Schedules**), Nymox makes the following representations and warranties to Recordati as of the Effective Date and, limited to the representations and warranties under letters (a) and (e), throughout the Term. In the event, during the Term, Nymox becomes aware that any of these representation or warranties are no longer accurate, Nymox will provide prompt written notice to Recordati specifying the respect in which such representations or warranties are no longer accurate, provided that Nymox shall take no action nor suffer that others take unopposed action in such a manner that such representation or warranties become no longer accurate.

- (a) Nymox has title to, owns or Controls the Nymox Patents, the Nymox Know-How and all of the other Nymox Intellectual Property licensed to Recordati pursuant to this Agreement;
- **(b)** Annex C sets forth a true and complete list of the Nymox Patents as of the Effective Date, indicating the current status, date and country of filing and issuance, related to the Compound or Product in the Territory;
- (c) Nymox has no Knowledge of any information that would render invalid and/or unenforceable any of the Nymox Patents and none of the Nymox Patents are currently involved in any interference, reissue, reexamination, or opposition proceeding;
- (d) There are no claims or actions of which Nymox (or any of its Affiliates) has received notice, and, to Nymox s Knowledge, there are no allegations made, pending, or threatened, in any court or tribunal or before any governmental agency specifically alleging that any of the Nymox Intellectual Property is invalid, unenforceable or that the use of any such Nymox Intellectual Property (including the use in the Development, manufacturing and Commercialization of Product) constitutes an infringement or misappropriation of Intellectual Property owned by a Third Party;
- (e) Nymox has not (and its Affiliates have not) granted any rights related to the Compound or Product to any Third Party which would conflict with the rights granted to Recordati hereunder;

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- (f) To Nymox s Knowledge, the research, Development, Manufacture, importation, packaging, use, Commercialization, sale, storage, or handling of the Compound or the Product in the Territory do not infringe any Intellectual Property rights of any Third Party.
- (g) All documents and information provided by Nymox to Recordati relating to the Compound and the Product are accurate, not misleading and free from material omissions and no material fact or circumstance that could reasonably be anticipated to materially impair the commercial value of the Compound or the Product in the Territory has been withheld from Recordati.
- (h) Nymox has not been debarred by the FDA under the Generic Drug Enforcement Act of 1992 (or by any analogous agency or under any analogous law or regulation), and neither it nor, to its Knowledge, any of its officers or directors has ever been convicted of a felony under the laws of the USA and/or European Union for conduct relating to the development or approval of a drug product or relating to the marketing or sale of a drug product, and further, to its Knowledge, no individual or firm debarred by any governmental authority will participate in the performance, supervision, management or review of the production of Compound or Product supplied to Recordati under this Agreement;
- 9.3 Representations, Warranties and Covenants of Recordati to Nymox.
- **9.3.1 Representations and Warranties of Recordati.** Except as otherwise disclosed on <u>Schedule 9.2</u> (the **Recordati Disclosure Schedules** ), Recordati makes the following representations and warranties to Nymox as of the Effective Date. In the event, during the Term, Recordati becomes aware that any of these representation or warranties are no longer accurate, Recordati will provide prompt written notice to Nymox specifying the respect in which such representations or warranties are no longer accurate, provided that Recordati shall take no action nor suffer that others take unopposed action in such a manner that such representation or warranties become no longer accurate.
- (a) Recordati has been provided access to, and has had the opportunity to review all material documents provided by Nymox relating to the Compound and the Product and has had the opportunity to bring up any material issue of conflict or other relevance.
- (b) Recordati has sufficient expertise, experience, personnel and resources to evaluate all material information and Data relating to the Nymox Intellectual Property, the Compound and the Product provided or made available by Nymox.
- (c) Recordati has not been debarred by the FDA under the Generic Drug Enforcement Act of 1992 (or by any analogous agency or under any analogous law or regulation), and neither it nor, to its Knowledge, any of its officers or directors has ever been convicted of a felony under the laws of the USA and/or European Union for conduct relating to the development or approval of a drug product or relating to the marketing or sale of a drug product, and further, to its Knowledge, no individual or firm debarred by any governmental authority will participate in the research, Development or Commercialization of the Compound or Product by or on behalf of Recordati under this Agreement.
- **9.4 Recovery.** No Party shall (i) recover from the other Party more than once for a single cause of action under any liability or warranty granted under this Agreement or (ii) recover if such Party has been relieved by or has recovered from a Third Party.
- **9.5 LIMITATION OF LIABILITY.** NO PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF

SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, (I) NOTHING IN THIS SECTION 9.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE XIII AND (II) NOTHING IN THIS SECTION 9.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY TO THE EXTENT A THIRD PARTY RECOVERS ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES FROM THE OTHER PARTY.

**9.6 Express Warranties.** Any claims the Parties may have for breach of warranty shall be based solely on the warranties expressly set forth in this Agreement. Notwithstanding the foregoing, nothing herein shall relieve any Party from any liability for fraud.

9.7 DISCLAIMER OF WARRANTIES. EXCEPT AS SPECIFICALLY SET FORTH IN THIS AGREEMENT NEITHER PARTY MAKES ANY REPRESENTATIONS NOR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, OR WITH RESPECT TO THE INTELLECTUAL PROPERTY LICENSED HEREUNDER, THE COMPOUND OR THE PRODUCT, OR THAT THE USE OF SUCH INTELLECTUAL PROPERTY, COMPOUND, PRODUCT OR ANYTHING DEVELOPED OR SOLD UNDER THIS AGREEMENT WILL NOT INFRINGE ANY THIRD PARTY RIGHTS. THE LIMITED WARRANTIES CONTAINED IN THIS AGREEMENT ARE THE SOLE WARRANTIES GIVEN BY THE PARTIES AND ARE MADE EXPRESSLY IN LIEU OF AND, EXCEPT AS SPECIFICALLY SET FORTH IN THIS AGREEMENT, EXCLUDE ANY IMPLIED REPRESENTATIONS OR WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR TITLE, OR THAT ANY PATENT WILL ISSUE BASED UPON ANY PENDING PATENT APPLICATION OR THAT ANY PATENT WHICH ISSUES OR IS ALREADY ISSUED WILL BE OR IS VALID OR THAT THE USE OF ANY LICENSE GRANTED HEREUNDER OR THE USE OF ANY INTELLECTUAL PROPERTY WILL NOT INFRINGE THE PATENT OR PROPRIETARY RIGHTS OF ANOTHER PERSON, AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES PROVIDED BY ANY STATUTE, COMMON LAW, OR OTHERWISE ARE HEREBY DISCLAIMED BY EACH PARTY.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

# ARTICLE X. CONFIDENTIALITY

- **10.1 Undertaking.** Unless provided herein otherwise, each Party shall keep confidential, and shall not use or disclose, directly or indirectly, any trade secrets, confidential or proprietary information, or any other confidential or proprietary Knowledge, information, documents or materials, owned, Developed or first acquired by the other Party, including without limitation, any such information as was disclosed pursuant to the Confidentiality Agreement (the **Information**), whether in tangible or intangible form, such Information including but not limited to Nymox Intellectual Property and Recordati Intellectual Property.
- **10.1.1** Each Party shall use reasonable care (but in no case less than the degree of care such Party uses with its own Information) to prevent the unauthorised use and disclosure of the other Party s Information, and to prevent unauthorised persons or entities from obtaining or using such Information.
- **10.1.2** Each Party may disclose any Information to its Affiliates, officers, employees and agents (including attorneys and consultants), to its Sublicensees and subcontractors, in connection with the research, Development, manufacture, packaging and Commercialization of the Compounds or Product, to the extent necessary to enable such Parties to perform their obligations hereunder or under the applicable Sublicense or subcontract, as the case may be; provided, that such Affiliates, officers, employees, agents (including attorneys and consultants), Sublicensees and subcontractors are subject to obligations of confidentiality and non-use at least as strict as those contained in this Agreement and that Nymox or Recordati, as applicable, shall enforce such obligations in a diligent manner.
- **10.1.3** Neither Party shall make any use of the other Party's Information except as expressly permitted hereunder.
- **10.1.4** Each Party shall be liable for any unauthorised use and disclosure of such information by its officers, employees and agents, Affiliates and any such Sublicensees and subcontractors.
- **10.2 Exceptions.** The provisions of Section 10.1 hereof shall not apply to Information that:
- (a) was known to the receiving Party prior to the disclosure by the disclosing Party as demonstrated by written records of the receiving Party;
- (b) has entered the public domain without such Party s breach of any obligation owed to the disclosing Party;
- (c) is permitted to be disclosed by the prior written consent of the disclosing Party;
- (d) has become known to the receiving Party from a source other than the disclosing Party, other than by breach of any obligation of confidentiality owed to the disclosing Party by contract or otherwise, as evidence by written records of the receiving Party;
- (e) is independently developed by the receiving Party without breach of this Agreement as proven by written evidence of the receiving Party; or
- (f) is required to be disclosed by the receiving Party to comply with Applicable Laws or the order of court of competent jurisdiction, to defend or prosecute litigation arising under this Agreement, or otherwise to comply with its obligations, or enforce its rights, under this Agreement, in each case, provided that the receiving Party, to the extent permitted by Applicable Law and practical, provides prior written notice of such disclosure to the disclosing Party in sufficient time to permit the respective Party to object and to take certain precautions (for example, filing of Patents or

filing of a protective order), if the respective Party so desires. The receiving Party shall use Commercially Reasonable Efforts to take any and all reasonable and lawful actions to avoid or minimize the degree of any such disclosure. The Parties will co-operate in interposing an objection to such requirement or in seeking appropriate limitations or protections in connection therewith.

In addition, nothing in this provision will prevent either of the Parties from issuing statements that such Party reasonably determines to be necessary to comply with Applicable Law (including the disclosure requirements of any stock exchange on which securities issued by such Party are traded); provided that, to the extent practicable under the circumstances, such Party shall provide the other Party with a copy of the proposed text of such statements sufficiently in advance of the scheduled release thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

**10.3 Publicity.** The Parties may only disclose the statements set forth in Annex G as attached hereto (in that form or in substantially similar form) for their press releases or other public communications relating to this Agreement. Should a Party wish to refer to any content beyond the scope of Annex G the Parties will agree upon such content of any press release or other public communications relating to this Agreement and the transactions contemplated herein. The timing of the first press release or public communication shall be mutually agreed between the Parties.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- **10.3.1** Except to the extent defined in Annex G, or already disclosed in a press release or other public communication approved by the other Party, neither Party shall make a public announcement concerning the existence or the terms of this Agreement, either directly or indirectly, by Nymox or Recordati, except as may be legally required by Applicable Laws, regulations, or judicial order including the disclosure requirements of any stock exchange on which securities issued by such Party are traded (provided that, to the extent practicable under the circumstances, such Party shall provide the other Party with a copy of the proposed text of such statements sufficiently in advance of the scheduled release thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text), without first obtaining the approval of the other Party and agreement upon the nature, text, and timing of such announcement, which approval and agreement shall not be unreasonably withheld. For avoidance of doubt, the foregoing shall not limit either Party s right or ability to disclose any financial results, including earnings (or losses), incurred in connection with the activities described herein.
- **10.3.2** The Party desiring to make any such public announcement shall provide the other Party with a written copy of the proposed announcement in sufficient time prior to public release to allow such other Party to comment upon such announcement, prior to public release.

#### 10.4 Publications.

- **10.4.1** Each Party shall submit to the JSC for review and approval all publications produced by or on behalf of such Party (or any of its Affiliates or Sublicensees) relating to Clinical Trials of the Compound or Product (including the results thereof; but excluding Non-Regulatory Clinical Trials) prior to the publication thereof. With respect to any publication concerning the Compound or Product produced by or on behalf of a Party (or any of its Affiliates or Sublicensees) related to Non-Regulatory Clinical Trials, such Party shall, prior to the publication thereof, submit such publication to the JSC for its review and comment (but not approval), and such Party shall consider any comments of the JSC thereto in good faith.
- **10.4.2** All publications relating to the Compound and/or the Product shall be prepared, presented and/or published in accordance with pharmaceutical industry accepted guidelines including, but not limited to: (1) International Committee of Medical Journal Editors (ICMJE) guidelines, (2) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, (3) Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines, and (4) Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results and for publications in Europe, comparable European guidelines.
- **10.4.3** The Parties shall have the right to use reprints of the publications (including posters) produced by or on behalf of either Recordati, its Affiliates or Sublicensees or Nymox, its Affiliates or Participating Sublicensees, in each case, relating to the Compound and/or the Product in a manner which is not inconsistent with this Agreement.
- **10.5 Extension of Obligation.** Without limiting the applicability of all restrictions and obligations hereunder, the Parties will specifically obligate their respective Affiliates, subcontractors, Sublicensees or other relevant partners to under this Article X.

**10.6 Survival.** The provisions of this Article X, excluding Section 10.4, shall survive the termination of this Agreement and shall extend for a period of ten (10) years thereafter.

ARTICLE XI.
DISPUTE RESOLUTION

**11.1 Governing Law.** This Agreement shall be governed by, and interpreted in accordance with the laws of the State of New York, without reference to conflicts of laws principles; provided however, that the validity of all Intellectual Property rights hereunder shall be determined under the laws of that jurisdiction in which those Intellectual Property rights are registered or for which an application for registration has been filed. The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this Agreement.

## 11.2 Disputes; Jurisdiction and Arbitration.

**11.2.1 JSC Disputes.** In the event that the JSC is unable to resolve a dispute within its authority pursuant to Section 7.2.4, the disputed matter will be referred to senior (CEO or other executives delegated by it) executives of Nymox and Recordati who will discuss the matter in good faith and attempt to find a mutually satisfactory resolution to the issue. If the CEOs of the Parties are unable to reach a joint consensus within [\*\*\*] after such dispute is first presented to them, then the provisions of Section 11.2.2 shall apply with respect to such dispute.

#### 11.2.2 Decision Making Authority.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (a) Nymox shall have final decision-making authority in resolving conflicts between the Parties relating to the Development of the Product and Compound, in each case, subject to the exceptions provided in 11.2.2(b) as applicable. In no event shall Nymox exercise such decision-making authority in a manner that would (i) impose additional costs (including reimbursement obligations) or otherwise materially increase Recordati s obligations hereunder (including obligations to devote resources or personnel) without the prior written consent of Recordati in its sole discretion or (ii) modify (i.e. reduce and/or increase) the general scope of activities to be performed by the Parties under the initial Development Plan, without the written consent of Recordati in its sole discretion.
- (b) Recordati shall have final decision-making authority in resolving conflicts between the Parties relating to: (i) specific Development activities that are required by Regulatory Authorities or useful to obtain or maintain Regulatory Approval for the Product in the Initial Indication or any Agreed Indications in the Territory, (ii) regulatory matters with respect to the Product in the Territory, including any regulatory submissions, communications and filings, but (subject to Section 11.2.2(b)(iii)) excluding such matters to the extent relating to the manufacture of the Compound or Product by Nymox, or by a Third Party on behalf of Nymox, including the contents of any DMF, (iii) manufacturing matters with respect to the Compound and Product in the Territory to the extent Recordati (or its Affiliates or subcontractors) is manufacturing Compound or Product in accordance with the terms of this Agreement, and (iv) Commercialization of the Product within the Territory, including the contents of any Commercialization Plan.
- (c) Nymox shall have final decision-making authority in all matters relating to the Compound and Product outside the Territory, including (i) Development activities, (ii) obtaining and maintaining Regulatory Approvals and (iii) all Commercialization matters, each outside the Territory.
- (d) Notwithstanding the foregoing, neither Party shall exercise any such final decision making authority (and except as otherwise expressly set forth herein, neither Party (nor its Affiliates or its Sublicensees) shall undertake any Development or Commercialization of the Product) in a manner that would reasonably be anticipated to have a material adverse affect on the Development or Commercialization of the Product within the other Party s territory, except to the extent that such activities are required by Applicable Law, or are otherwise required by Regulatory Authorities to obtain or maintain Regulatory Approval for the Product for an Indication for which such Party has the right to Develop and Commercialize the Product in such Party s territory. To the extent the Parties disagree on whether a given decision (or a specific Development or Commercialization activity) would have a material adverse affect on the Development or Commercialization of the Product within the other Party s territory, such issue will be resolved pursuant to arbitration as set forth in Section 11.2.3. In addition, any dispute of the JSC related to Development which is not resolved pursuant to 11.2.1 and that is not subject to the final decision making authority of either Party pursuant to this Section 11.2.2 shall be resolved pursuant to arbitration as set forth in Section 11.2.3.
- (e) Notwithstanding the foregoing provisions of Section 11.2.2, neither Party shall exercise its right to finally resolve a dispute pursuant to the provisions of Section 11.2.2, as applicable, in a manner that conflicts with the provisions of this Agreement, excuses such Party from any of its obligations specifically enumerated under this Agreement or in a manner that negates any consent rights or other rights specifically allocated to a Party under this Agreement. In addition, a Party that has the right to finally resolve a dispute pursuant to the provisions of Section 11.2.2 shall act in good faith.
- **11.2.3 Arbitration.** Any dispute relating to the validity, performance, construction or interpretation of this Agreement which cannot be resolved amicably between the Parties (or any other dispute which is subject to arbitration pursuant to Section 11.2.2 or as otherwise expressly set forth in this Agreement) shall be submitted to binding arbitration, to be held in New York, NY, in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce (the **ICC Rules**). Any arbitration proceeding under this Agreement shall be conducted in the English language before an arbitration panel composed of three (3) arbitrators, who shall be selected as follows: (i) each Party

shall select one (1) arbitrator within [\*\*\*] after the date on which one of the Parties gives written demand for arbitration in accordance with the ICC Rules; and (ii) the third arbitrator, who shall act as chairman of the arbitration panel, shall be selected by the other two arbitrators, within [\*\*\*] after the other two arbitrators have been selected; provided, however, that, in the event that a Party fails to select an arbitrator, or the two arbitrators selected by the Parties fail to select a third arbitrator, in accordance with the provisions of this Section 11.2.3, such arbitrator shall be selected by the Chairman of the International Chamber of Commerce, upon written request therefor by either of the Parties. The decision and award of the arbitrators in any arbitration proceeding between the Parties under this Section 11.2.3 shall be: (i) in writing, stating the reasons therefor; (ii) based solely on the terms and conditions of this Agreement, as interpreted in accordance with the laws of the State of New York; and (iii) final and binding upon the Parties hereto.

# ARTICLE XII. TERM AND TERMINATION

#### A. TERM

- **12.1 Term.** This Agreement shall become effective upon the Effective Date and the Term of this Agreement ( **Term** ) shall extend until the expiration of the Royalty Term for all countries within the Territory, unless this Agreement is earlier terminated by mutual agreement between the Parties or otherwise in accordance with the provisions of this Section.
- **12.2 Termination.** The Parties will negotiate with Commercially Reasonable Efforts in good faith to find an amicable way to resolve unforeseen problems not dealt with in this Agreement. In case of early termination in accordance with the terms hereof, the Parties will cooperate in good faith towards a transition of assets or activities that minimizes or avoids disruption in the Development and Commercialization of the Product.

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#### **B. REASONS FOR TERMINATION**

12.3 Termination for Material Breach. In addition to rights of termination which may be granted to either Party under other provisions of this Agreement, either Party may terminate this Agreement: (a) upon [\*\*\*] prior written notice to the other Party following failure by the other Party to make any payment as and when due hereunder and (b) upon [\*\*\*] prior written notice to the other Party following any other material breach by such other Party of any of its material representations, material warranties (which include all representations and warranties set out in Sections 9.1, 9.2 and 9.3), material covenants or material obligations under this Agreement, provided in each case that such termination shall become effective only if the written notice specifies the nature of the breach and the breaching Party shall fail to remedy or cure the breach within [\*\*\*] of receiving such notice and provided that the notice of termination shall be delivered within [\*\*\*] of the date the Party giving notice becomes aware of the material breach on which the intended termination is founded. If a Party s right to terminate this Agreement pursuant to this Section 12.3 is being disputed by the other Party, which dispute is being diligently pursued by such other Party by appropriate proceedings hereunder, such termination shall not be deemed effective unless an arbitration decision confirms a material breach of this Agreement as described above and the breaching Party fails to cure such breach within [\*\*\*] following such arbitration decision. Both Parties will be required to perform in accordance with this Agreement during the pendency of any such dispute.

12.4 Termination for Bankruptcy. Nymox or Recordati, as the case may be, shall have the right to terminate this Agreement, immediately upon giving written notice of termination to the other Party, in the event that the other Party files a voluntary petition, or suffers the filing of a substantiated involuntary petition under the bankruptcy provisions of Applicable Law, is declared insolvent, undergoes voluntary or involuntary dissolution, makes an assignment for the benefit of creditors, or suffers the appointment of a receiver or trustee over all, or substantially all, of its assets or properties. The Parties agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party, the other Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under Applicable Law, subject to performance by such licensee Party of its obligations under this Agreement. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) all of such bankrupt party s Intellectual Property and Know-How that is subject to a license under this Agreement, if not already in such non-bankrupt Party s possession, and that such materials shall be promptly delivered to such non-bankrupt Party upon any such commencement of a bankruptcy proceeding upon written request therefore by such non-bankrupt Party.

**12.5 Termination by Recordati.** Recordati shall be permitted to terminate this Agreement as provided in this Section 12.5.

**12.5.1 Commercial Infeasibility.** In the event that Recordati reasonably determines that (i) it cannot market, distribute or sell the Products for the Indication(s) in any (or all) country or countries within the Territory on a profitable basis (considering the Territory as a whole), or (ii) is otherwise unable to obtain all Regulatory Approvals based on Commercially Reasonable Effort (to the reasonable satisfaction of Recordati, including with respect to the labelling) for the Product in any (or all) country or countries, in each case, Recordati shall have the right but not the obligation upon delivering [\*\*\*] written notice to Nymox to delete that country or those countries from the Territory; provided, however that to the extent Recordati so deletes (A) [\*\*\*] or (B) [\*\*\*], then this Agreement shall terminate in its entirety upon such notice.

## C. EFFECTS OF TERMINATION

**12.6 Effect of Termination.** Termination of this Agreement for any reason, or expiration of this Agreement, will not affect: (i) obligations, including the payment of any royalties or other amounts hereunder, which have accrued as to the date of termination or expiration, and (ii) rights and obligations which, from the context thereof, are intended to survive termination or expiration of this Agreement. Notwithstanding any expiration or termination of this Agreement, the terms and conditions of this Agreement shall apply to the determination and payment of any royalties or other amounts hereunder that have accrued before termination or, as set forth in Section 12.6.5, after termination, and remain unpaid or owing after the date of termination or expiration.

12.6.1 If Recordati terminates this Agreement according to Section 12.5.1, or Nymox terminates this Agreement under Sections 3.4.5, 12.3 or 12.4, or if this Agreement automatically terminates under Section 4.1.1, in addition to any other remedies available to Nymox or to Recordati at law or in equity: (A) all licenses granted to Recordati for such countries that are covered by termination shall end immediately and Recordati shall have no further right to use or cross-reference Nymox s Data and Regulatory Approvals in such countries, or to use Nymox Intellectual Property, or to use Joint Intellectual Property for the Product in such countries; (B) Recordati shall transfer and assign (or license or provide a right of reference, as applicable, to the extent Recordati is prohibited from transferring or assigning) to Nymox, any regulatory filings or Regulatory Approvals (e.g. MAs) covering the Product in such countries, all Data Exclusivity and non-clinical and Clinical Data owned or Controlled by Recordati covering the Product in such countries and all other information (including all Data) owned or Controlled by Recordati necessary to enable Nymox to Develop or Commercialize Product in such countries, and if terminated for the entire Territory, all Recordati ownership portions in any Joint Intellectual Property to the extent these relate exclusively to the Product, at Recordati s costs and without any compensation; (C) if terminated for the entire Territory, at Nymox s request, Recordati shall deliver to Nymox, subject to the payment by Nymox of Recordati s Cost of Goods thereof, all inventory of finished Product for such countries in Recordati s possession or control; and (D) Recordati shall grant to Nymox an exclusive, fully-paid-up, transferable, perpetual, royalty free right and license for the Product for such countries under such Recordati Intellectual Property (provided that Nymox shall be required to pay any royalties or other amounts due to Third Parties on account of the use of such Recordati Intellectual Property).

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- **12.6.2** If Recordati has the right to terminate the Agreement under Sections 12.3 or 12.4, Recordati may choose (i) in addition to any other remedies available at law or in equity, that the Agreement continue in force and effect, or (ii) that the Agreement continue in force and effect, provided that Recordati s obligation to make payments hereunder, and certain other rights and obligations of the Parties hereunder, shall be modified as set forth in Section 12.6.3, or (iii) in addition to any other remedies available at law or in equity, that the Agreement and the licenses granted herein shall terminate, either effective immediately or within six (6) months, at Recordati s sole discretion, and on a country-by-country basis.
- **12.6.3** If Recordati chooses to permit the Agreement to continue as described in Section 12.6.2(ii), then this Agreement shall continue in all other respects except that the royalties and milestones payable under Article III shall be reduced by [\*\*\*]. If Recordati s right to terminate arose under Section 12.3, then such royalty reduction shall continue for so long as the relevant material breach remains uncured. If Recordati s right to terminate arose under Section 12.4, then such royalty reduction shall remain in effect for the remainder of the Term. All other remedies that would otherwise be available to Recordati hereunder in connection with the breach by Nymox shall be waived by Recordati, its Affiliates and Sublicenses if and when Recordati chooses to continue its licenses as described in Section 12.6.2(ii).
- **12.6.4** Upon expiration of this Agreement pursuant to Section 12.1, if Recordati has made all payments as and when they became due hereunder (including with respect to any cure period), and Recordati is not otherwise in breach of any of its material obligations hereunder (subject to cure during any cure period), then Recordati shall have a perpetual, irrevocable, fully paid-up, non-exclusive license and right of reference under the Nymox Intellectual Property, Regulatory Documentation and Regulatory Approvals to research, Develop, manufacture, package, import, market, promote, sell, distribute and use the Compound and the Product for the Agreed Indications in the Territory after the expiration of the Royalty Term.
- **12.6.5 Sale of Stock at Termination.** Subject to Nymox s right as provided for under Section 12.6.1 (C), and without prejudice to Recordati s other rights under this Agreement, upon termination of this Agreement in respect of the Territory or any part thereof and for up to [\*\*\*] thereafter (and if additional purchase orders are pending, for up to [\*\*\*] after their delivery), Recordati may continue Commercializing the residual stock of Product. Notwithstanding any expiration or termination of this Agreement, the terms and conditions of this Agreement shall apply to Recordati s Commercialization of the residual stock of Product.
- **12.6.6 Survival.** Notwithstanding anything to the contrary contained herein, the following provisions shall survive any expirat Section 12.6.6 or otherwise expressly set forth herein, upon termination or expiration of this Agreement all other rights and obligations of the Parties shall cease.

# ARTICLE XIII. INDEMNIFICATION

- **13.1 Indemnification by Recordati.** Recordati will indemnify and hold Nymox, and its Affiliates, and their employees, officers, directors and agents (each a **Nymox Indemnitee**) harmless against any loss, damages, action, suit, claim, demand, liability, expense, bodily injury, death or property damage (a **Loss**), asserted against or suffered by a Nymox Indemnitee in connection with a claim asserted by a Third Party against a Nymox Indemnitee to the extent such Loss is based on or arises out of:
- **13.1.1** the research, Development, manufacture, packaging, use, Commercialization, sale, storage or handling of the Compound or a Product by Recordati or its Affiliates, or its or their representatives, agents, Sublicensees or subcontractors (in each case, excluding a Nymox Indemnitee), or any actual or alleged violation of law resulting

therefrom (including Losses based on infringement or misappropriation of Intellectual Property rights);

- **13.1.2** the breach by Recordati of any of its material obligations, covenants, representations or warranties set forth in this Agreement;
- **13.1.3** acts or omissions of any of Recordati s Affiliates, or its or their representatives, agents, Sublicensees or subcontractors that constitute material breach of any provisions of this Agreement; or
- **13.1.4** the gross negligence or intentional misconduct of Recordati or its Affiliates, or its or their representatives, agents, Sublicensees or subcontractors (in each case, excluding any Nymox Indemnitee) relating to the matters that are the subject of this Agreement;

provided however, that the foregoing indemnification under Section 13.1 shall not apply to any Loss to the extent such Loss is caused by the breach by a Nymox Indemnitee of any material obligation, covenant, representation or warranty set forth in this Agreement, or the grossly negligent or intentional misconduct of a Nymox Indemnitee.

**13.2 Indemnification by Nymox.** Nymox will indemnify and hold Recordati and its Affiliates, and their employees, officers, directors and agents (each a **Recordati Indemnitee**) harmless against any Loss, asserted against or suffered by a Recordati Indemnitee in connection with a claim asserted by a Third Party against a Recordati Indemnitee to the extent such Loss is based on or arises out of:

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- **13.2.1** the research, Development, manufacture, packaging, use, Commercialization, sale, storage or handling of the Compound or a Product, by Nymox or its Affiliates or its or their representatives, agents, Sublicensees or subcontractors (in each case, excluding any Recordati Indemnitee), or any actual or alleged violation of law resulting therefrom (including Losses based on infringement or misappropriation of Intellectual Property rights);
- **13.2.2** the breach by Nymox of any of its material obligations, covenants, representations or warranties set forth in this Agreement;
- **13.2.3** acts or omissions of any of Nymox s Affiliates, or its or their representatives, agents, Sublicensees or subcontractors that constitute material breach of any provisions of this Agreement; or
- **13.2.4** the gross negligence or intentional misconduct of Nymox or its Affiliates, or its or their representatives, agents, Sublicensees or subcontractors (in each case, excluding any Recordati Indemnitee) relating to the matters that are the subject of this Agreement;

provided however, that the foregoing indemnification under Section 13.2 shall not apply to any Loss to the extent such Loss is caused by the breach by a Recordati Indemnitee of any material obligation, covenant, representation or warranty set forth in this Agreement, or the grossly negligent or intentional misconduct of a Recordati Indemnitee.

- 13.3 Control of Defence. In the event a Party seeks indemnification under Article XIII, it shall inform the other Party (the Indemnifying Party ) of a claim as soon as reasonably practicable after it receives notice of the claim, shall permit the Indemnifying Party to assume direction and control of the defence of the claim (including the right to settle the claim solely for monetary consideration and with an unconditional release of claims against the indemnitee), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defence of the claim. The indemnitee shall be entitled to participate, at its own expense and with its own counsel, in the defence of any indemnified claim and the Indemnifying Party shall not settle or compromise any such matter in any manner which would have an adverse effect upon the indemnitee without such indemnitee s consent, which shall not be unreasonably withheld or delayed. In addition, if the Indemnifying Party believes that it is not obligated to provide indemnity as to a matter as to which it is requested to do so by an indemnitee and promptly so notifies the indemnitee, the indemnitee may either take action to enforce its rights hereunder or assume the defence of such claim with its own counsel at its own expense, provided that the Indemnifying Party will be responsible for the payment of such expenses if it is ultimately determined such indemnitee was entitled to indemnification hereby.
- **13.4 Mitigation.** For the avoidance of doubt no Party shall recover from the other Party more than once for a single cause of action under an indemnity granted by an Indemnifying Party pursuant to this Agreement or recover if or to the extent the indemnitee has been relieved by or recovered from any Third Party. Each Party shall take and shall cause its Affiliates to take all reasonable steps to mitigate any Loss upon becoming aware of any event which would reasonably be expected to, or does, give rise thereto, including incurring costs only to the minimum extent necessary to remedy a breach that gives rise to the Loss.

#### 13.5 Insurance

13.5.1 During the Term hereof, Recordati, at its own expense, shall to the extent it Develops and Commercializes the Product as contemplated hereby, within the Territory maintain insurance, including product liability, bodily harm and property insurance, in an amount consistent with indemnity standards for claims and actions that might be brought against it in connection with the activities contemplated to be performed by Recordati hereunder. If requested, Recordati shall provide Nymox a certificate of insurance evidencing such coverage. Upon request Nymox shall provide to Recordati all necessary documentation (e.g. contingency plans) that are required for Recordati to obtain

business interruption insurance. Nymox shall subsequently keep Recordati updated on any changes hereto and Recordati shall be entitled to notice from the insurance carrier in the event the policy is materially amended or terminated.

13.5.2 During the Term hereof, Nymox, at its own expense, shall to the extent it manufactures the Product as contemplated hereby, within the Territory maintain insurance, including product liability, bodily harm and property insurance, in an amount consistent with indemnity standards for claims and actions that might be brought against it in connection with the activities contemplated to be performed by Nymox hereunder. If requested, Nymox shall provide Recordati a certificate of insurance evidencing such coverage. Upon request Recordati shall provide to Nymox all necessary documentation (e.g. contingency plans) that are required for Nymox to obtain business interruption insurance. Recordati shall subsequently keep Nymox updated on any changes hereto and Nymox shall be entitled to notice from the insurance carrier in the event the policy is materially amended or terminated.

# ARTICLE XIV. MISCELLANEOUS PROVISIONS

**14.1 Official Language.** English shall be the official language of this Agreement, and all communications between the Parties hereto shall be conducted in that language. For avoidance of doubt, neither Party shall be required to translate documents originally prepared in other languages and required to be delivered under this Agreement, but if a translation into English is available to and controlled by a Party, the translation shall be delivered along with the original document.

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- **14.2 Clinical Quality Assurance Agreement.** As soon as practicably possible after the Effective Date, the Parties shall enter into a separate and more detailed agreement concerning quality assurance in relation to clinical research, including Investigational Medicinal Product, and Data protection. Such agreement shall specifically include an obligation on the part of each of the Parties, whereby the Parties shall be obligated to reasonably aid and assist each other to the extent that either Party is required to comply with specific regulatory requirements and to the extent such compliance is dependent upon the cooperation between the Parties in the delivery of required information, documents and material.
- **14.3 Pharmacovigilance.** Each Party shall, and shall cause its respective Affiliates and Sublicensees to, furnish timely notice (as required by applicable worldwide regulations) to all competent governmental agencies within the Territory or outside the Territory of all side effects, drug interactions and other adverse effects identified or suspected with respect to the Product for the Indications administered, distributed, marketed and sold in accordance with the terms and conditions set forth in the Pharmacovigilance Agreement entered into by and between Nymox and Recordati as soon as practicable after the Effective Date.
- **14.4 Compliance with Laws.** Nothing in this Agreement shall be deemed to permit a Party to export, including outside Territory, re-export or otherwise transfer any Compound or Product sold under this Agreement without compliance with Applicable Laws. No later than [\*\*\*] prior to any planned launch of a Product that is to be marketed and/or sold for the Initial Indication and all Agreed Indications (if any) in the Territory, the Parties shall initiate negotiations, if relevant, in order to avoid any conflict with relevant competition laws.
- **14.5 Waiver.** No provision of the Agreement may be waived except in writing by both Parties hereto. No failure or delay by either Party hereto in exercising any right or remedy hereunder or under Applicable Law will operate as a waiver thereof, or a waiver of a particular right or waiver of any right or remedy on any subsequent occasion unless provided otherwise in this Agreement.
- **14.6 Force Majeure.** Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any Term of this Agreement, when such failure or delay is caused by or results from fire, floods, embargoes, government regulations, prohibitions or interventions, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts, acts of God, or any other cause beyond the reasonable control of the affected Party if such Party has taken the reasonable precautions a reasonable businessman of average diligence would take to avoid such cause.
- **14.7 Parties in Interest.** All of the terms and provisions of this Agreement shall be binding upon, inure to the benefit of and be enforceable by the Parties hereto and their respective permitted successors and assigns.
- **14.8 No Brokerage.** Each Party represents and warrants to the other that, except to the extent any such payment is the sole responsibility of such Party, no finder s fee, brokerage fee, commission or other payment is due to any Third Party claiming through such Party or its Affiliates with respect to the execution of this Agreement or the consummation of the transactions contemplated hereby.
- **14.9 Registration of License.** Each Party, where applicable, may, at its expense, register the License granted under this Agreement in any country in the Territory. Upon request by a Party, the other Party agrees promptly to execute any short form licenses submitted to it by such Party in order to affect the foregoing registration in such country, but such licenses shall in no way alter or affect the obligations of the Parties hereunder.
- **14.10 Severability.** It is the intention of the Parties to comply with all Applicable Laws domestic or foreign in connection with the performance of its obligations hereunder. In the event that any provision of this Agreement, or

any part hereof, is found invalid or unenforceable, the remainder of this Agreement will be binding on the Parties hereto, and will be construed as if the invalid or unenforceable provision or part thereof had been deleted, and the Agreement shall be deemed modified to the extent necessary to render the surviving provisions enforceable to the fullest extent permitted by law unless the initial intention of the Agreement is no longer reflected by the surviving provisions. The Parties will negotiate in good faith any modification of this Agreement with a view to revising this Agreement in a manner which reflects, as closely as is reasonably practicable, the commercial terms and legal intent of this Agreement as originally signed.

**14.11 Government Acts.** In the event that any act, regulation, directive, or law of a government, including its departments, agencies or courts, should make impossible or prohibit, restrain, modify or limit any material act or obligation of Recordati or Nymox under this Agreement, the Party, if any, not so affected shall have the right, at its option, to suspend or terminate this Agreement as to such country, unless good faith negotiations between the Parties to make such modifications to this Agreement as may be necessary to fairly address the impact thereof, after a reasonable period of time produce objectively acceptable modifications to this Agreement.

**14.12 Government Approvals.** Each Party undertakes to obtain any government approval required to enable this Agreement to become effective, or to enable any payment hereunder to be made, or any other obligation hereunder to be observed or performed. Each Party will keep the other informed of progress in obtaining any such approvals.

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14.13 Assignment. Except as provided in Sections 2.1 and 2.2, neither Party shall have the right or the power to assign any of its rights or any of its obligations under this Agreement, without the prior written authorization of the other Party, which authorization shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, Recordati may assign this Agreement in whole or in part to an Affiliate (provided that, as a precondition to such an assignment to an Affiliate, Recordati Industria Chimica e Farmaceutica S.p.A. shall provide a guaranty of such Affiliate s obligations hereunder) or successor company (whether by merger, asset acquisition or otherwise) and Nymox shall be free to assign this Agreement to any Affiliate (provided that, as a precondition to such an assignment to an Affiliate, Nymox Pharmaceutical Corporation shall provide a guaranty of such Affiliate s obligations hereunder) or successor company (whether by merger, asset acquisition or otherwise); provided however that in no instance may either Party assign this License and Collaboration Agreement to a Person without assigning the Supply Agreement simultaneously to the same Person. Any permitted assignment hereunder by either Party, whether to an Affiliate or pursuant to the prior written authorization of the other Party as provided in this Section shall not relieve the assigning Party of any of its obligations under this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.13 shall be null, void and of no legal effect.

**14.14 Affiliates.** Each Party may perform its obligations hereunder personally or through one or more Affiliates, although each Party shall nonetheless be solely responsible for the performance of its Affiliates. Neither Party shall permit any of its Affiliates to commit any act (including any act of omission), which such Party is prohibited hereunder from committing directly.

**14.15** Counterparts. This Agreement is executed in duplicate, both of which shall be deemed to be originals, and both of which shall constitute one and the same Agreement. This Agreement shall be deemed executed and delivered by the Parties upon the delivery by the second Party of a signed copy of the signature page below, such delivery to be deemed to occur upon receipt of such signed copy of the signature page by facsimile transmission by the first Party, with originally executed copies to be exchanged promptly thereafter by the Parties.

**14.16** No Agency. Nothing herein contained shall be deemed to create an agency, joint venture, amalgamation, partnership or similar relationship between Recordati and Nymox. Notwithstanding any of the provisions of this Agreement, neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever. Subject to the terms and conditions of this Agreement, all contracts, expenses and liabilities undertaken or incurred by one Party in connection with or relating to the Development, manufacture, packaging or sale of the Compound or Product shall be undertaken, incurred or paid exclusively by that Party, and not as an agent or representative of the other Party.

**14.17 Notice.** All communications between the Parties with respect to any of the provisions of this Agreement will be sent to the addresses set out below, or to other addresses as designated by one Party to the other by notice pursuant hereto, by prepaid certified air mail, or by cable, facsimile transmission, or other electronic means of communication (such electronic means shall be deemed received when confirmed), with confirmation by letter given by the end of the next following Business Day.

If to Recordati, at: Recordati Ireland Ltd, Raheens East, Ringaskiddy, Co Cork, Ireland Fax:[\*\*\*] Attention: Chairman and Managing Director.

with a copy to: Recordati S.p.A., Via M. Civitali 1

20148 Milano, Italy

Fax: [\*\*\*]

Attention: Legal Dept.

and if to Nymox, at: Nymox Pharmaceutical Corporation

9900 Cavendish Blvd. Suite 306

St.-Laurent, Quebec, Canada H4M 2V2

Fax: [\*\*\*]

Attention: Chief Financial Officer

With copies to: Nymox Pharmaceutical Corporation 9900 Cavendish Blvd. Suite 306 St.-Laurent, Quebec, Canada H4M 2V2

Fax: [\*\*\*]

Attention: General Counsel

**14.18 Headings.** The paragraph headings are for convenience only and will not be deemed to affect in any way the language of the provisions to which they refer.

**14.19 Language.** Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) include, includes and including are not limiting; (b) hereof, hereto, herein and and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (c) words of one gender include the other gender; (d) references to a contract or other agreement mean such contract or other agreement as from time to time amended, modified or supplemented (to the extent permitted by this Agreement); (e) references to an entity or person are also to its permitted successors and assigns; (f) references to an Article, Section, Annex or Schedule refer to an Article or Section of, or an Annex or Schedule to, this Agreement, unless expressly stated otherwise; and (g) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement.

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- **14.20 Authority.** The undersigned represent that they are authorised to sign this Agreement on behalf of the Parties hereto. The Parties each represent that no provision of this Agreement will violate any other agreement that such Party may have with any other person. Each Party has relied on that representation in entering into this Agreement.
- **14.21 No Strict Construction; Interpretation.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.
- **14.22 Further Assurances.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to perform all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- **14.23 Entire Agreement.** This Agreement, including the Annexes appended hereto, contains the entire understanding of the Parties relating to the matters referred to herein and may only be amended by a written document, duly executed on behalf of the respective Parties. For clarity, this Agreement shall supersede the terms and conditions of the Confidentiality Agreement, and from and after the Effective Date, the Confidentiality Agreement shall be of no further force and effect.

#### [NO FURTHER TEXT ON THIS PAGE]

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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorised representatives in duplicates as of the day, month and year first above written.

## Nymox Pharmaceutical Corp.

Signature: /s/ Paul Averback MD

Name: Paul Averback

Function: C.E.O.

Date: <u>December 16, 2010</u>

#### Recordati Ireland Ltd.

Signature: /s/ Andrea Recordati
Name: Andrea Recordati

Function: Chairman and Managing Director

Date: <u>December 16, 2010</u>

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#### LIST OF ANNEXES AND SCHEDULES

**Annex A: Compound** 

**Annex B: Initial Development Plan** 

**Annex C: Nymox Patents Annex D: Specifications** 

**Annex E: Territory** 

Annex F: Nymox In-Licensed Rights

**Annex G: Approved Statements** 

**Annex H: Supply Agreement** 

**Schedule 9.1: Nymox Disclosure Schedules** 

**Schedule 9.2: Recordati Disclosure Schedules** 

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# **Annex A: Compound**

[\*\*\*]

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

# **Annex B: Initial Development Plan**

[\*\*\*]

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

# **Annex C: Nymox Patents**

[\*\*\*]

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# **Annex D: Specifications**

[\*\*\*]

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#### **Annex E: Territory**

#### Geographical Europe:

The member states of the EU: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark and Farøer Is., Estonia, Finland and Åland Is., France and DOM TOM, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain (including Ceuta and Melilla), Sweden, and United Kingdom.

All other European countries, including Switzerland, Norway and Svalbard Is., Iceland, Bosnia and Herzegovina, Croatia, Macedonia, Montenegro, Albania, Serbia, Kosovo, Vatican City State, Monaco, Andorra, Gibraltar, Jersey, Guernsey, Isle of Man, Liechtenstein, and San Marino.

The member states of the CIS: Russia, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan and Ukraine.

The following other Asian countries: Turkmenistan and Uzbekistan

The Middle East region countries: Turkey, Egypt, Iran, Bahrain, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syria, United Arab Emirates (UAE), Yemen, Gaza Strip, and West Bank

The Maghreb: Algeria, Libya, Mauritania, Morocco (including Western Sahara) and Tunisia.

The following southern Africa countries: South Africa.

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# **Annex F: Nymox In-Licensed Rights**

[\*\*\*]

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### **Annex G: Approved Statements**

# Recordati and Nymox Pharmaceutical Corporation Announce European Licensing Agreement for NX-1207

Milan, Italy and Hasbrouck Heights, NJ (XXXX ##, 2010) Recordati (Milan: REC.MI) and Nymox Pharmaceutical Corporation (NASDAQ: NYMX) announced today the signing of a European licensing agreement for the development and commercialization of NX-1207, Nymox s Phase III investigational drug currently in clinical development in the U.S. for the treatment of benign prostatic hyperplasia (BPH).

Under the terms of the agreement, Recordati receives exclusive rights to develop and subsequently market and sell NX-1207 in Europe including Russia and the CIS, the Middle East, the Maghreb area of North Africa and South Africa (i.e. a total of 81 countries). The licensing agreement covers the use of NX-1207 for the treatment of BPH as the initial indication for development and commercialization. Recordati will make an upfront payment to Nymox of 10 million (approximately \$13 million); approval and sales milestones payments; and tiered supply and royalty payments of a minimum of 26% to increase progressively up to 40% of total net sales in the case specific contractual conditions are achieved.

RBC Capital Markets Corporation served as financial advisor and provided assistance to Nymox with respect to this transaction.

Giovanni Recordati, Chairman and CEO of Recordati said, We are very pleased with our new partnership with Nymox and believe the inclusion of NX-1207 in our development pipeline to be very important and in line with our commitment to increase the availability of new effective treatments for urological disorders. Dr. Paul Averback, CEO of Nymox said, The Board and Management of Nymox consider Recordati to be an ideal partner in Europe for this potential major advance in the treatment of BPH. Recordati has a long history in Europe of clinical, regulatory and commercial expertise and has provided a strong commitment to the development and marketing of NX-1207.

#### **About BPH**

Benign prostatic hyperplasia (BPH) or enlarged prostate is a common affliction of older men that causes difficulties with urination that can have a detrimental impact on health and quality of life and that can lead to acute urinary retention, incontinence, and other serious consequences. The disorder affects approximately half of men over age 50 and close to 90% of men by age 80, and is associated with growth in prostate size as men age. It is estimated that more than 100 million men worldwide suffer from the symptoms of BPH, including more than an estimated 20 million men in Europe alone. This market is anticipated to grow as the population ages.

# About NX-1207

NX-1207 is a novel patented drug developed by Nymox which is currently in Phase 3 trials in the United States for the treatment of BPH. The drug involves a new targeted approach to the treatment of BPH. The drug is administered by a urologist in an office setting directly into the zone of the prostate where the enlargement occurs. The procedure takes only a few minutes, causes little or no pain or discomfort, and does not require anaesthesia or catheterization. The drug has successfully completed a series of blinded controlled multi-center U.S. clinical trials where a single dose of NX-1207 has been found to produce very promising symptomatic improvements without causing the sexual or cardiovascular side effects associated with currently approved drugs. Follow-up studies have shown evidence of long lasting benefit with a significant proportion of men who received a single dose reporting maintained improvement in BPH symptoms without other treatments for several years.

#### About Recordati

Recordati, established in 1926, is a European pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of over 2,800, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. It has headquarters in Milan, Italy, operations in the main European countries, and a growing presence in the new markets of Central and Eastern Europe. A European field force of around 1,400 medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati s current and growing coverage of the European pharmaceutical market makes it a partner of choice for new product licenses from companies which do not have European marketing organizations. Recordati is committed to the research and development of new drug entities within the cardiovascular and urogenital therapeutic areas and of treatments for rare diseases. Consolidated revenue for 2009 was 747.5 million, operating income was 162.2 million and net income was 110.6 million. More information about Recordati is available at www.recordati.com; email: inver@recordati.it.

### About Nymox

Nymox is a biotechnology company engaged in the research and development of therapeutics and diagnostics, with a particular emphasis on products targeted for the unmet needs of the aging population. In addition to NX-1207 for BPH, Nymox has a number of drug development programs for oncology (prostate cancer and hepatocellular carcinoma), Alzheimer's disease, *E. coli* food contamination, and other indications. The Company offers NicAlert® and TobacAlert® tests for measuring tobacco product exposure, and has developed AlzheimAlert®. More information about Nymox is available at www.nymox.com; email: info@nymox.com, or 800- 936-9669.

This press release contains certain forward-looking statements as defined in the United States Private Securities Litigation Reform Act of 1995 that involve a number of risks and uncertainties. There can be no assurance that such statements will prove to be accurate and the actual results and future events could differ materially from management s current expectations. Development of drug products involves substantial risks and actual results may differ materially from expectations. Such factors are detailed from time to time in Nymox s filings with the United States Securities and Exchange Commission and other regulatory authorities.

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**Annex H: Supply Agreement** 

Nymox Pharmaceutical Corp.

and

Recordati Ireland Ltd.

# **SUPPLY AGREEMENT**

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#### SUPPLY AGREEMENT

**THIS SUPPLY AGREEMENT**, dated 16<sup>th</sup> of December, 2010 (the "**Effective Date**"), is by and between **Nymox Pharmaceutical Corp.**, a corporation organized and existing under the laws of Canada, with its principal business office located at 9900 Cavendish Blvd., Suite 306, St. Laurent, Quebec, Canada, H4M 2V2 ( **Nymox** ), and Recordati Ireland Ltd., a limited liability company organized and existing under the laws of Ireland, with a principal business office located at Raheens East, Ringaskiddy, Co Cork, Ireland (hereinafter, **Recordati** ).

#### **RECITALS**:

**WHEREAS**, Nymox and Recordati entered into a License and Collaboration Agreement, dated as of the date hereof, pursuant to which Nymox granted certain rights to Recordati to commercialize the Product (as hereinafter defined) in the Territory (the License and Collaboration Agreement );

**WHEREAS**, Nymox has developed and intends to manufacture (or have manufactured on its behalf) and sell Products (as hereinafter defined); and

**WHEREAS**, Recordati markets and distributes prescription and non-prescription medicines, including finished dosage prescription medicines; and

WHEREAS, Recordati has requested that Nymox manufacture (and/or have manufactured on its behalf) and sell to Recordati Products, to be sold by Recordati pursuant to the License and Collaboration Agreement; and

**WHEREAS**, subject to the terms and conditions set forth herein and in the License and Collaboration Agreement, Recordati wishes to Develop and Commercialize the Products and Nymox wishes to manufacture and supply the Products to Recordati for the above activities as provided herein and therein.

**NOW, THEREFORE**, in consideration of the premises and the covenants, representations, warranties, terms, conditions and agreements contained herein, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

#### 1. **DEFINITIONS**.

Defined terms will have the meaning set forth in the License and Collaboration Agreement except that terms specifically defined herein will have the meaning specifically defined herein, as listed below or in the body of this Agreement.

1.1. Affiliate shall mean any individual, corporation, partnership, firm, joint venture or other entity, which, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, Recordati or Nymox, as the case may be, including any entity controlled, directly or indirectly, by the entity having the ultimate control of a Party. An entity will be regarded as in control of another entity for purposes of this definition, only if it owns or controls more than fifty per cent (50%) of the shares of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority) or otherwise possesses the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of the outstanding voting securities or by contract or otherwise.

- **1.2. API** or **Active Pharmaceutical Ingredient** shall mean the Compound as manufactured for use in the manufacture of the drug Product as defined in the Marketing Authorization.
- 1.3. Calendar Month shall mean a month that is one of the twelve (12) months that comprise a Calendar Year.
- **1.4.** Calendar Quarter shall mean the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.
- 1.5. Calendar Year shall mean the twelve (12) month period from Januar fthrough December 31st.
- **1.6. Certificate of Analysis** shall mean a document signed by an authorized representative of Manufacturer describing the Specifications for, shelf life of, testing methods applied to and results of such testing with respect to a specified batch of Product manufactured by Manufacturer and attesting that the batch of Product meets Recordati s purchasing and Marketing Authorization Specifications.
- **1.7. Certificate of Conformance** shall mean a document signed by the Qualified Person as defined in 2001/83/EC of Manufacturer attesting that a batch of Product was manufactured in compliance with GMP and Marketing Authorization.
- **1.8.** Clinical Supplies shall mean the drug products containing the Compound (whether in the form of API or otherwise) and the relevant placebo intended to be utilized for Development, in particular for administration to humans during Clinical Trials and where applicable conforming to the IMPD.

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- **1.9.** [\*\*\*]
- **1.10. COMPOUND** shall mean the chemical compound known as NX-1207, as further defined in Annex A attached to the License and Collaboration Agreement, including both acid and salt forms as well as optical isomers, hydrates and solvates thereof.
- **1.11. Effective Date** has the meaning set forth in the first paragraph of this Supply Agreement.
- **1.12. EMA** shall mean the European Medicines Agency and the respective deciding body (European Commission), or respective successor agencies in case the EMA no longer exists.
- **1.13.** EU for the purpose of this Agreement shall mean the member states of the European Union at any given time.
- **1.14.** Facility or Facilities means a manufacturing facility or facilities located in the EU, operated by Nymox or by a Third Party contractor designated by Nymox in accordance with Section 3.9 of this Agreement, and authorized and intended to manufacture and actually manufacturing the drug Product.
- 1.15. Good Manufacturing Practice , Current Good Manufacturing Practice , GMP or cGMP shall mean in th EU the rules and Guidelines for Good Manufacturing Practice for medicinal products for human use as defined under Directive 2003/94/EC and Volume 4 Good Manufacturing Practice (GMP) Guidelines in The Rules Governing Medicinal Products in the European Union, Part I and II, in each case, as amended from time to time.
- **1.16. IMPD** shall mean Investigational Medicinal Product Dossier for the Product and the Compound (whether in the form of API or otherwise) manufactured according to Volume 4 of cGMP Guidelines and in particular to Annex 13 of such guidelines.
- **1.17. Key Countries** [\*\*\*]
- **1.18. Manufacturer** shall mean the Person who is the authorized (by the competent Regulatory Authority and other authorities of the country where the Facility is located and, as applicable, by the other competent Regulatory Authorities in the Territory) operator of the Facility where the Product is manufactured.
- **1.19. Person** means an individual, firm, trust, corporation, partnership, limited liability company, governmental authority or other entity.
- **1.20. Product** or **Products** shall mean a drug product in finished dosage form and packaging containing the API as an active ingredient and (save for the Clinical Supplies) conforming to the Marketing Authorization.
- **1.21. Product Labeling** shall mean, with respect to the Product in a given country or other regulatory jurisdiction, all labels and other written, printed or graphic matter upon a container, wrapper, box, package, or any package insert utilized with or for the Product as approved by the applicable Regulatory Authority (to the extent

necessary).

- **1.22. Product Supply Specifications** shall mean the Specifications for the Product to be supplied by Supplier pursuant to this Agreement as set forth in Annex D of the License and Collaboration Agreement as amended by agreement of Nymox and Recordati in accordance with this Agreement and with Section 5.3 of the License and Collaboration Agreement.
- **1.23. Quality Agreement** shall mean the agreement that shall be entered into, within [\*\*\*] from the Effective Date, between Nymox, the Supplier if different and Recordati, specifying their respective responsibilities for the testing, storage, release, cGMP, regulatory and other quality assurance requirements relating to manufacture, shipping, storage, and handling of Product. The Quality Agreement, once entered into, shall become an integral part of this Agreement and be attached as Exhibit A to this Agreement.
- **1.24.** Raw Material(s) means all bulk ingredients (active and inactive) and other related items necessary or required for Nymox s manufacture and supply of the Products in accordance herewith.
- **1.25.** [\*\*\*]
- **1.26. Supply Agreement** means this agreement and any and all Exhibits attached hereto, as may be amended, modified or supplemented from time to time in accordance with the terms hereof.
- **1.27. Supplier** means Nymox and/or a Third Party contractor designated by Nymox in accordance with Section 3.9 or 4.4 of this Agreement that is responsible for supplying Product to Recordati in accordance with this Supply Agreement and the License and Collaboration Agreement.

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- **1.28. Term** shall mean the Term of this Agreement as specified in Section 2.
- **1.29.** Third Party shall mean any person or entity, which is not a Party or an Affiliate of any Party to this Agreement.
- **1.30.** [\*\*\*]
- 2. TERM.

This Supply Agreement will commence on the Effective Date and, unless sooner terminated or extended as set forth in this Supply Agreement, will continue until the expiration or termination of the License and Collaboration Agreement.

### 3. MANUFACTURE AND SUPPLY

### 3.1. Manufacture & Supply Obligations.

Supplier shall supply Recordati with Products as Recordati requires on a commercial basis in accordance with GMP and Marketing Authorization and with the terms of this Supply Agreement. Recordati shall exclusively purchase the Products from Supplier during the Term. For avoidance of doubt, and despite the licenses granted to Recordati in the License and Collaboration Agreement, Recordati, its Affiliates and Sublicensees shall all be prohibited from manufacturing Compound or Product and from purchasing or receiving Compound or Product from any Person or entity other than Nymox or its designee during the Term of the Supply Agreement, save as provided for in this Agreement. Supplier will manufacture and release, or have manufactured and released, the batches of Product supplied to Recordati in EU. Raw Material and Compound for use as API may be manufactured outside of EU at the Supplier s discretion.

# **3.2.** Product Packaging.

- (a) Supplier will provide Products that comply with cGMP, Product Supply Specifications, and Marketing Authorization requirements. Any proposed modifications to the Product Supply Specifications will be subject to Section 3.14.
- (b) [\*\*\*]
- (c) Supplier will be responsible and shall bear the costs for ongoing stability testing of manufactured Product in accordance with GMP.
- (d) Supplier will be responsible to prepare and provide to Recordati the Periodic Product Review according to GMP as applied in the EU.

# 3.3. Forecasts; Excess Orders; Capacity.

- (a) Recordati will, [\*\*\*], provide Supplier with a written, rolling forecast of Recordati s requirements from Supplier for each Product [\*\*\*]
- (b) Each subsequent written forecast will update the prior forecast and include an estimate of requirements for [\*\*\*].
- (c) Supplier will maintain an adequate supply of Raw Materials based upon [\*\*\*].
- (d) If Recordati fails to order the amount of Product required by Section 3.3(a) for any applicable period, or if the Product Supply Specifications are modified at Recordati s request and with Supplier s agreement (but excluding the cases where the Product Supply Specifications are modified as a consequence of a request of Supplier s or a request of a Regulatory Authority), then Recordati will reimburse Nymox for the reasonable, direct, out-of-pocket costs of any packaging and packaging components and Raw Materials or Products that are rendered obsolete by virtue of such change up to an amount reasonably held in inventory by Supplier to fulfill Recordati s requirements hereunder as defined in Section 3.3(c) above [\*\*\*]; in each case only to the extent such costs can not be canceled or recovered by Supplier.

#### 3.4. Purchase Orders.

Recordati shall, [\*\*\*], issue purchase orders for no less than the amount of Product required to be purchased under Section 3.3(a) hereof during such [\*\*\*] period. All purchase orders for Product submitted to Supplier by Recordati will be in writing in paper or electronic form and will specify the delivery date, package sizes, quantities [\*\*\*] and destination. The delivery dates specified in Recordati s purchase orders will not be less than [\*\*\*] from the dates of such orders and not more than [\*\*\*] from the dates of such order unless the Supplier consents in writing to earlier delivery. Recordati and Supplier shall cooperate in good faith to coordinate the timing of placement of purchase orders, manufacturing schedules and delivery dates for Product. Subject to the requirements of Section 3.3(a), Recordati may modify or cancel purchase orders, provided, however, that each purchase order submitted by Recordati pursuant to this Section 3.4 that is not modified or canceled by Recordati at least [\*\*\*] prior to the delivery date specified in the original purchase order will constitute a firm obligation ( In-Process Order ) for Supplier to deliver to Recordati s freight carrier FCA (Incoterms 2000) at the Facility and for Recordati to purchase the quantities of packaged Product set forth in such purchase order. If Recordati modifies or cancels a purchase order upon written notice to Supplier less than [\*\*\*] prior to the delivery date specified in the original purchase order, Recordati will reimburse Supplier the reasonable, direct out-of-pocket costs actually incurred by Supplier solely as a result of such modification or cancellation, but only to the extent (i) such modification or cancellation renders unusable (for other Products or for products of Nymox s or its designee s other customers) Raw Materials, packaging or Products and such items cannot be returned to source suppliers or orders placed with such source suppliers for such items cannot be canceled, or (ii) any other such costs resulting solely from such modification or cancellation cannot otherwise be recovered by Supplier. In the event of reimbursement by Recordati pursuant to this Section 3.4(a), Supplier shall, upon Recordati s request and in Recordati s sole discretion, destroy any Raw Materials, packaging or Products subject to such reimbursement and provide Recordati with appropriate evidence thereof. The terms and conditions of this Supply Agreement will control over any conflicting terms and conditions used by Recordati or Supplier in any purchase order, confirmation, acceptance or other document, unless specifically agreed to in writing by both parties.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (b) In addition to the foregoing, if Recordati submits purchase orders for the Products in excess of [\*\*\*] ( **Excess Orders** ), Supplier will use Commercially Reasonable Efforts to fill the excess portion of such Excess Orders as promptly as practicable, but will not be in breach hereof if, notwithstanding such efforts, it will be unable to fill such excess portion;
- (c) For the avoidance of doubt no double reimbursement under 3.3 and 3.4 or otherwise no double reimbursement in respect of the same obsolete or unusable item under any provision in this Supply Agreement shall apply.

### 3.5. Product Samples.

Supplier will retain samples according to the Quality Agreement and to GMP and regulatory requirements.

### 3.6. Delivery.

- (a) Supplier will use Commercially Reasonable Efforts to deliver the Products in accordance with the Product Supply Specifications and in accordance with the quantities and delivery dates specified in purchase orders sent in compliance with Section 3.3 and 3.4. Supplier will promptly notify Recordati in writing of any anticipated delay. Such notice by Supplier will specify an alternative delivery date which will not be more than [\*\*\*] after Recordati s originally specified delivery date.
- (b) The Products will be delivered to Recordati s authorized carrier FCA (Incoterms 2000) at the Facility in finished dosage packaging in accordance with the Product Supply Specifications (including any additional packaging material necessary in order to guarantee the labeled storage conditions of the Product). Recordati shall assume title to and risk of loss of the Product according to the abovementioned FCA (Incoterms 2000). Supplier will include in each shipment of the packaged Products delivered to Recordati s authorized freight carrier an itemized packing list, Certificate of Analysis and Certificate of Conformance, and will, at the same time, provide to Recordati copies thereof and of any other documentation required to be delivered to Recordati pursuant to the License and Collaboration Agreement.
- (c) The residual shelf-life of delivered Product at the time of delivery shall be [\*\*\*] of the approved shelf-life.

#### 3.7. Acceptance and Rejection.

(a) (i) Recordati shall have a period of [\*\*\*] from delivery to reject any Product for any deviations from the Product Supply Specifications at the time of delivery which are readily apparent from visual inspection as commonly carried out when receiving goods in the industry (unit count, batch number by sample, expiration date by sample, evident packaging defects) ( Visual Inspection ). Recordati may reject the entire shipment that contains Products that deviate from the Product Supply Specifications where there is a reasonable basis for so doing. Recordati shall give written notice of such rejection to Supplier and specify the grounds for such rejection. Failure to give such written notice within [\*\*\*] from the date of delivery shall constitute a waiver of all claims with respect to the Product delivered for any deviations from the Product Supply Specifications that would have been readily apparent on Visual Inspection.

(ii) At any time after delivery of packaged Product to Recordati or its authorized carriers at the specified delivery location pursuant to Section 3.6 (b) and before the expiry date for the Product in question, if for any reason Recordati becomes aware of (i) a Product that deviates from Product Supply Specifications where the deviation is not readily apparent on Visual Inspection and not otherwise caused by mishandling after delivery to Recordati, or (ii) a breach of any applicable requirement or warranty under this Supply Agreement or the License and Collaboration Agreement that may reasonably affect whether the Products delivered meet Product Supply Specifications, comply with the Marketing Authorization, or were manufactured in accordance with GMP and Applicable Law, then Recordati will have the right to reject (or revoke acceptance of) such defective or non-conforming Products and any shipment containing such Products where there is a reasonable basis for so doing. Recordati will give written notice of such rejection or revocation of acceptance to Supplier and specify the grounds for such rejection or revocation within [\*\*\*] of confirming such defect, deviation, non-compliance, or non-conformity. Failure to give notice of rejection or revocation of acceptance within [\*\*\*] shall constitute a waiver by Recordati of the right to reject or revoke acceptance with respect to such Product.

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- (iii) At Recordati s option, but subject to Section 3.7(b), the Products which were rejected or had their acceptance revoked in accordance with Sections 3.7 (a) (i) or (ii) (Rejected Product) will be returned to Supplier at Supplier s expense. With respect to such Rejected Products, Recordati may, at its option, (i) receive a refund, (ii) receive credit, or (iii) require Supplier to use its Commercially Reasonable Efforts to promptly replace the Rejected Products with non-defective, conforming Products at no cost to Recordati. As soon as reasonably practicable, Supplier will comply with such option. In the event that it is determined by dispute resolution or agreed by the parties that the grounds for rejection or revocation of acceptance of any Rejected Product was unfounded, Recordati will make Supplier whole by returning any refund received, re-paying any credit received, or paying for replacement Product provided at no cost.
- (iv) Recordati and Supplier will cooperate together in any investigation of the circumstances surrounding the rejection of the Rejected Product and of the grounds for such rejection.
- (b) If Supplier disputes Recordati s grounds for rejecting (or revoking its acceptance of) all or part of any shipment of the Products as set forth above, and such dispute is not resolved by mutual agreement of the parties within [\*\*\*] of Recordati s notice of rejection (or revocation of acceptance), such dispute will be resolved by an independent accredited testing organization mutually agreed upon by the parties, the appointment of which will not be unreasonably delayed by either party. The determination of such testing entity with respect to all or part of any shipment will be final and binding upon all parties, but only as to reasons given by Recordati in rejecting (or revoking acceptance of) the shipment or portion thereof and will have no effect on any matter for which such testing organization did not render a determination. The fees and expenses of the testing organization will be paid by the party against which the determination is made.

### 3.8. Documentation; Inspection.

- (a) Supplier will maintain true and complete copies of all Data and documents relating to the manufacture, supply stability testing and packaging of the Products hereunder and related receipt, testing, storage and/or shipment thereof as are required by Regulatory Authorities in the Territory or the License and Collaboration Agreement. Recordati will have the right to inspect and review the Facilities, books and records, as may be necessary to ensure Supplier s compliance with the terms and conditions set forth herein.
- (b) Recordati will maintain true and complete copies of all Data and documents relating to the inspection, testing, shipping, storage, and handling of Product and to the determination whether Product meets Product Supply Specifications. Nymox will have the right to inspect such records in the event of a dispute over Rejected Products.
- (c) Supplier and Recordati, its Affiliates and Sublicensees shall each maintain such records as may be necessary to permit a recall of any Product delivered to Recordati pursuant to this Agreement.

# 3.9. Third Party Contractors.

Nymox reserves for itself the manufacturing rights and Know-How in relation to the licensed Products and Compound. Nymox may contract with one or more qualified Third Parties for the manufacture, supply, and stability testing of Products hereunder (and/or related storage, testing and shipment thereof); provided, however, that: (i) Nymox will cause each and every such Third Party to agree in writing to comply fully with the terms and conditions set forth in this Supply Agreement and provide Recordati with proof of such agreement, and monitor and ensure that such Third Party is in compliance; (ii) Nymox will remain fully liable to Recordati for the Products and for the

manufacture, supply, and stability testing of such Products and any related obligations hereunder contracted by Nymox to any such Third Party, as well as for any liability related thereto; and (iii) Nymox will notify Recordati in writing at least [\*\*\*] in advance of its intention to contract all or some of its manufacture, supply, stability testing, or other obligations hereunder to a Third Party. Recordati may, within [\*\*\*], give Nymox written notice rejecting the use of such Third Party on any reasonable grounds.

[\*\*\*]

[\*\*\*]

The Parties agree that in view of the complexity, resource and process time and cost which result from updating Marketing Authorizations and meeting other regulatory requirements, they will refrain from introducing changes in Manufacturers unless necessary to maintain the continuous provision of Products to patients or as otherwise agreed by both Parties, and in any case will implement such changes in a manner compatible with updating Marketing Authorizations and meeting other regulatory requirements.

### 3.10. Technical Assistance.

Supplier will furnish Recordati with such technical bulletins and Data relative to the Products as it makes available to its internal personnel, source suppliers and other customers, and as is otherwise reasonably appropriate from time to time.

# 3.11. Intentionally Left Blank.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

# 3.12. Intentionally Left Blank.

### 3.13. Specification Approval.

Supplier will use only the Product Supply Specifications for the manufacture and supply of Products. Any changes in the Product Supply Specifications shall be agreed upon by Nymox and Recordati in writing, be compliant with Regulatory Authorities requirements, and be validated in accordance with GMP prior to implementation. Supplier will provide to Recordati a copy of (a) the current manufacturing formula, (b) in-process, stability and release test Specifications and methods, (c) list of Raw Materials (and all sources thereof), Specifications, and process instructions, (d) bulk packaging components (and all sources thereof), and (e) any changes to the foregoing agreed upon by Nymox and Recordati in accordance with Section 3.14 below, and (f) anything else that may be or become necessary to satisfy regulatory requirements during the Term.

### **3.14.** Specification Changes.

Any proposed change to Product stability or other testing methods or Specifications, Raw Materials, Specifications, processes, procedures and/or controls, equipment, Facilities or Third-Party laboratories, suppliers or packagers utilized by Supplier for the manufacturing, supply, testing and/or packaging of Products that is required by any governmental authority or proposed by either party will be made only in accordance with Sections 3.15 and 3.16 below. The Parties agree that in view of the complexity, resource and process time and cost which result from updating Marketing Authorizations and meeting other regulatory requirements, they will refrain from requesting changes unless necessary to maintain the continuous provision of Products to patients or as otherwise agreed by both Parties.

#### 3.15. Change Control.

Supplier will maintain a system (consistent with standard industry practice) to control and implement changes to Specifications (including but not limited to Raw Materials), manufacturing and packaging processes, testing and qualification procedures, and documentation related thereto, in accordance with Applicable Law. Nymox will notify Recordati in advance and in writing of any changes in (i) Raw Materials (including but not limited to any active raw material specified in this Supply Agreement) or their Specifications, (ii) the manufacturing or packaging process (including but not limited to the Third Party contractor(s), contract manufacturing company(ies), location(s), Facilities or equipment used to manufacture and package any Product), (iii) methods of testing, (including but not limited to stability and retains), and (iv) storage of any Product or packaging, or delivery of any packaged Product to Recordati s authorized freight carrier for shipment. Recordati will have the right to review and approve or reject any such changes in writing prior to implementation, if not an unplanned deviation, and will have the right to require validation of any such change. Recordati will have the right to review any unplanned deviation specific to any Product and require validation. Recordati will have the right to deny use of any Raw Material that is derived from an unapproved source.

# 3.16 Change Required by Governmental Authority.

In the event that any change described in Sections 3.14 or 3.15 above is required by any governmental authority (including a Regulatory Authority), the Party having Knowledge thereof will deliver written notice thereof to the other Party. Such change will also be subject to review and written approval by Recordati. Recordati will notify Nymox if Recordati determines that it cannot agree to such change. Thereafter, Recordati and Nymox will negotiate in good faith an amendment to this Supply Agreement altering the terms hereof or adding such other terms as may be just and equitable in the circumstances. If such amendment is agreed to, Nymox will provide to Recordati copies of the amendment and other revised documents for its review and approval.

# 3.17 Clinical Supplies.

Nymox shall provide Clinical Supplies in a timely manner according to the planning and delivery terms agreed between the Parties and according to the timeline included in the Development Plan. Clinical Supplies shall be supplied according to the specific supply chain and the responsibilities described in Exhibit B of this Agreement. Clinical Supplies shall be invoiced by Nymox at [\*\*\*] Clinical Supplies arrangements for Development of additional Indications or for other Clinical Trials carried out in accordance with the Development Plan shall be supplied according to this Section 3.17. Save as specified in this Section 3.17, all other conditions of the Supply Agreement shall apply.

#### 3.18 Product for Commercial Sampling.

Nymox shall provide Product for commercial free sampling in reasonable quantities in a timely manner according to the planning and delivery terms agreed between the Parties. Product for commercial sampling shall be invoiced by Nymox at [\*\*\*].

#### 4. DELIVERY SHORTFALLS

### 4.1. Safety Stock of API and Product.

To facilitate timely supplies of Product, after Marketing Authorization (MA) in the Territory Nymox undertakes to maintain at its expense a safety stock of API, in quantities of [\*\*\*]. Nymox further undertakes to maintain at its expense a safety stock of Product, [\*\*\*]. As of the date of MA and for the [\*\*\*], Nymox undertakes to maintain at its own expense a launch safety stock of API and Product based on Recordati's good faith forecast of its expectations of orders for [\*\*\*]. Such forecast will be provided to Nymox in accordance with Section 3.3 (a). Safety stock of API and Product, including launch safety stock, will comply with Product Supply Specifications (other than packaging and labeling requirements), cGMPs, and Marketing Authorization requirements.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

#### 4.2. Reserve Product

Recordati shall maintain at its own risk and expense a safety stock (including the safety stock of its Affiliates and its Sublicensees) of [\*\*\*] supply of Product ( **Reserve Product** ), determined as of any date by the rolling forecast for [\*\*\*] as made by Recordati pursuant to Section 3.3 of this Agreement.

# 4.3. Inventory.

Recordati's forecasts and orders will reflect its good faith expectations of customer demand and Recordati will act in a commercially reasonable manner to schedule orders to avoid creating production problems for Supplier.

### **4.4.** Inability to Supply.

[\*\*\*]

# 4.5. Resumption of Supply.

- (a) If after the commencement of an Inability to Supply Supplier is ready to fully resume its obligations to supply packaged Product to Recordati in accordance with this Supply Agreement, Supplier will notify Recordati in writing of its ability to resume supply of all Recordati orders (the "Resumption Notice"). The Resumption Notice must: (i) list a date on which Supplier will be able to fully resume supply; (ii) include reasonable evidence of Supplier s ability to resume such obligations by that date; and (iii) provide assurances, reasonably acceptable to Recordati, of Supplier s ability to successfully meet its obligations by such resumption date and (as applicable) thereafter.
- (b) Recordati will review the Resumption Notice in a timely manner and promptly advise Supplier of any issues which Recordati may have concerning Supplier s evidence and assurances contained in the Resumption Notice. Recordati and Supplier shall cooperate in good faith for the timely resolution of such issues on a commercially reasonable basis and in accordance with industry standards and will amend the Resumption Notice accordingly if necessary. Upon acceptance of the Resumption Notice as it may be amended, then Recordati will resume ordering Product from Supplier and Supplier resume the manufacture of Product in accordance with the terms of this Supply Agreement and the assurances in the Resumption Notice.
- (c) [\*\*\*]

#### 5. PRICE AND PAYMENT TERMS.

#### **5.1. Price.**

Nymox shall invoice, and Recordati shall pay Nymox, a [\*\*\*] supply price for each unit of Product supplied to Recordati [\*\*\*] equal to [\*\*\*] [\*\*\*]

# 5.2. Payment.

Nymox will invoice Recordati upon delivery of Products to Recordati authorized carrier or promptly when the information necessary for the calculation of provisional and final amounts for a Calendar Quarter according to Section 5.1 is available. Likewise, Nymox will issue a credit note promptly in case of overpayment to be refunded to Recordati. Recordati will pay each invoice (net of any outstanding credit notes) in full within [\*\*\*] after the receipt of each invoice and shipment, unless such shipment is rejected or its acceptance revoked by Recordati in accordance herewith.

- 6. REGULATORY MATTERS.
- **6.1.** Intentionally Left Blank.
- 6.2. Intentionally Left Blank.
- **6.3.** Regulatory Information.

Each party agrees to provide the other with all reasonable assistance and take all reasonable actions requested by the other that are necessary or desirable to enable the other party to comply with any law or regulation applicable to any Product or any active ingredient in any Product, or to the testing or packaging of any Product, including, but not limited to, compliance with obligations to provide adverse event reports and serious adverse event reports to the FDA or EMA, and/or other Regulatory Authorities. Such assistance and actions will include, without limitation, keeping the other party informed of any action by, or notification or other information which it receives (directly or indirectly) from the FDA or EMA, or any other Regulatory Authority which (a) raises any material concerns regarding the marketability, safety or efficacy of any Product or Product packaging, (b) indicates or suggests a potential material liability for either party to Third Parties arising in connection with any Product or Product packaging, or (c) is reasonably likely to lead to an EMA or FDA Field Alert report, recall, market withdrawal or seizure of any Product or Product packaging; *provided* that neither party will be obliged to disclose information in breach of Applicable Law.

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# **6.4.** Applicable Law.

Supplier will comply with Applicable Law and the warranties set forth in the License and Collaboration Agreement

#### 6.5. Product Recall or Seizure

- (a) To the extent a recall or seizure is due to negligence or a breach of this Agreement (including a failure to meet Product Specifications or requirements of the Marketing Authorization) or of the Applicable Law by Supplier or any of Nymox s Affiliates, or by any agents, subcontractors, suppliers or Third Parties retained by Supplier in connection with this Supply Agreement, Supplier will (i) pay or reimburse, as the case may be, all reasonable direct out-of-pocket costs and expenses, including but not limited to reasonable attorney's fees and expenses and credits and recall or seizure expenses claimed by and paid to customers, incurred by Recordati (including its Affiliates and Sublicensees) or Supplier in connection with performing any such recall or responding to any such seizure, and (ii) at Recordati s option, (1) replace the amount of Products, packaging or Raw Materials subject to such recall or seizure or give a refund to Recordati for same to the extent the purchase price has been paid, or (2) give credit to Recordati, against outstanding receivables due from Recordati and future purchases of the packaged Product in an amount equal to the amount paid by Recordati for the Product subject to such recall or seizure or otherwise owing by Recordati hereunder.
- (b) To the extent a recall or seizure is due to negligence or a breach of this Agreement or of the Applicable Law by Recordati, its Affiliates and Sublicensees or by any agents, subcontractors, or Third Parties retained by Recordati, its Affiliates, or Sublicensees in connection with the marketing, distribution, or sale of Product, Recordati will pay or reimburse, as the case may be, all reasonable direct out-of-pocket costs and expenses, including but not limited to reasonable attorney's fees and expenses and credits and recall or seizure expenses claimed by and paid to customers, incurred by Recordati or Supplier in connection with performing such recall or responding to any such seizure.
- (c) In all other instances, the Parties will share all reasonable direct out-of-pocket costs and expenses, including but not limited to reasonable attorney's fees and expenses and credits and recall or seizure expenses claimed by and paid to customers, incurred by Recordati or Supplier in connection with performing such recall or responding to any such seizure on a fifty/fifty basis.
- (d) If the parties are unable to agree on the allocation of liability under Section 6.5 (a) and 6.5 (b) within [\*\*\*] of the initiation of the recall or seizure, then either of the parties may commence arbitration proceedings in accordance with Section 12 below.
- (e) Prior to any reimbursement pursuant to this Section 6.5, the party claiming reimbursement will provide the other with reasonably acceptable documentation of all reimbursable costs.

### 7. INSURANCE

Each party will maintain in effect at all times during the Term of this Supply Agreement, and for a period of at least five (5) years after its termination or expiration, commercial general insurance, including product liability, bodily harm and property insurance, in an amount consistent with indemnity standards for claims and actions that might be

brought against it in connection with the activities contemplated to be performed by the parties hereunder. In addition, during such period each Party will maintain standard business insurance per the practice of the country and industry in which it operates. On or before the Effective Date and thereafter, upon reasonable request, each party will provide the other with certified copies of all applicable endorsements and certificates of insurance evidencing such product liability coverage.

### 8. INDEMNIFICATION

Indemnification by Nymox or Recordati shall be governed by Article 13 of the License and Collaboration Agreement.

# 9. REPRESENTATIONS; WARRANTIES.

Representations, Warranties and Covenants shall be governed by Article 9 of the License and Collaboration Agreement. In addition, Supplier warrants that:

(i) all Products delivered under this Agreement shall throughout the Term meet the Product Supply Specifications and comply with the Marketing Authorization, and be manufactured in accordance with GMP and Applicable Law and regulations.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(ii) Nymox has no Knowledge of any information pursuant to which it knows or would have reason to know, it would not be able to perform its obligations under this Supply Agreement.

#### 10. TERMINATION.

# 10.1. Termination Upon The Termination or Expiration of the License and Collaboration Agreement

- (a) This Supply Agreement shall terminate upon the termination or expiration of the License and Collaboration Agreement as set forth in Section 2 above.
- (b) Before expiration of this Supply Agreement, and in any case within [\*\*\*], Nymox shall provide free of charge any information and reasonable assistance to Recordati and its contractor(s) in order to qualify and obtain the necessary Regulatory Approvals in the Territory for an independent supply chain for API and for finished dosage forms of Products in order for Recordati to have the possibility to manufacture or have manufactured the API and/or the Products after the expiration of this Supply Agreement.
- (c) After such expiration, Recordati shall have the right to cease purchasing Product from Supplier for part or all of its requirements and, upon Recordati request, Supplier shall permit its or its contractors suppliers of API or other Raw Materials to supply API or Raw Materials to Recordati without any compensation to Supplier or its other contractors and without any restrictions.

### 10.2. Termination by Recordati.

Prior to expiration of the Term set forth in Section 2 above, Recordati may terminate this Supply Agreement:

- (a) by mutual written agreement of Recordati and Nymox at any time; or
- (b) upon [\*\*\*] written notice of termination, if Nymox breaches or defaults in the performance or observance of any of its material obligations under this Supply Agreement and such breach or default is not cured within [\*\*\*] after receipt of written notice from Recordati specifying the nature of such breach or default, provided that the notice of termination shall be delivered within [\*\*\*] of the date Recordati became aware of the material breach on which the intended termination is founded. For greater certainty and avoidance of doubt, an Inability to Supply as set forth in Section 4.4 shall not of itself but provided Nymox is in compliance with the other provisions of this Supply Agreement, including in particular those provisions intended to limit the adverse consequences of such Inability to Supply constitute a breach by Nymox of its material obligations under this Supply Agreement.

In case this Supply Agreement is terminated according to the provisions of this Section 10.2:

(i) Nymox shall provide free of charge any information and reasonable assistance to Recordati and its contractor(s) in order to qualify and obtain the necessary Regulatory Approvals in the Territory for an

independent supply chain for API and for finished dosage forms of Products in order for Recordati to have the possibility to manufacture or have manufactured the API and/or the Products after the termination of this Supply Agreement.

- (ii) After such termination, Recordati shall have the right to cease purchasing Product from Supplier for part or all of its requirements and, upon Recordati request, Supplier shall permit its contractors or its contractors suppliers of API or other Raw Materials to supply API or Raw Materials to Recordati without any compensation to Supplier or its other contractors and without any restrictions.
- (iii) During the period from such termination until Recordati is effectively ready (including as to the variations to Marketing Authorizations and other Regulatory Approvals) to manufacture the Products on a country-by-country basis, Nymox shall, at Recordati discretion, continue to supply the Products to Recordati according to the terms of this Supply Agreement.

### 10.3. Termination by Nymox

Prior to expiration of the Term set forth in Section 2 above, Nymox may terminate this Supply Agreement:

- (a) by providing Recordati with reasonable advance notice, and in any case no less than [\*\*\*], (including the time required for Recordati to review and decide on the matter, to identify and contract alternative suppliers, perform the necessary set-up and validation steps and obtain the required Regulatory Approvals in the Territory) of its desire to terminate the Supply Agreement. In such a case, Nymox shall provide free of charge to Recordati an option to take over the manufacturing of the Product and Recordati shall opt whether to appoint a Manufacturer for the Product. Nymox shall then provide free of charge any information and reasonable assistance to Recordati and its contractor(s) in order to complete the technology transfer of the manufacturing.
- (b) upon [\*\*\*] written notice of termination, if Recordati breaches or defaults in the performance or observance of any of its material obligations under this Supply Agreement and such breach or default is not cured within [\*\*\*] after receipt of written notice from the non-breaching party specifying the nature of such breach or default, provided that the notice of termination shall be delivered within [\*\*\*] of the date Nymox became aware of the material breach on which the intended termination is founded.

[\*\*\*] indicates that certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

# 10.4. Disputed Termination.

If a Party s right to terminate this Agreement pursuant to Section 10.2(b) or 10.3(b) is being disputed by the other Party, which dispute is being diligently pursued by such other Party by appropriate proceedings hereunder, such termination shall not be deemed effective unless an arbitration decision confirms a material breach or default of this Agreement as specified in the written notice from the non-breaching Party and the breaching Party fails to cure such breach within [\*\*\*] following such arbitration decision. Both Parties will be required to perform in accordance with this Agreement during the pendency of any such dispute.

#### 10.5. Post-Termination.

Expiration or termination of this Supply Agreement will not relieve the parties of any obligations accruing prior to such expiration or termination.

#### 11. CONFIDENTIALITY.

Confidentiality shall be governed by Article 10 of the License and Collaboration Agreement.

### 12. DISPUTE RESOLUTION.

Dispute Resolution shall be governed by Article 11 of the License and Collaboration Agreement, except to the extent otherwise provided in Section 3.7 (b).

#### 13. INDEPENDENT CONTRACTOR.

The relationship between Supplier on the one hand, and Recordati on the other, is that of independent contractors and nothing herein will be deemed to constitute or give rise to any employer-employee, agency, partnership or joint venture relationship among or between the parties. Neither party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other party.

#### 14. MISCELLANEOUS.

### 14.1. Force Majeure.

Neither party will be liable for failure or delay in the performance of any of its obligations hereunder, if such failure or delay is due to causes beyond its reasonable control (other than those causes resulting from acts or omissions of such party) including, without limitation, acts of God, earthquakes, fires, strikes, acts of war, acts of terrorism, government

proclamations, or intervention of any governmental authority. Failure to perform as a result of a violation of or non-compliance with any law, order or regulation, or failure to obtain (or loss of) any Regulatory Approval, will not be deemed to be beyond a party s reasonable control and therefore will not be considered an event of Force Majeure.

## 14.2. Limitation Of Liability.

NO PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, (I) NOTHING IN THIS SECTION 14.2 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE 8 OF THIS AGREEMENT AND (II) NOTHING IN THIS SECTION 14.2 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY TO THE EXTENT A THIRD PARTY RECOVERS ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES FROM THE OTHER PARTY.

### 14.3. Assignment.

Except as provided otherwise in this Supply Agreement, neither party will assign or transfer this Supply Agreement without the prior written consent of the other party, which consent will not to be unreasonably withheld. However, without the consent of the other party, each party may assign or transfer this Supply Agreement, in whole or in part, (a) to any of its Affiliates, or (b) to any successor by merger, or (c) upon a sale or transfer of all or substantially all of its assets or the assets of that portion of its pharmaceutical business involving the Products, provided however that in no instance may a Party assign this Supply Agreement to a Person without assigning the License and Collaboration Agreement simultaneously to the same Person. This Supply Agreement will be binding upon and will inure to the benefit of the parties and their successors and permitted assigns.

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#### **14.4.** Notice.

All notices required to be given hereunder will be in writing and will be given by (a) personal delivery with signature acknowledgement of receipt required, or (b) facsimile transmission with proof of receipt, or (c) internationally recognized overnight courier, or (d) registered or certified mail, postage prepaid with return receipt requested. Notices will be addressed to the parties as follows (or as the parties may subsequently designate by notice):

If to Recordati, at: Recordati Ireland Ltd,

Raheens East, Ringaskiddy,

Co Cork, Ireland

Fax: [\*\*\*]

Attention: Chairman and Managing Director.

with a copy to: Recordati S.p.A.,

Via M. Civitali 1

20148 Milano, Italy

Fax: [\*\*\*]

Attention: Director Group Logistics and Manufacturing.

and if to Nymox, at: Nymox Pharmaceutical Corporation

9900 Cavendish Blvd. Suite 306

St.-Laurent, Quebec, Canada H4M 2V2

Fax: [\*\*\*]

Attention: Chief Financial Officer

With copies to: Nymox Pharmaceutical Corporation

9900 Cavendish Blvd. Suite 306

St.-Laurent, Quebec, Canada H4M 2V2

Fax: [\*\*\*]

Attention: General Counsel

## For Quality Matters

Notices will be deemed received upon proof of delivery or when delivery has been refused. A party may change its address by written notice in accordance with this Section 14.4.

#### 14.5. Amendments.

Any amendment or modification of this Supply Agreement will only be valid if made in writing and signed by an authorized representative of each of the parties hereto.

# 14.6. Counterparts.

This Supply Agreement may be executed in counterparts, each of which will be deemed an original and all of which will constitute a single document.

### 14.7. Entire Agreement; Conflict Between Provisions.

This Supply Agreement and the License and Collaboration Agreement represent the entire agreement of the parties with respect to the subject matter hereof; superseding all prior agreements and understandings, written or oral. Notwithstanding the foregoing, any prior confidentiality agreement between the parties will remain in effect in accordance with its terms with respect to previously disclosed information unless agreed to otherwise in writing. In the event of any conflict between any of the terms of this Supply Agreement and the terms of the License and Collaboration Agreement or any other exhibit attached to this Supply Agreement, the terms of the License and Collaboration Agreement will take precedence and govern, unless this Supply Agreement or other exhibit expressly states that the Supply Agreement or such other exhibit takes precedence and governs notwithstanding any contrary provision in the License and Collaboration Agreement.

### 14.8. Benefit; Binding Effect.

This Supply Agreement will be binding upon and will inure to the benefit of the parties hereto and their respective successors and permitted assigns.

### 14.9. Survival.

Notwithstanding anything to the contrary contained in this Supply Agreement, the provisions of Sections 1, 5, 6, 7, 8, 9, 10, 11, 12, 13, and 14 will survive any expiration or termination of this Supply Agreement, as well as the provisions of those Sections which by their nature are meant to survive termination.

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14.10. **Further Assurances.** 

The parties hereto agree that they will take all appropriate actions, including, without limitation, the execution or filing of any documents or instruments, which may be reasonably necessary or advisable to carry out the intent and

accomplish the purposes of any of the provisions hereof.

14.11. Severability.

If any provision of this Supply Agreement will be held invalid or unenforceable for any reason by a court of competent jurisdiction, such provision or part thereof will be considered separate from the remaining provisions of this Supply Agreement, which will remain in full force and effect. The Parties shall replace the invalid or unenforceable provision or part thereof with a new valid and enforceable provision negotiated in a just and equitable manner so as to result in a composition of the Parties economic and other interests as similar, as much as practically

possible, to the original invalid or unenforceable provision or part thereof.

14.12. Waiver of Rights.

Exercise by any party of any of its rights under this Supply Agreement will not be deemed to limit any other right or remedy that such party may have in law or equity. No waiver by any party of any default or breach by the other of any provision hereof will be deemed to be a waiver of any subsequent default or breach of that or any other provision

hereof.

14.13. Captions.

The Captions used in this Supply Agreement are solely for convenience and will have no part in the interpretation of this Supply Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized

representatives in duplicates as of the day, month and year first above written.

Nymox Pharmaceutical Corp.

Signature: /s/ Paul Averback MD

Name: Paul Averback

Function: C.E.O.

Date: December 16, 2010

Recordati Ireland Ltd.

Signature: /s/ Andrea Recordati

Name: Andrea Recordati

Function: Chairman and General Manager

Date: <u>December 16, 2010</u>

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# **Exhibit A:** Quality Agreement

To be attached once entered into.

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# **Exhibit B:** [\*\*\*]

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# **Schedule 9.1: Nymox Disclosure Schedules**

Not applicable.

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# Schedule 9.2: Recordati Disclosure Schedules

Not applicable

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