

U.S. SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 40-F**

(Check One)

Registration statement pursuant to Section 12 of the Securities Exchange Act of 1934

or

Annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended May 31, 2004

Commission file number 0-19763

**LORUS THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

**Province of Ontario, Canada**  
(Province or other jurisdiction of  
incorporation or organization)

**2836**  
(Primary Standard Industrial  
Classification Code Number (if  
applicable))

**Not applicable**  
(I.R.S. Employer  
Identification Number (if Applicable))

**2 Meridian Road,  
Toronto, Ontario, Canada, M9W 4Z7  
416-798-1200**

(Address and Telephone Number of Registrant's Principal Executive Offices)

**Torys LLP, 237 Park Avenue, New York, NY, U.S.A. 10017  
(212) 880-6000**

(Name, Address (Including Zip Code) and Telephone Number  
(Including Area Code) of Agent For Service in the United States)

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Shares	American Stock Exchange

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.

For annual reports, indicate by check mark the information filed with this Form:

Annual Information Form

Audited Annual Financial Statements

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: 171,794,174

Indicate by check mark whether the registrant by filing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934 (the "Exchange Act"). If "Yes" is marked, indicate the file number assigned to the registrant in connection with such rule.

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 Exchange Act 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 \_\_\_

**FORM 40-F**

**Principal Documents**

The following documents filed as Exhibits 99.1, 99.2 and 99.3 hereto, are hereby incorporated by reference into the Annual Report on Form 40-F:

- (a) Annual Information Form dated October 8, 2004;
- (b) Management's Discussion and Analysis for the fiscal year ended May 31, 2004; and
- (c) Consolidated Financial Statements for the fiscal year ended May 31, 2004, together with the report of the auditors thereon. As explained in Note 14 to the Consolidated Financial Statements (page 28 of the registrant's annual report), the registrant does not have any material measurement differences between Canadian GAAP and United States GAAP that apply to the consolidated financial statements.

## ADDITIONAL DISCLOSURE

### Certifications and Disclosure Regarding Controls and Procedures.

- (a) Certifications. See Exhibits 99.4 and 99.5 to this Annual Report on Form 40-F.
- (b) Disclosure Controls and Procedures. As of the end of the registrant's fiscal year ended May 31, 2004, an evaluation of the effectiveness of the registrant's "disclosure controls and procedures" (as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) was carried out by the registrant's principal executive officer and principal financial officer. Based upon that evaluation, the registrant's principal executive officer and principal financial officer have concluded that as of the end of that fiscal year, the registrant's disclosure controls and procedures are effective to ensure that information required to be disclosed by the registrant in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

It should be noted that while the registrant's principal executive officer and principal financial officer believe that the registrant's disclosure controls and procedures provide a reasonable level of assurance that they are effective, they do not expect that the registrant's disclosure controls and procedures or internal control over financial reporting will prevent all errors and fraud. A control system, no matter how well conceived or operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

- (c) Changes in Internal Control Over Financial Reporting. During the fiscal year ended May 31, 2004, there were no changes in the registrant's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the registrant's internal control over financial reporting.

### Notices Pursuant to Regulation BTR.

None.

### Audit Committee Financial Expert.

The registrant's board of directors has determined that J. Kevin Buchi, a member of the registrant's audit committee, qualifies as an "audit committee financial expert" (as such term is defined in Form 40-F) and that each of the three members of the registrant's audit committee is an "independent director", as that term is defined in the listing standards of the American Stock Exchange.

### Code of Ethics.

The registrant has adopted a "Code of Ethics" (as that term is defined in Form 40-F), that

applies to all directors, officers, employees and agents including its principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions (together, the "Financial Supervisors").

The registrant is in the process of making the Code of Ethics available for viewing on the registrant's website at [www.lorusthera.com](http://www.lorusthera.com) and until such time, also undertakes to provide a copy to any person without charge, upon written request by prepaid ordinary post to the Corporate Secretary, Lorus Therapeutics Inc., 2 Meridian Road, Toronto, Ontario, Canada M9W 4Z7 or by e-mail to [Legal@lorusthera.com](mailto:Legal@lorusthera.com).

Since the adoption of the Code of Ethics, there have not been any amendments to the Code of Ethics or waivers, including implicit waivers, granted from any provision of the Code of Ethics.

#### **Principal Accountant Fees and Services.**

The following table provides information about the fees billed to the registrant for professional services rendered by KPMG LLP during fiscal 2004 and 2003:

<i>(US \$000s)</i>	<b>2004</b>	<b>2003</b>
Audit Fees	\$61,972	\$56,037
Audit-Related Fees	4,720	---
Tax Fees	---	10,569
All Other Fees	43,989	14,901
<b>Total</b>	<b>\$110,682</b>	<b>\$81,507</b>

**Audit Fees.** Audit fees include fees for services that would normally be provided by the external auditor in connection with statutory and regulatory filings or engagements, including fees for services necessary to perform an audit or review in accordance with generally accepted auditing standards. This category also includes services that generally only the external auditor reasonably can provide, including comfort letters, statutory audits, attest services, consents and assistance with and review of certain documents filed with securities regulatory authorities.

**Audit-Related fees.** Audit-related fees are for assurance and related services, such as due diligence services, that traditionally are performed by the external auditor. More specifically, these services include, among others: accounting consultations regarding internal processes.

**Tax fees.** Tax fees are principally for assistance in tax return preparation and tax advisory services.

**All Other Fees.** All other fees include fees for translation, audit and review services related to an offering prospectus and advisory support services.

## Pre-Approval Policies and Procedures.

- (a) The audit committee of the registrant's board of directors has within the charter of the audit committee adopted specific responsibilities and duties regarding the provision of services by the registrant's external auditors, currently KPMG LLP. This charter requires audit committee pre-approval of all permitted audit and audit-related services. Any non-audit services must be submitted to the board of directors of the registrant for review and approval.

Under the charter, all permitted services to be provided by KPMG LLP must be pre-approved by the audit committee. The pre-approval of services may be given at any time up to a year before commencement of the specified service.

Subject to the charter, the audit committee may establish fee thresholds for a group of pre-approved services. In such cases, the description of services must be sufficiently detailed as to the particular services to be provided to ensure that (i) the audit committee knows precisely what services it is being asked to pre-approve and (ii) the audit committee's responsibilities are not delegated to management. All such services will be ratified at the next scheduled meeting of the audit committee, and upon such ratification will no longer be included in determining the aggregate fees covered by this limited approval. The audit committee then recommends to the board of directors approval of the fees and other significant compensation to be paid to the independent auditors.

- (b) Of the fees reported in this Annual Report on Form 40-F under the heading "Principal Accountant Fees and Services", none of the fees billed by KPMG LLP were approved by the audit committee of the board of directors of the registrant pursuant to the *de minimis* exception provided by Section (c)(7)(i)(C) of Rule 2-01 of Regulation S-X.

## Off-Balance Sheet Arrangements.

The registrant does not have any material off-balance sheet arrangements.

## Tabular Disclosure of Contractual Obligations.

The following table presents contractual obligations of the company at May 31, 2004.

<i>US\$ Millions</i>		Payments Due by Period			
			Less than One Year	1 – 3 Years	4 – 5 Years
<i>Contractual Obligations</i>	<b>Total</b>				
Long term debt					
Operating Lease Obligations	.110	.110	---	---	---
Contract Research Organizations	4.798	2.585	2.213	---	---
Total	4.908	2.698	2.213	---	---

**Identification of the Audit Committee.**

The registrant has a separately-designated standing audit committee established in accordance with section 3(a)(58)(A) of the Exchange Act. The members of the audit committee are J. Kevin Buchi, Donald W. Paterson and Graham Strachan.

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## UNDERTAKING AND CONSENT TO SERVICE OF PROCESS

### A. Undertaking.

The registrant undertakes to make available, in person or by telephone, representatives to respond to inquiries made by the Securities and Exchange Commission (the "Commission") staff, and to furnish promptly, when requested to do so by the Commission staff, information relating to: the securities registered pursuant to Form 40-F; the securities in relation to which the obligation to file an annual report on Form 40-F arises; or transactions in said securities.

### B. Consent to Service of Process.

The Company has previously filed a Form F-X in connection with the class of securities in relation to which the obligation to file this report arises.

Any change to the name or address of the agent for service of process of the registrant shall be communicated promptly to the Securities and Exchange Commission by an amendment to the Form F-X referencing the file number of the registrant.

## SIGNATURES

Pursuant to the requirements of the Exchange Act, the registrant certifies that it meets all of the requirements for filing on Form 40-F and has duly caused this annual report to be signed on its behalf by the undersigned, thereunto duly authorized, on October 18, 2004.

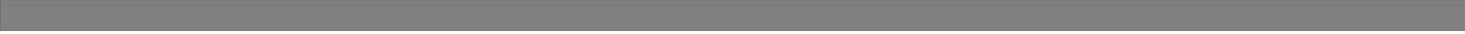
### **Lorus Therapeutics Inc.**

By: "Dr. Jim A. Wright"  
Name: Dr. Jim A. Wright  
Title: Chief Executive Officer

By: "Paul J. Van Damme"  
Name: Paul J. Van Damme  
Title: Chief Financial Officer

## EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	<a href="#"><u>Annual Information Form dated October 8, 2004</u></a>
99.2	<a href="#"><u>Management's Discussion and Analysis</u></a> for the fiscal year ended May 31, 2004 found at pages 8 to 15, inclusive, of the 2004 Annual Report of the Registrant
99.3	<a href="#"><u>Consolidated Financial Statements</u></a> for the fiscal year ended May 31, 2004, together with the report of the auditors thereon. As explained in Note 14 to the Consolidated Financial Statements (page 28 of the registrant's annual report), the registrant does not have any material measurement differences between Canadian GAAP and United States GAAP that apply to the consolidated financial statements.
99.4	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14 of the Securities Exchange Act of 1934
99.5	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14 of the Securities Exchange Act of 1934
99.6	Section 1350 Certification of Chief Executive Officer
99.7	Section 1350 Certification of Chief Financial Officer
99.8	Consent of KPMG LLP



**CERTIFICATION PURSUANT TO RULE 13a-14 OR 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Dr. Jim A. Wright, certify that:

1. I have reviewed this annual report on Form 40-F of Lorus Therapeutics Inc.;
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 issuer as of, and for, the periods presented in this report;
4. The issuer'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)) for the issuer and 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 issuer, 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) Evaluated the effectiveness of the issuer'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
  - (c) Disclosed in this report any change in the issuer'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 issuer's internal control over financial reporting; and
5. The issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer'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 issuer's ability 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 issuer's internal control over financial reporting.

Dated: October 18, 2004

“Dr. Jim A. Wright”  
Dr. Jim A. Wright  
Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION PURSUANT TO RULE 13a-14 OR 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Paul J. Van Damme, certify that:

1. I have reviewed this annual report on Form 40-F of Lorus Therapeutics Inc.;
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 issuer as of, and for, the periods presented in this report;
4. The issuer'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)) for the issuer and 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 issuer, 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) Evaluated the effectiveness of the issuer'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
  - (c) Disclosed in this report any change in the issuer'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 issuer's internal control over financial reporting; and
5. The issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer'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 issuer's ability 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 issuer's internal control over financial reporting.

Dated: October 18, 2004

Paul J. Van Damme  
Paul J. Van Damme  
Chief Financial Officer  
(Principal Financial Officer)



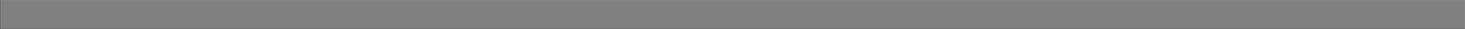
**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE  
SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Lorus Therapeutics Inc. (the "Company") on Form 40-F for the year ended May 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dr. Jim A. Wright, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: "Dr. Jim A. Wright"  
Dr. Jim A. Wright  
Chief Executive Officer

October 18, 2004



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

In connection with the Annual Report of Lorus Therapeutics Inc. (the "Company") on Form 40-F for the year ended May 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul J. Van Damme, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: "Paul J. Van Damme"  
Paul J. Van Damme  
Chief Financial Officer

October 18, 2004



**AUDITORS' CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors  
Lorus Therapeutics Inc.

We consent to the use inclusion in this Annual Report on Form 40-F of our audit report dated July 16, 2004, except as to note 13 which is as of October 5, 2004 on the consolidated balance sheets of Lorus Therapeutics Inc. as at May 31, 2004 and 2003 and the consolidated statements of loss and deficit and cash flows for each of the years in the three year period ended May 31, 2004, and the related consolidated statements of loss and deficit and cash flows for the period from inception on September 5, 1986 to May 31, 2004 incorporated by reference in this annual report on Form 40-F.

/s/ KPMG LLP

Chartered Accountants

Toronto, Canada

October 5, 2004

**L O R U S**  
Therapeutics Inc.

**ANNUAL INFORMATION FORM**

Fiscal year ended May 31, 2004

October 8, 2004

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Statements contained herein that are not based on historical fact, including without limitation statements containing the words "believes," "may," "likely," "plans," "will," "estimate," "continue," "anticipates," "intends," "expects" and similar expressions, constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such factors include, without limitation, changing market conditions, our ability to obtain patent protection and protect our intellectual property rights, commercialization limitations imposed by intellectual property rights owned or controlled by third parties, intellectual property liability rights and liability claims asserted against us, the successful and timely completion of clinical studies, the impact of competitive products and pricing, new product development, uncertainties related to the regulatory approval process, product development delays, our ability to attract and retain business partners and key personnel, future levels of government funding, our ability to obtain the capital required for research, operations and marketing and other risks detailed from time-to-time in the Company's ongoing quarterly filings, annual information forms and annual reports.

We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this annual information form might not occur.

#### DOCUMENTS INCORPORATED BY REFERENCE

The following documents are incorporated by reference in this annual information form:

- Our management's discussion and analysis of financial condition and results of operations for the fiscal years ended 2004 and 2003 (the "**MD&A**") found at pages 8 to 15 inclusive of our annual report for fiscal 2004 (the "**Annual Report**");
- Our audited consolidated balance sheets as at May 31, 2004 and May 31, 2003, the audited consolidated statements of loss and deficit and the consolidated statements of cash flows for each of the years in the three year period ended May 31, 2004, including the auditors' report therein (collectively, the "**2004 Financial Statements**") found at pages 16 to 28 inclusive of the Annual Report; and
- Our management information circular dated October 7, 2004 (the "**Circular**") prepared in connection with the November 18, 2004 annual and special meeting of the shareholders of Lorus Therapeutics Inc., other than the sections entitled "Composition of the Governance Committee", "Report on Executive Compensation" and "Performance Graph". Those portions of the Circular not so incorporated by express reference do not form part of this annual information form.

Copies of the MD&A, Annual Report, 2004 Financial Statements and Circular are available as filed with the Canadian securities regulatory authorities on SEDAR at [www.sedar.com](http://www.sedar.com).

Unless otherwise indicated, or the context requires otherwise, the information appearing in this annual information form is stated as at May 31, 2004 and references in this annual information form to "\$" or "dollars" are to Canadian dollars. Information contained on our website is not part of this annual information form.

Virulizin® is a trademark of the Company. All other trademarks or trade names referred to in this annual information form are the property of their respective owners.

For ease of reference, a glossary of terms used in this annual information form can be found beginning on page 30.

## THE COMPANY

Lorus Therapeutics Inc. was incorporated under the *Business Corporations Act* (Ontario) on September 5, 1986 under the name RML Medical Laboratories Inc. On October 28, 1991, RML Medical Laboratories Inc. amalgamated with Mint Gold Resources Ltd., resulting in the Company becoming a reporting issuer (as defined under applicable securities law) in Ontario, on such date. On August 25, 1992, the Company changed its name to IMUTEC Corporation. On November 27, 1996, the Company changed its name to Imutec Pharma Inc., and on November 19, 1998, the Company changed its name to Lorus Therapeutics Inc.

The address of the Company's head and principal office is 2 Meridian Road, Toronto, Ontario, Canada, M9W 4Z7.

In this annual information form the terms "Lorus", "we", "us", "our", "the Company", and similar expressions refer to Lorus Therapeutics Inc. together with its subsidiaries, unless otherwise noted or the context otherwise requires. Lorus' subsidiaries are GeneSense Technologies Inc. ("**GeneSense**"), a corporation incorporated under the laws of Canada of which Lorus owns 100% of the issued and outstanding share capital, and NuChem Pharmaceuticals Inc. ("**NuChem**"), a corporation incorporated under the laws of Ontario of which Lorus owns 80% of the issued and outstanding voting share capital and 100% of the issued and outstanding non-voting preference share capital.

## BUSINESS OF THE COMPANY

### OVERVIEW

Lorus Therapeutics Inc. is a life sciences company focused on the research, development and commercialization of effective anti-cancer therapies with high safety. Lorus has worked diligently to establish a diverse, marketable anti-cancer product pipeline, with products in various stages of development ranging from pre-clinical to a global Phase III clinical trial that has reached full enrollment. This product pipeline is supported by a growing intellectual property portfolio.

Our success is dependent upon several factors, including establishing the efficacy and safety of our products in clinical trials, obtaining the necessary regulatory approvals to market our products and maintaining sufficient levels of funding through public and/or private financing. Lorus has not commercially marketed any product other than Virulizin®, which is being sold in the private market in Mexico.

We believe that the future of cancer treatment and management lies in drugs that are effective, safe and have minimal side effects thereby improving patient quality of life. Many of the drugs currently approved for the treatment and management of cancer are toxic resulting in severe side effects that limit dosing and efficacy. Therefore, we predict that a product development plan based on effective and safe drugs would have broad applications in cancer treatment. Lorus' strategy is to continue the development of our product pipeline using several therapeutic approaches. Each therapeutic approach is dependent on different technologies, which we believe mitigates the development risks associated with a single technology platform. We evaluate the merits of each product throughout the clinical trial process and consider commercialization. The most advanced anti-cancer drugs in our pipeline, each of which flow from different platform technologies, are: Immunotherapeutics (Virulizin®); antisense (GTI compounds); small molecule and tumor suppressor technology.

From January 1987 to December 1997, we focused our efforts solely on the development of Virulizin®, a product candidate functioning as a biologic response modifier for the treatment of cancer.

In November 1997 we sub-licensed, on an exclusive world-wide basis until the later of patent expiry or marketing approval, from Ion Pharmaceuticals, Inc. ("Ion") (a subsidiary of MAP Pharmaceuticals, Inc.) analogs of clotrimazole ("CLT"), a molecule with anti-angiogenic and anti-proliferative properties, for anti-cancer indications as well as actinic keratosis.

In September 2003, we out-licensed the CLT analogs to Cyclacel Limited ("Cyclacel"). See "License Agreements".

On October 29, 1999, we acquired all of the issued and outstanding shares of GeneSense (the "**GeneSense Acquisition**"), a private biopharmaceutical company that specializes in developing novel oligonucleotide therapeutics for cancer and infectious diseases. Pursuant to the GeneSense Acquisition, we obtained two anti-cancer products in late-stage, pre-clinical development, in addition to several other products in the research stage. We believe that the GeneSense Acquisition also added depth to our research and development capabilities.

As a consequence of the GeneSense Acquisition, we now hold an exclusive worldwide license from the University of Manitoba and Cancer Care Manitoba (formerly The Manitoba Cancer Treatment and Research Foundation) ("**Cancer Care**") to develop certain oligonucleotide technologies. Antisense technology, one of the oligonucleotide technologies, works at the genetic level to interrupt the process by which disease-causing proteins are produced in order to treat a wide range of diseases, including cancer and infectious diseases.

## **CANCER THERAPY TECHNOLOGIES**

### ***Cancer Biotherapy***

Chemotherapeutic drugs have been the predominant medical treatment option for cancer, particularly metastatic cancer, for the past 30 years. However, a wide range of new cancer drugs have been developed by biotechnology companies that improve patients' quality of life. Unlike chemotherapies which are chemically based, these new drugs are biological, based on naturally occurring proteins or genetic material. Biotherapies currently in development include immunotherapy, gene therapy, and angiogenesis inhibitors. While chemotherapy drugs are typically toxic and delivered systemically, these biological agents are targeted to the tumor and, more specifically, to individual molecules or genes. These agents promise to have fewer and milder side effects, meaning that, in theory, larger and therefore more effective doses can be administered.

Our lead products discussed below span three classes of anti-cancer therapies: (i) immunotherapy, based on macrophage-stimulating biologic response modifiers; (ii) antisense therapies, based on synthetic segments of DNA designed to bind to the messenger RNA (mRNA) that is responsible for the production of proteins over-expressed in cancer cells, and (iii) small molecule therapies based on anti-angiogenic, anti-proliferative and anti-metastatic agents.

In addition, we also have a number of other anti-cancer technologies in the research and pre-clinical stages of development, including gene therapy and U-Sense technology. See "Principal Products".

### ***Immunotherapy***

Immunotherapy is a form of treatment that stimulates the body's immune system to fight diseases such as cancer. Immunotherapy may help the immune system to fight cancer by recognizing the difference between healthy cells and cancer cells, or it might stimulate the production of certain cancer fighting cells.



The human immune system and other protective cellular and molecular systems constitute a complex network of organs, tissues and cells which protect the body against foreign substances such as viruses, bacteria and foreign tissue. In addition to foreign substances, these systems specifically recognize and destroy aberrant cells that lead to cancer. As a result, appropriate immune system response is critical to both health and survival. When the immune system functions properly, it recognizes and effectively eliminates foreign substances and cancer cells. Conversely, inadequate or suppressed immune function may result in disease and, possibly, death. When inadequate or suppressed immune function occurs, modification or enhancement of the immune system may restore normal function. Immune system modification or enhancement may be achieved through the use of therapeutic products that stimulate or activate the immune system to achieve a desired response.

In recent years, a major focus of the biotechnology industry has been to develop naturally occurring human therapeutics, which are referred to broadly as biologic response modifiers (“**BRMs**”), and are so described because they are able to influence specific cellular events in the body. Many different substances are classified as BRMs and they have varied biological activities. Some of the major categories of BRMs include interferons (naturally occurring proteins capable of killing cancer cells or inhibiting their growth), interleukins (growth factors that stimulate cells of the immune system to fight cancer) and cytokines (substances produced by immune system cells, usually to send messages to other cells). BRMs have applications in a variety of diseases, including cancer, and are currently being employed in cancer immunotherapy. BRMs may be used alone, in various combinations with other BRMs, or as adjuncts to other therapies.

Our immunotherapeutic drug Virulizin<sup>(R)</sup>, discussed below, has been shown to be a non-toxic immunotherapy that recruits monocytes and macrophages to attack tumor cells. Since the drug works by stimulating the immune system to attack the cancer, rather than directly killing the cancerous cells, it produces fewer negative side effects than commonly used chemotherapy agents. See “Principal Products -- Virulizin<sup>(R)</sup>”.

### ***Antisense therapies***

The human metabolic system is essentially controlled by proteins produced by the body in response to specific conditions. Since most human diseases, including cancer, can be traced to faulty protein production or regulation, traditional therapeutics are designed to interact with the disease-causing proteins. Most current anti-cancer drugs damage either DNA or proteins within cells (e.g., chemotherapy) or inhibit protein or small molecule function ( e.g., estrogen blockers, such as Tamoxifen). Antisense therapeutics take a different approach to treatment in that they are designed to prevent the production of proteins causing diseases.

The premise of this therapeutic approach is to target an earlier stage of the biochemical process than is usually possible with conventional drugs. Most traditional therapies interact with the final synthesized or processed protein. Often this interaction lacks specificity that would allow for interaction with only the intended target, resulting in undesired side effects. In contrast, this newer approach alters an earlier expression of the gene with exquisite specificity such that the expression of only the intended target is affected. We believe that drugs based on this approach may have broad applicability, greater efficacy and fewer side effects than conventional drugs.

We have developed a number of antisense drugs, of which our lead products are GTI-2040 and GTI-2501. These products target the different mRNAs (messenger ribonucleic acids) of ribonucleotide reductase (“**RNR**”) components. RNR is a highly regulated, cell cycle-controlled protein required for DNA synthesis and repair. RNR is made up of two components, R1 and R2, encoded by different genes, and promotes the formation of deoxyribonucleotides, which are the building blocks of DNA. Since RNR activity is highly elevated in tumor cell populations and is associated with tumor cell proliferation, we have developed antisense molecules specific for the mRNA of the R1 or the R2 components of RNR. Furthermore, the R2 component also appears to be a signal molecule in cancer cells and its elevation is believed to modify a biochemical pathway that can increase the malignant properties of



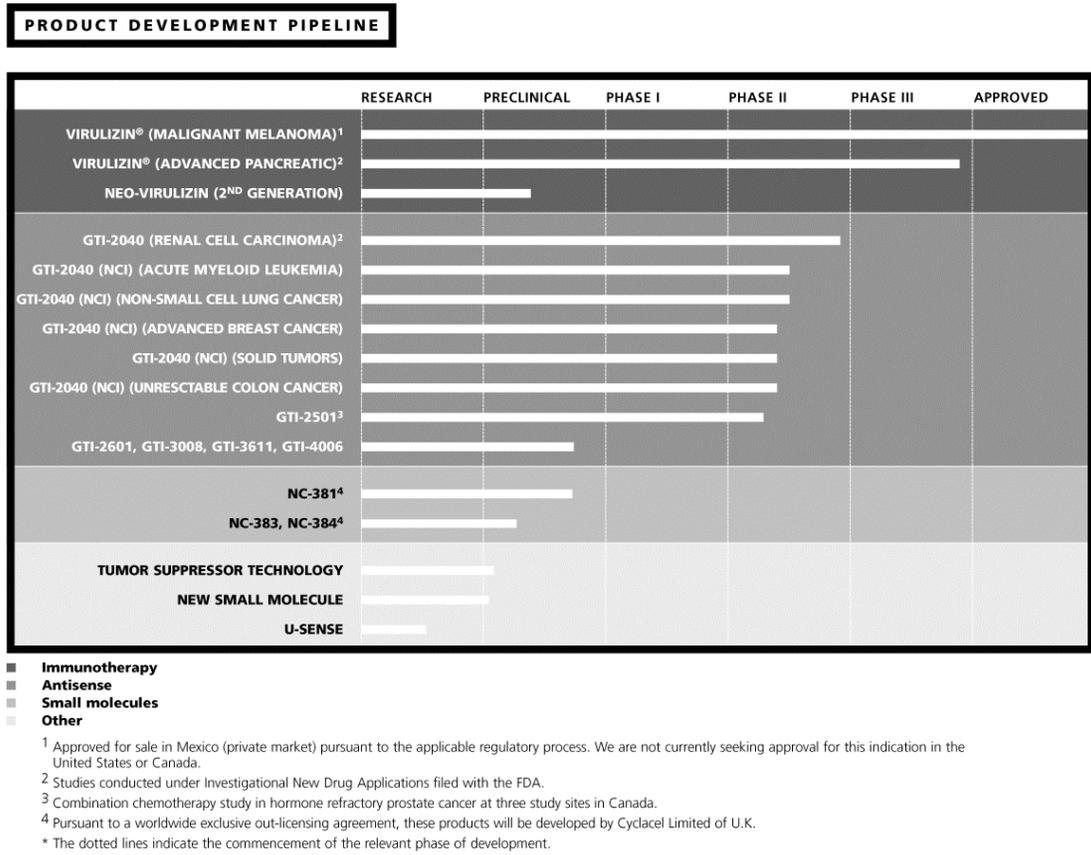
tumor cells. Consequently, reducing the expression of the RNR components in a tumor cell with antisense drugs is expected to have antitumor effects.

**Small Molecule Therapies**

Most anti-cancer chemotherapeutic treatments are DNA damaging, cytotoxic agents, designed to act on rapidly dividing cells. Treatment with these drugs typically includes unpleasant or even serious side effects due to the inability of these drugs to differentiate between normal and cancer cells. In addition, these drugs often lead to the development of tumor-acquired drug resistance. As a result of these limitations, a need exists for more effective anti-cancer drugs. One approach is to develop small molecules with a greater specificity as anti-cancer drugs. Chemical compounds weighing less than 1000 daltons (a unit of molecular weight) are designated as small or low molecular weight molecules. These molecules can be designed to target specific proteins or receptors that are known to be involved with disease.

**PRINCIPAL PRODUCTS**

We have product candidates in each of the three classes of anti-cancer therapies identified above, (i) immunotherapy, (ii) antisense therapies, and (iii) small molecule therapies based on anti-angiogenic, anti-proliferative and anti-metastatic agents. We also have product candidates based on other anti-cancer technologies in the research and pre-clinical stages of development, including gene therapy and U-Sense technology. The following chart illustrates our current view of the clinical development of each of our products. This chart reflects the regulatory approval process for biopharmaceuticals in each of Canada and the United States (with the exception of Virulizin® for malignant melanoma which is approved for use in the private market in Mexico). Please see “--Regulatory Requirements” below for a description of the regulatory approval process in Canada and the United States. These qualitative estimates of the progress of our products are intended solely for illustrative purposes and the information contained herein is qualified in its entirety by the information appearing elsewhere or incorporated by reference in this annual information form.



## **Immunotherapeutics**

### **Virulizin®**

Virulizin<sup>(R)</sup>, Lorus' immunotherapeutic drug, has been shown to be a non-toxic immunotherapy that stimulates monocytes and macrophages to infiltrate tumor tissue and attack tumor cells. Types of white blood cells, monocytes and macrophages are key players in the immune response to foreign invaders and tumor cells. When macrophages and monocytes are activated, they produce proteins called cytokines which have the ability to kill tumor cells directly. Virulizin<sup>(R)</sup> stimulates the release of tumor necrosis factor (TNF-alpha), one type of cytokine, in immune cells to induce apoptosis (programmed cell death) of tumor cells. Because the drug works by encouraging the immune system to attack the cancer, rather than killing the cancerous cells directly, it has been demonstrated that Virulizin<sup>(R)</sup> produces fewer negative side effects than commonly used chemotherapy agents.

### **Pre-clinical Testing**

Toxicity studies conducted at independent laboratories have shown Virulizin® to have a good safety profile. No demonstrable LD<sub>50</sub> was determined during these studies, and repeated administrations of Virulizin® did not result in organ system toxicities. In November 1998, additional preclinical data on the efficacy of Virulizin® was obtained from studies performed at the University of Nebraska Medical Center. We performed these supporting studies to determine the efficacy of Virulizin® in connection with gemcitabine, an Eli Lilly product that is the standard for first-line treatment of pancreatic cancer, in a human tumor xenograft model commonly used for pancreatic cancer. After extended daily administration, Virulizin® significantly inhibited tumor growth in this model compared to a placebo. Virulizin® also showed a trend towards a cooperative anti-tumor activity when combined with gemcitabine.

Over the past few years Lorus has made great progress in understanding the potential for Virulizin<sup>(R)</sup> in the treatment of cancer. Pre-clinical studies, using experimental models of human cancer, demonstrate anti-tumor efficacy for Virulizin<sup>(R)</sup> against pancreatic, prostate, breast and ovarian cancers and melanoma. These studies demonstrate efficacy that typically exceeds standard therapy and furthermore demonstrate improved efficacy when Virulizin<sup>(R)</sup> is given in combination with standard therapy. Also of importance is that Virulizin<sup>(R)</sup> is effective against chemotherapy resistant pancreatic cells. These studies have been published in peer reviewed scientific journals and the data presented at a number of international scientific and clinical research conferences. In addition to understanding the potential applications of Virulizin<sup>(R)</sup>, the scientists at Lorus have made considerable progress in elucidating the mechanism by which Virulizin<sup>(R)</sup> acts as a BRM and anti-cancer agent. Two recent publications in the *International Journal of Oncology* and the *Cancer Immunology and Immunotherapy* summarize a number of studies aimed at understanding the cellular and molecular mechanism by which Virulizin<sup>(R)</sup> acts on the immune system to produce an anti-tumor immune response. These studies identified two major components of the innate immune system, namely macrophages and natural killer (NK) cells, as targets for Virulizin<sup>(R)</sup> action. *In vitro* and *in vivo* data support a mechanism in which Virulizin<sup>(R)</sup> sets in motion a complex and intricately controlled pathway that starts with macrophages and results in expansion of NK cells, recruitment of macrophages and NK cells to the tumor site, and a concomitant increase in programmed cell death (termed "apoptosis") of tumor cells. These studies form the basis for ongoing studies on the detailed molecular events that are responsible for the cellular changes observed upon Virulizin<sup>(R)</sup> treatment.

### **Clinical Development Program**

Our early clinical trials were primarily established to determine the safety and efficacy of Virulizin<sup>(R)</sup> as a single therapeutic agent for treating the most serious or life threatening cancer indications. These clinical trials involved Stage III and Stage IV cancer patients who had been diagnosed with cancers that were life threatening and for which there were no established effective therapies. Approximately 250 patients were enrolled in the clinical trials conducted in the United States, Canada, and Mexico and others have received Virulizin<sup>(R)</sup> through Lorus' special access program.



Lorus received orphan drug designation from the United States Food and Drug Administration ("FDA") in February 2001 for Virulizin<sup>(R)</sup> in the treatment of pancreatic cancer. Orphan drug status is awarded to drugs used in the treatment of a disease that afflicts less than 200,000 patients annually in the United States to encourage research and testing. This status means that the FDA will help to facilitate the drug's development process by providing financial incentives and granting seven years of market exclusivity in the United States (independent of patent protection) upon approval of the drug in the United States.

Currently, we have completed full enrollment for a Phase III clinical trial to evaluate Virulizin<sup>(R)</sup> for the treatment of advanced pancreatic cancer. We intend to present the results of this clinical trial to the FDA in a new drug application at the completion of the study. This double-blinded, randomized clinical trial is being conducted at approximately 136 sites in North America and Europe with enrolment of 436 patients with advanced pancreatic cancer. Patients enrolled in the study were randomized to receive either treatment with gemcitabine or treatment with gemcitabine in combination with Virulizin<sup>(R)</sup>. Those patients who fail or become resistant to gemcitabine will then be treated with 5-Fluorouracil (5-FU) or with 5-FU in combination with Virulizin<sup>(R)</sup>. Our study protocol provides that all study subjects will be monitored throughout the remainder of their lifespan. The end points of the study are survival and clinical benefits, and the duration is expected to be approximately three years. We anticipate that the Phase III trial results should be available in late 2005 and that this clinical study report will be pivotal in the application for marketing approval for Virulizin<sup>(R)</sup>, which we are planning to submit to the FDA in the first half of 2006.

In November 2003, we announced the further global expansion of the compassionate use program for for advanced pancreatic cancer. The program has grown to include a total of 12 countries, with over 78 patients having received for treatment of advanced pancreatic cancer in the past year. Countries that have granted regulatory authorization for use of as a compassionate drug now include the United States, Canada, Japan, Australia, Argentina, Italy, Israel, Greece, Cyprus, Korea, Poland and Taiwan.

## **Clinical Trial Results**

### ***Malignant Melanoma***

In September 1993, we completed a Phase II clinical trial of Virulizin<sup>(R)</sup> in Mexico in the treatment of advanced malignant melanoma. Advanced malignant melanoma is a type of skin cancer with a tendency to spread via the lymphatic system and blood supply to other organs and tissues. Based upon the results of the Mexican trial, we filed an NDA in November 1996, to obtain marketing approval of Virulizin<sup>(R)</sup> in Mexico as a treatment for advanced malignant melanoma. In October 1997, we received a license from the SSA to sell Virulizin<sup>(R)</sup> in Mexico in the private market for the treatment of malignant melanoma. We currently do not plan to conduct further clinical trials for this indication.

### ***Pancreatic Cancer***

In September 1992, we completed a Phase II clinical trial of Virulizin<sup>(R)</sup> in Canada for the treatment of pancreatic adenocarcinoma. Pancreatic adenocarcinoma develops in the glands that produce enzymes that travel through the pancreatic duct to the small intestine to aid digestion. Approximately 90% of pancreatic cancers are pancreatic adenocarcinomas.

In August 1998, we released results of the Phase I/II trial evaluating Virulizin<sup>(R)</sup> in patients with pancreatic cancer at the Rush Cancer Institute. Of the 26 patients enrolled, 19 were deemed evaluable according to the study protocol. We announced that the overall median survival for all evaluable patients was 6.7 months and the six-month survival rate was 58%. These results confirmed and extended the previous studies we had conducted in Canada in pancreatic cancer patients. Results of the Phase I/II



trial also showed that Virulizin<sup>(R)</sup> exhibited an excellent safety profile, and there was an increasing trend and a statistically significant improvement in total quality-of-life change score.

#### **Future Indications**

We believe that *in vitro* and *in vivo* research supports the therapeutic potential of Virulizin<sup>(R)</sup> in the treatment of diseases associated with immune system disorders other than cancer. We previously sponsored research studies at Rush-Presbyterian-St. Luke's Medical Center in Chicago to study the potential of Virulizin<sup>(R)</sup> in the treatment of endometriosis. Our scientists have also conducted pre-clinical research in the use of Virulizin<sup>(R)</sup> in combination with known cytotoxic or chemotherapeutic agents in the treatment of a number of different cancer indications.

#### **Antisense Therapeutics**

##### **GTI-2040**

Our lead antisense therapy is GTI-2040, an antisense drug that targets the R2 component of RNR and has exhibited anti-tumor properties against over a dozen different human cancers in standard mouse models, including chemotherapy resistant tumors. We are nearing completion of a Phase II clinical trial of GTI-2040 for advanced or metastatic renal cell carcinoma. We also have commenced a multiple Phase II clinical trial program in cooperation with the NCI, for the study of GTI-2040 for the treatment of AML, breast cancer, lung cancer, colon cancer, and a series of solid tumors.

The R2 component is an effective target for drug intervention because it is the rate-limiting component in the RNR activity important for cancer cell proliferation. It also appears to be bi-functional since an elevation in the R2 component in cancer cells can alter the activity of an important biochemical signal pathway called the MAP Kinase Pathway, which is known to play a role in mechanisms leading to the development of cancer. We have designed antisense molecules that specifically target the R2 mRNA, resulting in:

- reduced R2 protein and R2 mRNA levels in human tumor cells grown in culture;
- significant inhibition of tumor cell growth *in vitro*;
- statistically significant reduction of tumor growth and tumor cell dissemination (metastasis) in animal models; and
- increase in survival in models of haematological malignancy.

Since it has been noted that levels of R2 are elevated in cancer cells, an antisense molecule that binds to the mRNA coding for R2 inhibits the replication of diseased cells. Further, research indicates that reducing levels of R2 expressed in cells lowers resistance levels to other pharmaceutical compounds that might be used in combination therapy with GTI-2040. This is consistent with the observed improved efficacy of standard chemotherapeutics when given in combination with GTI-2040 in animal models of human cancer.

#### **Pre-Clinical Testing**

Formal preclinical development of GTI-2040, including manufacturing and toxicology studies, was initiated in mid-1998. Pre-clinical studies, including GLP toxicology studies in standard



animal models have demonstrated that GTI-2040 is well tolerated at concentrations that exceed commensurate therapeutic doses in humans.

### **Clinical Development**

An IND application filed with the FDA was approved on January 24, 2000 for a Phase I clinical trial of GTI-2040, given as a 21-day continuous intravenous infusion in the treatment of solid tumor and lymphoma. This trial was conducted under the direction of Dr. Richard Schilsky of the Chicago Cancer Research Center. A total of 30 patients with advanced or metastatic solid tumors were enrolled in this study and evaluated. The results established that Phase I clinical endpoints for safety and tolerability were met. Doses studied ranged from 18.5 mg/m<sup>2</sup>/day to 222.0 mg/m<sup>2</sup>/day and were found to display favourable safety profiles establishing that the recommended Phase II dose for GTI-2040 administered as a single agent is 185.0 mg/m<sup>2</sup>/day. An additional six patients with renal cell carcinoma were enrolled in this study which confirmed the favorable toxicity profile at this dose in this specific patient population.

On March 12, 2003, the FDA awarded Orphan Drug Status to GTI-2040 for the treatment of renal cell carcinoma.

In July 2003, we announced the FDA's approval of the NCI sponsored Investigational New Drug ("IND") application for a clinical trial of GTI-2040 in combination with cytarabine, in patients with refractory or relapsed acute myeloid leukemia ("AML"). Cytarabine is the current established drug for treating AML patients. The new study is part of a Phase II clinical program to be conducted under the sponsorship of the Cancer Treatment Evaluation Program of the NCI pursuant to a clinical trials agreement between Lorus and the NCI.

In August 2003, we announced that the FDA had approved the NCI's IND to begin a Phase II clinical trial to investigate GTI-2040 as a treatment for metastatic breast cancer in combination with capecitabine (Xeloda, manufactured by Roche Laboratories Inc.).

In September 2003, we received approval from Health Canada for initiation of a clinical trial of GTI-2040 in combination with docetaxel for the treatment of advanced non-small cell lung cancer ("NSCLC"), as part of a Phase II clinical program of GTI-2040 in collaboration with the NCI.

In January 2004, we announced interim results from a recently conducted exploratory Phase II clinical trial of GTI-2040 in patients with advanced, end-stage renal cell cancer in the United States, and extension of enrolment to meet statistical requirements for evaluation. This trial is a single-arm pilot study examining the safety and efficacy of GTI-2040 used in combination with the anticancer agent capecitabine. Results to date in the ongoing study were announced on September 30, 2004. To date, data have been collected on 25 patients evaluable for tumor assessment, with 4 more patients still to be evaluated. The majority of patients had failed two or more prior therapies before entering the study, exhibited extensive metastases, and were representative of a population with very poor prognostic outcome in renal cell cancer. In the present clinical study, few treatment-related toxicities outside of those already known to occur with the test drugs were observed. More than half of the 25 evaluable patients in this study exhibited disease stabilization, ranging up to ten months. Tumor shrinkages of index tumors compared to baseline measurements were observed in some patients including sustained shrinkage in the longest duration stable diseases and in a patient with confirmed partial response. A full assessment of tumor responses and safety of the study regimen will be completed following conclusion of the study.

In February 2004 we announced the initiation of a Phase II clinical trial examining the use of GTI-2040 in combination with gemcitabine in patients with solid tumors. This study is part of a larger clinical program sponsored and coordinated by the NCI.

In May 2004, we announced the initiation of a Phase II clinical trial examining GTI-2040 in combination with oxaliplatin and capecitabine in the treatment of advanced unresectable colon cancer. This study is part of a clinical trials program sponsored by the NCI. This study is ongoing.



### **GTI-2501**

Our other antisense therapy is GTI-2501, designed to specifically target the R1 mRNA, resulting in:

- reduced R1 protein and R1 mRNA levels;
- significant inhibition of tumor cell growth *in vitro*;
- statistically significant reduction of tumor growth and tumor cell dissemination (metastasis) in animal models with total regression observed in some tumor models;
- increase in survival in models of haematological malignancy;
- efficacy against chemotherapy resistant tumor models; and,
- improved efficacy of standard chemotherapy when given as a combination with GTI-2501.

Research indicates that GTI-2501 specifically prevents the formation of the R1 protein required for RNR activity

### **Pre-Clinical Testing**

GTI-2501 has demonstrated anti-tumor activity in a wide range of human cancers in standard mouse models including human breast, kidney and prostate cancers. Pre-clinical studies have demonstrated that GTI-2501 is well tolerated in standard animal models at concentrations that exceed commensurate therapeutic doses in humans.

### **Clinical Development Program**

GLP-toxicology studies for GTI-2501 were completed in November 2000, and approval of an IND was received from the U.S. FDA February 2001. This Phase I dose-escalating study at the University of Chicago Medical Centre was designed to establish the recommended clinical Phase II dose as well as look at the safety profile of GTI-2501. A total of 32 patients with solid tumors or lymphoma were enrolled and are presently being evaluated following clinical completion. Preliminary evaluation has confirmed favorable safety profiles as a single agent at doses ranging from 6 mg/m<sup>2</sup>/day to a recommended Phase II dose established in this study to be 210.9 mg/m<sup>2</sup>/day.

In December 2003, we announced that a Phase II clinical trial for the treatment of hormone refractory prostate cancer ("HRPC") had been initiated at the Toronto Sunnybrook Regional Cancer Centre, in which GTI-2501 is administered in combination with docetaxel. The combination of GTI-2501 and docetaxel in this clinical trial is being investigated in patients with asymptomatic or symptomatic HRPC where disease progression is uncontrolled. This represents the first clinical trial of GTI-2501 in Canada following the successful conclusion of the Phase I clinical trial in 2003 in the United States. We announced expansion of this ongoing HRPC trial to two additional sites in Canada in July 2004.



### **Small Molecule Therapies**

#### ***Clotrimazole Analogs***

In November 1997 we sub-licensed, on an exclusive world-wide basis until the later of patent expiry or marketing approval, CLT analogs for anti-cancer indications as well as actinic keratosis, from Ion. Research studies on this class of compounds resulted in Lorus publishing papers in a number of peer-reviewed scientific journals that specialize in medical chemistry. In September of 2004, we out-licensed the CLT analogs to Cyclacel. See "-- License Agreements".

#### ***Low Molecular Weight Compounds***

In May 2004, we announced the discovery of novel low molecular weight compounds with anticancer and antibacterial activity. The finding comes after three years of research by Lorus scientists through a small molecule discovery program. We subsequently signed a collaboration agreement with the University of Toronto to provide a further development and delivery strategy for the compounds.

#### ***Other Technologies***

Several promising new product opportunities have been introduced to our portfolio and are being assessed for their potential as new drug candidates. They include platform technologies in areas of tumor suppressor gene therapy, and U-Sense compounds that we believe to have the potential to work through a unique mechanism of action to decrease the expression of cancer relevant genes. Further antisense approaches for the treatment of cancer and drug resistant bacteria are also being investigated in the Lorus laboratory. We intend to continue developing these compounds with the aim to identify new drug candidates for clinical trials as the three lead drugs make their way through clinical trials and to market.

In June, 2004 we announced that GeneSense had been allowed a patent by the European Patent Office for its discovery of a gene which suppresses the growth of malignant tumors.

### **BUSINESS STRATEGY**

By developing cancer therapeutics using different mechanisms of action that may be efficacious against a wide variety of cancers, we seek to maximize our opportunity to address multiple cancer therapeutic markets. In its efforts to obtain the greatest return on its investment in each drug candidate, we separately evaluate the merits of each candidate throughout the clinical trial process and consider commercialization opportunities when appropriate. In the next fiscal year, we intend to pursue arrangements for the commercialization of Virulizin® and on partnerships and further development of our lead technologies. See "Co-development, Marketing and Distribution."

### **PRODUCTION AND TESTING**

Preclinical testing and certain research and development work has been performed at various contract laboratories. Clinical trials have been undertaken at various medical centres worldwide.

### **MANUFACTURING**

We have entered into a contract with Proligo LLC, a cGMP manufacturer, to produce its bulk active drug substance for its antisense compounds. The manufacturer supplied bulk active drug for Good Laboratory Practices (GLP) toxicology studies and drug stability studies and has supplied bulk active drug, subsequently formulated, for both the GTI-2040 and GTI-2501 clinical trials. Proligo has filed a drug master file (DMF) with the FDA and have supplied the necessary documentation to support the IND submission.



In March 2001, we signed an agreement with Dalton Chemical Laboratories Inc. for the manufacturing of Virulizin<sup>(R)</sup>. The drug is being manufactured for the Phase III clinical trial program that we initiated in fiscal 2002 as well as to supply our licensee, Mayne Pharma Inc. (formerly Faulding Canada Inc.) with Virulizin<sup>(R)</sup> for malignant melanoma treatment in Mexico.

In July 2004, we entered into negotiations with Diagnostics Chemicals Limited doing business as BioVectra dcl in Prince Edward Island for the commercial manufacture of Virulizin<sup>(R)</sup> and the contract should be executed after October 7<sup>th</sup>, 2004.

## **INTELLECTUAL PROPERTY AND PROTECTION OF CONFIDENTIAL INFORMATION AND TECHNOLOGY**

We believe that our issued patents and pending applications are important in establishing and maintaining a competitive position with respect to our products and technology. As at May 31, 2004, we own or have rights under more than 50 issued or pending patents in Canada and the United States, as well as over 120 other issued and pending patent applications in other jurisdictions around the world.

### ***Immunotherapy***

We have been issued two patents in Canada and three patents in the United States relating to our immunotherapy platform, which include composition of matter, method and process claims.

### ***Antisense***

We have been issued one patent in Canada and seven patents in the United States relating to our antisense platform, which includes composition of matter and method claims.

### ***Small Molecule***

We have been issued two patents in the United States, which include composition of matter and method claims, relating to the NuChem small molecule platform.

We either own these issued patents or have the exclusive right to make, use, market, sell or otherwise commercialize products using these patents to diagnose and treat cancer. We cannot assure you that we will continue to have exclusive rights to these patents.

We cannot assure you that pending applications will result in issued patents, or that issued patents will be held valid and enforceable if challenged, or that a competitor will not be able to circumvent any such issued patents by adoption of a competitive, though non-infringing product or process. Interpretation and evaluation of pharmaceutical or biotechnology patent claims present complex and often novel legal and factual questions. Our business could be adversely affected by increased competition in the event that any patent granted to it is held to be invalid or unenforceable or is inadequate in scope to protect our operations.

While we believe that our products and technology do not infringe proprietary rights of others, we cannot assure you that third parties will not assert infringement claims in the future or that such claims will not be successful. Furthermore, we could incur substantial costs in defending ourselves against patent infringement claims brought by others or in prosecuting suits against others.

In addition, we cannot assure you that others will not obtain patents that we would need to license, or that if a license is required that it would be available to us on reasonable terms, or that if a license is not obtained that we would be able to circumvent, through a reasonable investment of time and expense, such outside patents. Whether we obtain a license would depend on the terms offered, the degree of risk of infringement, the vulnerability of the patent to invalidation, and the ease of circumventing the patent.



Until such time, if ever, that further patents are issued to us, we will rely upon the law of trade secrets to the extent possible given the publication requirements under international patent treaty laws and/or requirements under foreign patent laws to protect our technology and our products incorporating the technology. In this regard, we have adopted certain confidentiality procedures. These include: limiting access to its confidential information to certain key personnel; requiring all of its directors, officers, employees and consultants and others who may have access to our intellectual property to enter into confidentiality agreements which prohibit the use of or disclosure of confidential information to third parties; and implementing physical security measures designed to restrict access to such confidential information and products. Our ability to maintain the confidentiality of our technology is crucial to our ultimate possible commercial success. We cannot assure you that the procedures adopted by us to protect the confidentiality of our technology will be effective, that third parties will not gain access to our trade secrets or disclose the technology, or that we can meaningfully protect our rights to our technology. Further, by seeking the aforementioned patent protection in various countries, it is inevitable that a substantial portion of our technology will become available to its competitors, through publication of such patent applications.

## **REGULATORY REQUIREMENTS**

### ***Overview***

Regulation by government authorities in Canada, the United States, Mexico and the European Union is a significant factor in our current research and drug development activities. In order to clinically test, manufacture and market drug products for therapeutic use, we must satisfy the rigorous mandatory procedures and standards established by the regulatory agencies in the countries in which we currently operate or intend to operate.

The laws of most of these countries require the licensing of manufacturing facilities, carefully controlled research and the extensive testing of products. Biotechnology companies must establish the safety and efficacy of their new products in clinical trials, cGMP, and control over marketing activities before being allowed to market their products. The safety and efficacy of a new drug must be shown through clinical trials of the drug carried out in accordance with the mandatory procedures and standards established by regulatory agencies.

The process of completing clinical trials and obtaining regulatory approval for a new drug takes a number of years and requires the expenditure of substantial resources. Once a new drug or product license application is submitted, we cannot assure you that a regulatory agency will review and approve the application in a timely manner. Even after initial approval has been obtained, further studies, including post-marketing studies, may be required to provide additional data on safety necessary to gain approval for the use of the new drug as a treatment for clinical indications other than those for which the new drug was initially tested. Also, regulatory agencies may require post-marketing surveillance programs to monitor a new drug's side effects. Results of post-marketing programs may limit or expand the further marketing of new drugs. A serious safety or effectiveness problem involving an approved new drug may result in a regulatory agency requiring withdrawal of the new drug from the market and possible civil action. We cannot assure you that we will not encounter such difficulties or excessive costs in our efforts to secure necessary approvals, which could delay or prevent us from manufacturing or marketing our products.

In addition to the regulatory product approval framework, biotechnology companies, including Lorus, are subject to regulation under local provincial, state and federal law, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, provincial, state, federal and foreign regulation, including possible future regulation of the biotechnology industry.



## Canada

In Canada, the manufacture and sale of new drugs are controlled by Health Canada (“**HC**”). New drugs must pass through a number of testing stages, including pre-clinical testing and clinical trials. Preclinical testing involves testing the new drug’s chemistry, pharmacology and toxicology *in vitro* and in animals. Successful results (that is, potentially valuable pharmacological activity combined with an acceptable low level of toxicity) enable the developer of the new drug to file a Clinical Trial Application (“**CTA**”) to begin clinical trials involving humans.

In order to study a drug in Canadian patients, a CTA submission must be filed with HC. The IND submission must contain specified information, including the results of the pre-clinical tests completed at the time of the submission and any available information regarding use of the drug in humans. In addition, since the method of manufacture may affect the efficacy and safety of a new drug, information on manufacturing methods and standards and the stability of the drug substance and dosage form must be presented. Production methods and quality control procedures must be in place to ensure an acceptably pure product, essentially free of contamination, and to ensure uniformity with respect to all quality aspects.

Provided HC does not reject a CTA submission, clinical trials can begin. Clinical trials are carried out in three phases or a combination thereof. Phase I involves studies to evaluate toxicity in humans. The new drug is administered to human patients who have met the clinical trial entry criteria to determine pharmacokinetics, human tolerance and prevalence of adverse side effects. Phases II and III involve therapeutic studies. In Phase II, efficacy, dosage, side effects and safety are established in a small number of patients who have the disease or disorder that the new drug is intended to treat. In Phase III, there are controlled clinical trials in which the new drug is administered to a large number of patients who are likely to receive benefit from the new drug. In Phase III, the effectiveness of the new drug is compared to that of standard accepted methods of treatment in order to provide sufficient data for the statistical proof of safety and efficacy for the new drug.

If clinical studies establish that a new drug has value, the manufacturer submits a New Drug Submission (“**NDS**”) application to HC for marketing approval. The NDS contains all information known about the new drug, including the results of pre-clinical testing and clinical trials. Information about a substance contained in an NDS includes its proper name, its chemical name, details on its method of manufacturing and purification, and its biological, pharmacological and toxicological properties. The NDS also provides information about the dosage form of the new drug, including a quantitative listing of all ingredients used in its formulation, its method of manufacture, manufacturing facility information, packaging and labeling, the results of stability tests, and its diagnostic or therapeutic claims and side effects, as well as details of the clinical trials to support the safety and efficacy of the new drug. Furthermore, for biological products, an on-site evaluation is required prior to the issuance of a Notice of Compliance. All aspects of the NDS are critically reviewed by HC. If an NDS is found satisfactory, a Notice of Compliance is issued permitting the new drug to be sold.

HC has a policy of priority evaluation of new drug submissions for all drugs intended for serious or life-threatening diseases for which no drug product has received regulatory approval in Canada and for which there is reasonable scientific evidence to indicate that the proposed new drug is safe and may provide effective treatment.

The monitoring of a new drug does not cease once it is on the market. For example, a manufacturer of a new drug must report any new information received concerning serious side effects, as well as the failure of the new drug to produce desired effects. As well, if HC determines it to be in the interest of public health, a notice of compliance for a new drug may be suspended and the new drug may be removed from the market.

An exception to the foregoing requirements relating to the manufacture and sale of a new drug is the limited authorization that may be available in respect of the sale of new drugs for emergency treatment. Under the special access program, HC may authorize the sale of a quantity of a new drug for



human use to a specific practitioner for the emergency treatment of a patient under the practitioner's care. Prior to authorization, the practitioner must supply HC with information concerning the medical emergency for which the new drug is required, such data as is in the possession of the practitioner with respect to the use, safety and efficacy of the new drug, the names of the institutions at which the new drug is to be used and such other information as may be requested by HC. In addition, the practitioner must agree to report to both the drug manufacturer and HC the results of the new drug's use in the medical emergency, including information concerning adverse reactions, and must account to HC for all quantities of the new drug made available.

The Canadian regulatory approval requirements for new drugs outlined above are similar to those of other major pharmaceutical markets. While the testing carried out in Canada is often acceptable for the purposes of regulatory submissions in other countries, supplementary testing may be requested by individual regulatory authorities during their assessment of any submission. We cannot assure you that the clinical testing conducted under HC authorization or the approval of regulatory authorities of other countries will be accepted by regulatory authorities outside Canada or such other countries.

### **United States**

In the United States, the manufacture and sale of new drugs are controlled by the FDA. New drugs require FDA approval of a marketing application (e.g. an NDA or product license application) prior to commercial sale. To obtain marketing approval, data from adequate and well-controlled clinical investigations, demonstrating to the FDA's satisfaction a new drug's safety and effectiveness for its intended use, are required. Such data are generated in studies conducted pursuant to an IND submission, similar to that required in Canada. As in Canada, clinical studies are characterized as Phase I, Phase II and Phase III trials or a combination thereof. In a marketing application, the manufacturer must also demonstrate the identity, potency, quality and purity of the active ingredients of the new drug involved, and the stability of those ingredients. Further, the manufacturing facilities, equipment, processes and quality controls for the new drug must comply with the FDA's cGMP regulations for drugs or biologic products both in a pre-licensing inspection before product licensing and in subsequent periodic inspections after licensing. In the case of a biologic product, an establishment license must be obtained prior to marketing and batch releasing.

A five-year period of market exclusivity for a drug comprising a New Chemical Entity ("NCE") is available to an applicant that succeeds in obtaining FDA approval of a NCE, provided the active ingredient of the NCE has never before been approved in a NDA. During this exclusivity period, the FDA may not approve any abbreviated application filed by another sponsor for a generic version of the NCE. Further, a three-year period of market exclusivity for a new use or indication for a previously approved drug is available to an applicant that submits new clinical studies that are essential to support the new use or indication. During the latter period of exclusivity, the FDA may not approve an abbreviated application filed by another sponsor for a generic version of the product for that use or indication.

The FDA has "fast track" regulations intended to accelerate the approval process for the development, evaluation and marketing of new drugs used to diagnose or treat life-threatening and severely debilitating illnesses for which no satisfactory alternative therapies exist. "Fast track" designation affords early interaction with the FDA in terms of protocol design, and permits, although it does not require, the FDA to issue marketing approval after completion of Phase II clinical trials (although the FDA may require subsequent clinical trials or even post-approval efficacy studies).

### **Mexico**

In Mexico, the manufacture and sale of new drugs are controlled by the SSA. The regulatory requirements in Mexico operate under similar regulatory principles as other international jurisdictions.



## REGULATORY STRATEGY

Our overall regulatory strategy is to work with HC in Canada, the FDA in the United States, the EMEA in Europe, the SSA in Mexico and any other local regulatory agencies to have drug applications approved for use of Virulizin<sup>(R)</sup>, GTI-2040, GTI-2501, and NuChem Analogs in clinical trials (alone and/or in combination with chemotherapeutic compounds) and subsequently for sale in international markets. Where possible, we intend to take advantage of opportunities for accelerated consideration of drugs designed to treat rare and serious or life-threatening diseases. We also intend to pursue priority evaluation of any application for marketing approval filed in Canada, the United States, the European Economic Community or Mexico, and to file additional drug applications in other markets where commercial opportunities exist. We cannot assure you that we will be able to pursue these opportunities successfully.

## LICENSE AGREEMENTS

The University of Manitoba (the "**University**"), Dr. Jim Wright, Dr. Aiping Young and Cancer Care entered into an exclusive license agreement (the "**License Agreement**") with GeneSense dated June 20, 1997 pursuant to which GeneSense was granted an exclusive world-wide license to certain patent rights with the right to sub-license. In consideration for the exclusive license to GeneSense of the patent rights, the University and Cancer Care are entitled to an aggregate of 1.67% of the net sales received by GeneSense from the sale of products or processes derived from the patent rights and 1.67% of all monies received by GeneSense from sub-licenses of the patent rights. GeneSense is solely responsible for the preparation, filing, prosecution and maintenance of all patent applications and patents included in the patent rights and all related expenses. Pursuant to the terms of the License Agreement, any and all improvements to any of the patent rights derived in whole or in part by GeneSense after the date of the License Agreement are not included within the scope of the License Agreement and do not trigger any payment of royalties.

In December 1997, Lorus, through NuChem, acquired certain patent rights and a sublicense from Ion to develop and commercialize the anti-cancer applications of CLT and new chemical entities related to CLT (the "**NuChem Analogs**"). The consideration for this acquisition was Ion's 20% common share interest in NuChem, US\$350,000 in common shares of the Company and amounts totaling up to US\$3,500,000 payable in cash. On June 15, 1998, we issued from treasury 583,188 common shares in settlement of the US\$350,000 obligation. To October 2004, NuChem had made cash payments totaling US \$500,000 to Ion. The balance is payable upon the achievement of certain milestones based on the commencement and completion of clinical trials related to the NuChem Analogs.

All research and development activities to be undertaken by NuChem are to be funded by us through subscriptions for non-participating preference shares of NuChem. As at May 31, 2004, we had provided a total of \$6,014,997 of funding to NuChem.

NuChem has agreed to actively proceed with research and development programs relating to the NuChem Analogs. If NuChem fails to make any of the payments described above, discontinues its research and development activities related to the NuChem Analogs or commits an act of insolvency or bankruptcy, Ion has the right to re-acquire the NuChem Analogs assigned to NuChem and to terminate the sublicense, upon the payment by Ion of a certain amount and subject to certain other conditions.

In September 2003, we announced that Lorus, NuChem and Cyclacel announced we had entered into an exclusive worldwide license agreement for the development and commercialization of the NuChem Analogs. Under the terms of the Agreement, Lorus will receive upfront fees of US \$400,000 and milestone payments, which assuming all milestones are achieved, will total approximately US \$11.6 million for our pre-clinical compound NC 381, and similar milestone payments for each of any other compounds developed from the compound library. In addition to these payments, we will receive royalties based on product sales. Cyclacel is responsible for all future drug development costs.



## **CO-DEVELOPMENT, MARKETING AND DISTRIBUTION**

Our objective is to maximize the therapeutic value and potential commercial success of Virulizin<sup>(R)</sup>, GTI-2040 and GTI-2501, and the small molecule platform. In the near term, we intend to pursue research and early clinical development with our own funds. In our efforts to obtain the greatest return on its investment in each drug candidate, we separately evaluate the merits of each candidate throughout the clinical trial process and will consider commercialization opportunities when appropriate. We intend to partner with pharmaceutical companies for the sale, marketing and distribution of our products.

We have a variety of academic partnerships including: Hospital for Sick Children; McGill University; Ontario Cancer Institute; United States National Cancer Institute; University of Western Ontario; and, the University of Chicago Cancer Center.

In September 2001, we executed a license and distribution agreement with Mayne Pharma Inc. (formerly Faulding Canada Inc.). Pursuant to the agreement, Mayne Pharma distributes and sells Virulizin<sup>(R)</sup> in Mexico for the treatment of malignant melanoma. Under the terms of the agreement, Mayne Pharma exercised its option to obtain the rights to distribute and sell Virulizin<sup>(R)</sup> in Brazil and Argentina. We arrange for the manufacture of Virulizin<sup>(R)</sup> and receive a royalty on sales.

In May 2004, we signed a collaboration agreement with the University of Toronto to provide a further development and delivery strategy for our novel low molecular weight compounds with anticancer and antibacterial activity. The development strategy is partially funded by a grant awarded to Lorus and the University from the Natural Sciences and Engineering Research Council of Canada/Collaborative Research and Development. The collaboration agreement provides for payment by us to the University of set fees and a percentage of net revenues derived from any intellectual property developed under the agreement if and when the intellectual property is commercialized.

## **COMPETITION**

The biotechnology and pharmaceutical industries are characterized by rapidly evolving technology and intense competition. There are many companies in both these industries that are focusing their efforts on activities similar to ours. Some of these are companies with established positions in the pharmaceutical industry and may have substantially more financial and technical resources, more extensive research and development capabilities, and greater marketing, distribution, production and human resources than us. In addition, we may face competition from other companies for opportunities to enter into collaborative agreements with biotechnology and pharmaceutical companies and academic institutions. Many of these other companies are not solely focused on cancer, as is the mission of our drug development. We specialize in the development of drugs that will help manage cancer. With products in late stage pre-clinical through to Phase III development, spanning three different platform technologies focused on cancer, we believe we have multiple opportunities for success.

Products that may compete with our products include chemotherapeutic agents, monoclonal antibodies, antisense therapies and immunotherapies with novel mechanisms of action. These are drugs that are delivered by specific means and are targeting cancers with large disease populations. We also expect that we may experience competition from established and emerging pharmaceutical and biotechnology companies that have other forms of treatment for the cancers that we target. There are many drugs currently in development for the treatment of cancer that employ a number of novel approaches for attacking these cancers. Cancer is a complex disease with more than 100 indications requiring drugs for treatment. The drugs in competition with our drugs have specific targets for attacking the disease, targets which are not necessarily the same as ours. These competitive drugs therefore could potentially also be used together in combination therapies with our drugs to manage the disease.



## **HUMAN RESOURCES**

As at May 31, 2004, we employed 60 full-time persons and 10 part-time persons in research and drug development and administration activities. Of our employees, 16 are medical doctors and/or Ph.D.s. We have a Medical and Scientific Advisory Board comprised of eight members who are each medical doctors or Ph.D.s. To encourage a focus on achieving long-term performance, employees and members of the board of directors have the ability to acquire an ownership interest in the Company through Lorus' stock option plan.

## **PROPERTIES**

Lorus' head office, which occupies 20,500 square feet, is located at 2 Meridian Road, Toronto, Ontario. The leased premises include approximately 8,000 square feet of laboratory and research space. We believe that our existing facilities are adequate to meet our requirements for the short term.

## **MANAGEMENT'S DISCUSSION AND ANALYSIS OF OPERATING RESULTS**

Our MD&A is incorporated herein by reference.

## **SHARE CAPITAL AND MARKET FOR SECURITIES**

### **SHARE CAPITAL**

We are authorized to issue an unlimited number of common shares. As of October 4, 2004, there were 171,804,989 common shares issued and outstanding. The holders of common shares are entitled to one vote per share at meetings of shareholders, to receive such dividends as declared by us and to receive our remaining property and assets upon our dissolution or winding up. Our common shares are not subject to any future call or assessment and there are no pre-emptive, conversion or redemption rights attached to such shares.

### **MARKET FOR SECURITIES**

Our common shares are currently listed on The Toronto Stock Exchange ("TSX") under the symbol "LOR" and on the American Stock Exchange under the symbol "LRP". The following table sets out the price ranges and trading volumes of our common shares on the TSX for the periods indicated:

	High (\$)	Low (\$)	Volume (#)
<b>2004</b>			
May	0.98	0.83	5,292,300
April	1.12	0.90	5,848,600
March	1.15	1.01	7,146,100
February	1.34	1.01	18,895,500
January	1.18	0.99	9,127,400
<b>2003</b>			
December	1.19	0.95	6,762,600
November	1.19	0.96	6,188,400
October	1.39	1.11	11,386,500
September	1.47	1.12	20,614,600
August	1.30	1.05	6,872,500
July	1.35	0.95	8,436,300
June	1.47	1.18	13,909,800

#### DIVIDENDS

Dividends on our common shares are declared at the discretion of our board of directors. To date, we have not paid any dividends and do not expect to do so in the foreseeable future.

#### LEGAL PROCEEDINGS

We are not a party to, nor the subject of, any outstanding legal proceedings, nor are we aware of any contemplated proceedings.

#### DIRECTORS AND OFFICERS

The following table and notes thereto provide the name, municipality, province and country of residence, positions with the Company, term of office and principal occupation of each person who serves as a director or officer of Lorus as at the date hereof.

Each director has been elected or appointed to serve until the next annual meeting or until a successor is elected or appointed. We have an Audit Committee, an Environmental Committee, a Corporate Governance and Nominating Committee and a Human Resources and Compensation Committee and the members of each such committee are shown below. As at May 31, 2004 our directors and executive officers, as a group, beneficially owned, directly or indirectly, or exercised control over 14,292,880 or approximately 8.3% of the common shares.

<b><u>Name and Municipality of Residence</u></b>	<b><u>Position</u></b>	<b><u>Director or Officer Since</u></b>
J. KEVIN BUCHI <sup>(1) (2)</sup> West Chester, Pennsylvania	Director	December 2002
ROBERT L. CAPIZZI <sup>(2) (5)</sup> Philadelphia, Pennsylvania	Director	January 2003
DONALD W. PATERSON <sup>(1) (3)</sup> Toronto, Ontario	Director	July 1991
ELLY REISMAN Richmond Hill, Ontario	Director	November 1999

<u>Name and Municipality of Residence</u>	<u>Position</u>	<u>Director or Officer Since</u>
ALAN STEIGROD <sup>(2)</sup> Newport Beach, California	Director	May 2001
GRAHAM STRACHAN <sup>(1) (2) (3)(4)</sup> Etobicoke, Ontario	Chairman, Director	May 2001
DR. JIM WRIGHT Oakville, Ontario	President and Chief Executive Officer, Director	October 1999
DR. AIPING YOUNG <sup>(4)</sup> Toronto, Ontario	Chief Operating Officer	October 1999
PAUL J. VAN DAMME Toronto, Ontario	Chief Financial Officer	September 2004
BRUCE ROWLANDS Toronto, Ontario	Senior Vice President, Planning and Public Affairs	January 2004
SHANE A. ELLIS Toronto, Ontario	Corporate Secretary, Vice President of Legal Affairs	February 1998

- (1) Member of Audit Committee.
- (2) Member of the Human Resources and Compensation Committee.
- (3) Member of the Corporate Governance Committee
- (4) Member of Environmental Committee.
- (5) Dr. Capizzi will not be standing for re-election at our November 18, 2004 annual meeting of shareholders.

The principal occupation and employment of each of the foregoing persons for the past five years is set forth below:

*J. Kevin Buchi:* Mr. Buchi is senior vice president and chief financial officer of Cephalon Inc., an international biopharmaceutical company. Mr. Buchi is responsible for finance, accounting, manufacturing and information systems and has been involved in raising significant financing for Cephalon. He is a certified public accountant and has received a master's degree in management from the J.L. Kellogg Graduate School of Management at Northwestern University.

*Dr. Robert L. Capizzi :* Dr. Capizzi is Vice President, Medical Affairs of Novacea, Inc. Prior to that, Dr. Capizzi served as President of Capizzi Clinical Resources Inc., and as professor of medicine and pharmacology, and as the Magee professor of medicine and chairman of the department of medicine at the Thomas Jefferson University in Philadelphia, PA.

*Donald W. Paterson:* Mr. Paterson is President of Cavandale Corporation, a corporation principally engaged in providing strategic corporate consulting to emerging growth companies within the technology industry.

*Elly Reisman:* Mr. Reisman is the President and Chief Executive Officer of Great Gulf Group, a real estate company.

*Alan Steigrod:* Mr. Steigrod is Managing Director of Newport Healthcare Ventures, a consulting firm for the healthcare industry, located in Newport Beach, California.

*Graham Strachan:* Mr. Strachan is President of GLS Business Development Inc., a life-science consulting firm located in Etobicoke, Ontario.

*Dr. Jim Wright:* Dr. Wright's present principal occupation is President and Chief Executive Officer of Lorus. Dr. Wright co-founded GeneSense in 1996, and served as its President, Chief



Scientific Officer and a director before becoming our President and Chief Scientific Officer in October 1999 on our acquisition of GeneSense.

*Dr. Aiping Young:* Dr. Young has been our Chief Operating Officer since November 20, 2003. Prior to that, Dr. Young had acted since 1999 as our Senior Vice President, Research and Development and Chief Technical Officer .

*Paul J. Van Damme.* Mr. Van Damme joined Lorus Therapeutics Inc. as Chief Financial Officer in September 2004. Prior to joining the Company, he was Chief Financial Officer of Affinity Express, Inc. From 2001 to 2003 he served as Vice-President, Finance & Chief Financial Officer of Electrovaya Inc. From 1999 to 2001, he was Vice-President, Finance – Canada for NPS Pharmaceuticals, Inc. Prior to his appointment, he was Senior Vice-President & Chief Financial Officer of Allelix Biopharmaceuticals Inc. until it was acquired by NPS Pharmaceuticals, Inc. in December 1999.

*W. Bruce Rowlands:* Mr. Rowlands joined the senior management team at Lorus Therapeutics Inc. as Senior Vice President, Planning and Public Affairs in January 2004. Prior to joining Lorus he served as a Senior Advisor to the company through his wholly owned consultancy W. B. Rowlands & Co. Ltd. from December 2002 through December 2003. From May 1999 to December 2002 Mr. Rowlands was Vice President & Director of Dominick & Dominick Securities.

*Shane A. Ellis.* Mr. Ellis is our Vice President, Legal Affairs and Corporate Secretary. Mr. Ellis has been with Lorus since 1998.

#### **AUDIT COMMITTEE**

The charter of our audit committee is attached as Schedule A. The current members of the audit committee are J. Kevin Buchi, Donald W. Paterson and Graham Strachan. Pursuant to Canadian securities laws, our board of directors has determined that Messrs. Buchi, Paterson and Strachan are financially literate as all have experience in reviewing and analysing the financial reports and ascertaining the financial position of a corporation. Mr. Buchi is a certified public accountant and holds the position of Chief Financial Officer in a pharmaceutical company. Pursuant to United States securities laws, Mr. Buchi is also a "financial expert". Mr. Paterson, in his position as President of Cavandale Corporation, is educated and experienced in reading and analyzing financial statements. Mr. Strachan has experience with reading and analysing financial statements both as President of his own life science consulting firm and in a prior position as President, Chief Executive Officer and a director of a biopharmaceutical company. Additionally, all three members of the audit committee qualify as "independent" as that term is defined in the relevant Canadian securities laws relating to the composition of the audit committee, and Mr. Buchi qualifies as an "independent director", pursuant to the rules of the American Stock Exchange.

The audit committee of our board of directors has within the charter of the audit committee adopted specific responsibilities and duties regarding the provision of services by the registrant's external auditors, currently KPMG LLP. This charter requires audit committee pre-approval of all permitted audit and audit-related services. Any non-audit services must be submitted to the board of directors of the registrant for review and approval. Under the charter, all permitted services to be provided by KPMG LLP must be pre-approved by the audit committee. The pre-approval of services may be given at any time up to a year before commencement of the specified service.

Subject to the charter, the audit committee may establish fee thresholds for a group of pre-approved services. In such cases, the description of services must be sufficiently detailed as to the particular services to be provided to ensure that (i) the audit committee knows precisely what services it is being asked to pre-approve and (ii) the audit committee's responsibilities are not delegated to management. All such services will be ratified at the next scheduled meeting of the audit committee, and upon such ratification will no longer be included in determining the aggregate fees covered by this limited approval. The audit committee then recommends to the board of directors approval of the fees and other significant compensation to be paid to the independent auditors.



The fees billed to us by our outside auditors for the past financial year are as follows:

<i>(Cdn \$000s)</i>	<b>2004</b>
Audit Fees	\$108,124
Audit-Related Fees	6,325
Tax Fees	2,112
All Other Fees	31,753
<b>Total</b>	<b>\$148,314</b>

#### **MEDICAL AND SCIENTIFIC ADVISORS BOARD**

Since October 2, 2002, Dr. Mace L. Rothenberg has served as our external medical advisor providing strategic medical advice on our growing international clinical and drug development programs. Dr. Rothenberg is an internationally recognized oncologist who is a Director, Phase I Drug Development Program and Professor of Cancer Research at the E. Bronson Ingram Cancer Centre, and Professor of Medicine, Division of Medical Oncology at the Vanderbilt University Medical Center.

We have a Medical and Scientific Advisory Board ("MSAB") comprised of certain medical and scientific experts whom we believe will enhance our capabilities. Members of the MSAB meet periodically to review the progress of our research and development activities and the results of ongoing clinical trials. The MSAB also advises us generally as to specific research programs, and as to advances in biotechnology, immunology and other areas of scientific expertise relevant to the further development of our technologies.

As at the date hereof, the members of the MSAB were:

*Dr. Donald P. Braun, Ph.D.:* Dr. Braun is a Professor, Department of Surgery at the Medical College of Ohio in Toledo, Ohio, and Administrative Director of the Cancer Institute. Dr. Braun is a member of the Scientific Advisory Committee on Immunology of the American Cancer Society.

*Dr. Gregory Curt, M.D.:* Dr. Curt is Medical Affairs Director, Field Medical Group, AstraZeneca. He was formerly a Clinical Director of the NCI in Bethesda, Maryland. He received his M.D. with Distinction in Research from the University of Rochester School of Medicine in 1977. After completing his training in Internal Medicine at Harvard, he came to the NCI for subspecialty training in Medical Oncology.

*Dr. Jaime G. de la Garza Salazar, M.D.:* Dr. de la Garza, a member of the Mayo Graduate School of Medicine, has been the Director General of the National Cancer Institute of Mexico since 1993. He is also the President of the Mexican Oncology Board. Prior to his appointment as Director, Dr. de la Garza was Associate Director in Clinical Research at the NCI.

*Dr. Robert Kerbel, Ph.D.:* Dr. Kerbel obtained his Ph.D. in microbiology and immunology from Queen's University in 1972. Dr. Kerbel is currently Senior Scientist, Molecular and Cellular Biology Research at Sunnybrook and Women's College Health Sciences Centre, and was formerly the Director of Biological Sciences and the Division of Cancer Biology Research at Sunnybrook and is also the John & Elizabeth Tory Professor of Experimental Oncology at the University of Toronto. He is a member of the editorial board of many international scientific journals and is editor-in-chief of Cancer Metastasis Review.

*Dr. Bishnu D. Sanwal, Ph.D., D.Sc., F.R.S.C.:* Dr. Sanwal is a Professor Emeritus and former Chairman of the Department of Biochemistry at the University of Western Ontario, London, Ontario. He has a long and distinguished career in biological and medical research. With over 146 publications, Dr. Sanwal is a member of or advisor to numerous scientific committees and journals such as the editorial board of *Archives of Biochemistry and Biophysics* and member of the Royal Society of London, and Fellow of the Royal Society of Canada. He received a Ph.D. from the University of Delhi and a Doctor of

Sciences from the Federal Institute of Technology, Zurich.

*Dr. Lesley Seymour, MBBCh, FCP (SA):* Dr. Seymour is a Co-Director of the Investigational New Drug Program of the National Cancer Institute of Canada Clinical Trials Group. She received her M.D. at the University of the Witwatersrand in South Africa in 1978 and subsequently completed Specialist training in Internal Medicine as well as Clinical Hematology and Medical Oncology.

*Dr. Louis Siminovitch, O.C., Ph.D., D.Sc., F.R.S.C., F.R.S.:* Dr. Siminovitch is a former founder and director of the Department of Medical Genetics, University of Toronto, the Department of Genetics, Hospital for Sick Children, the Samuel Lunenfeld Research Institute at Mount Sinai Hospital, former Director and President of the National Cancer Institute of Canada and is presently on the Scientific Advisory Board of the Canadian Medical Discoveries Fund, several biotechnology companies and institutes. He is a founding member and former Senior Editor of *Virology*, founding member and former member of the editorial board of *Cell*, the editorial board of *Annual Review of Genetics*, founding member and former Senior Editor of *Molecular and Cellular Biology*, former member of the editorial board of *Genetics* and of the advisory board of *Molecular Biology and Medicine*. Dr. Siminovitch received a Ph.D. from McGill University and was awarded a Doctor of Science, Honoris Causa, for his distinguished scientific research contributions from several Canadian universities: Memorial University, McMaster University, University of Montreal, McGill University, University of Western Ontario and University of Toronto. Dr. Siminovitch is a Companion of the Order of Canada and was inducted into the Canadian Medical Hall of Fame in 1997. Dr. Siminovitch is the chair of the MSAB.

*Dr. George R. Stark, Ph.D., F.R.S.:* Dr. Stark is the former Sherwin-Page Chairman of the Research Institute, The Cleveland Clinic Foundation, Cleveland, Ohio. He received a Ph.D. from Columbia University and completed postdoctoral studies at Rockefeller University. Dr. Stark has made significant contributions to the field of molecular biology. Dr. Stark led the development of the Northern and Western Blot techniques for analysis of specific RNAs and proteins. Much of his work has focused on the process of gene amplification in mammalian cells, leading to an appreciation both of the mechanisms that generate amplified structures in cell lines and tumor cells and the regulatory processes that prevent amplification from occurring in normal cells. Very recent work has led to the discovery of a new signal pathway that regulates gene expression in cancer cells. A former Professor of Biochemistry at Stanford University, Dr. Stark moved to London as the Associate Director of Research at the Imperial Cancer Research Fund in London, England (1983-1992). Dr. Stark received the H. A. Sober award of the American Society of Biological Chemists in 1986, was elected to the U.S.A. National Academy of Science in 1986 and to the Fellowship of the Royal Society in Britain in 1990.

#### **INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

One of our directors, Elly Reisman, is also a director of The Erin Mills Investment Corporation. Mr. Reisman declares his interest and refrains from voting on any matter involving The Erin Mills Investment Corporation. See "Material Contracts". Other than as aforesaid, there is no interest in material contracts at management or board level.

#### **RISK FACTORS**

For a discussion of the various risks and uncertainties facing Lorus and our business, please see the section entitled "Risks and Uncertainties" in our MD&A, which is incorporated by reference herein

We have not produced or commercially marketed any product other than Virulizin®, which has been approved for sale and is being sold in the private market in Mexico. Although we have commenced commercial sales of Virulizin®, there can be no assurance that we will realize future revenues from the product. In addition, we cannot assure you that we will ever realize revenues from any of our products in development, or that we will ever be profitable.



Our products are in various stages of development. We cannot assure you that we will have funds available to permit the successful commercialization of our products. Our funding needs may vary depending on many factors including: the progress and number of research and drug development programs; costs associated with clinical trials and the regulatory process; costs related to maintaining drug manufacturing sources; costs of prosecuting or enforcing patent claims and other intellectual property rights; collaborative and license agreements with third parties; and opportunities to in-license or acquire new products.

In order to commercialize our products, we must obtain regulatory approvals. Regulatory approvals can take a number of years and involve substantial expenditures. We cannot assure you that we will ever obtain necessary approvals or licenses for any of its products; that we will not encounter difficulties or excessive costs in its efforts to secure necessary approvals and licenses; or that we will be able to obtain sufficient funds to meet the necessary expenditures associated with obtaining regulatory approvals.

Even if our product candidates receive all necessary regulatory approvals and clearances, they may not gain market acceptance. Physicians, patients, third party payors and the medical community may not accept or utilize our products, and if our products do not achieve significant market acceptance our business and financial condition will be materially adversely affected. In addition, market acceptance is affected by the extent to which reimbursement for the cost of such products will be available from government health administration authorities, private health coverage insurers and other organizations. Lorus relies upon third parties to provide certain key services, including contract manufacturers to manufacture its products and independent investigators and contract research organizations to assist it in conducting its clinical trials. These third parties may encounter difficulties in meeting regulatory requirements and in maintaining quality control and quality assurance to meet our clinical development needs. If these third party service providers are unable to meet regulatory requirements or maintain quality control and quality assurance, or we are unable to retain such suppliers or obtain new third party suppliers, we may not be able to effectively conduct clinical trials or ultimately commercialize our products.

We currently hold licenses from third parties for certain technologies, including our antisense platform. We cannot assure you that these licenses will not terminate or that they will remain in good standing.

Our strategy is to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of our products. We cannot assure you that we will be able to establish such additional collaborations on favourable terms, if at all, or that our current or future collaborative arrangements will be successful or may not be terminated by our partners. We do not have any sales, marketing or distribution capabilities. In order to commercialize our products, if any are approved, we must either acquire or internally develop sales, marketing and distribution capabilities or make arrangements with third parties to perform these services for us. The inability to market our products could have a material adverse effect on our business and financial condition.

The sale and use of the products we develop could carry the risk of product liability proceedings. While we currently maintain limited product liability insurance, we cannot assure you that product liability insurance will continue to be available to us on commercially reasonable terms. Product liability claims might also exceed the amounts of such coverage.

Our discovery and development processes involve the controlled use of hazardous and radioactive materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by local laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.



Our interest income is subject to fluctuations of interest rates in our investment portfolio of debt securities. Investments are held to maturity and have staggered maturities to minimize interest rate risk. We cannot assure you that interest income fluctuations will not have an adverse impact on our financial condition. We maintain our accounts in Canadian dollars, but our revenues and a portion of our expenditures are in foreign currencies. We do not currently engage in hedging our foreign currency requirements to reduce exchange rate risk.

Our success depends in part on our ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. We cannot assure that our pending patent applications will result in patents being granted, that we will be able to develop additional proprietary products that are patentable, that patents already granted to us will provide us with any competitive advantage, or that patents of others will not have an adverse effect on our ability to do business.

Our success depends in large part upon our ability to attract and retain highly qualified scientific and management personnel. We face competition for such personnel from other companies, academic institutions, government entities and other organizations. We cannot assure you that we will retain our current personnel and will be able to continue to attract qualified personnel.

#### **TRANSFER AGENT AND REGISTRAR**

The transfer agent and registrar for our common shares is Computershare Trust Company of Canada at its principal office in the City of Toronto.

#### **MATERIAL CONTRACTS**

On October 6, 2004, the Corporation entered into a subscription agreement with The Erin Mills Investment Corporation.

#### **ADDITIONAL INFORMATION**

Additional information relating to Lorus may be found on SEDAR at [www.sedar.com](http://www.sedar.com). Certain additional information, including directors' and officers' remuneration and indebtedness, principal holders of our securities, and securities authorized for issuance under our stock option plan, is contained in the Circular. Additional financial information is provided in the 2004 Financial Statements and MD&A. Copies of:

- the Circular;
- the 2004 Financial Statements and our most recent unaudited financial statements that have been filed, if any, for any period subsequent to the year ended May 31, 2004;
- this annual information form and any document or the pertinent pages of any document incorporated by reference in this annual information form; and
- when our securities are in the course of a distribution pursuant to a short form prospectus or a preliminary short form prospectus, one copy of any other documents that are incorporated by reference into the short form prospectus or preliminary short form prospectus otherwise not referred to herein,

may be obtained upon request from our Corporate Secretary at 2 Meridian Road, Toronto, Ontario, M9W 4Z7, Canada. If our securities are in the course of a distribution pursuant to a short form prospectus or a preliminary short form prospectus, copies of the foregoing documents are available free of charge. At all other times, a reasonable fee may be charged if the request for copies is made by a person who is not a security holder of Lorus.



## GLOSSARY

The following is a glossary of terms that are used in this annual information form:

<b>Actinic keratosis:</b>	a condition that arises on the skin's surface. It can be the first step in the development of skin cancer and therefore is a precursor of cancer, or a precancer.
<b>Analog:</b>	a chemical derivative or variation of a parent molecule
<b>Anti-angiogenic:</b>	preventing blood vessel formation
<b>Anti-metastatic:</b>	the ability to inhibit the movement of tumor cells from a primary/original site to other organs in the body
<b>Anti-proliferative:</b>	preventing cancer cell division
<b>Apoptosis:</b>	programmed cell death
<b>BCD:</b>	Bureau of Control of Drugs, the regulatory agency controlling pharmaceutical drugs in Mexico
<b>Biologic response modifier or BRM:</b>	a substance which stimulates, modifies or enhances the body's response, including the response of the body's immune and other protective cellular and molecular systems, to certain diseases
<b>Carcinoma:</b>	any cancerous tumor that starts with the cells that cover the inner and outer body surfaces
<b>Clinical trials:</b>	the investigational use of a new drug in humans: Phase I clinical trials test a drug for safety, Phase II clinical trials test a drug for efficacy and safety in a relatively small sample of patients, and Phase III clinical trials test the drug for efficacy in larger numbers of patients and compares the drug with conventional therapies
<b>cGMP:</b>	current good manufacturing practices, as mandated from time to time by the HC and the FDA
<b>CLT:</b>	Clotrimazole
<b>Cytokine:</b>	a generic term for a non-antibody protein released by a cell population (e.g., activated macrophages) of the immune system on contact with chemical or biological stimuli
<b>Cytotoxic:</b>	pertaining to the destruction of cells
<b>Deoxyribonucleic acid (DNA):</b>	DNA is the carrier of genetic information which exists in all cells of the body. The building blocks of DNA are called nucleotides
<b>Efficacy:</b>	the ability of a drug to produce a desired result
<b>EMEA:</b>	European Medicine Evaluation Agency

<b>FDA:</b>	Food and Drug Administration, the government agency which regulates the use and sale of diagnostic and therapeutic drug products in the United States
<b>Gene expression:</b>	the synthesis of specific proteins on the basis of inherited or acquired genetic information
<b>GeneSense:</b>	GeneSense Technologies Inc., a subsidiary of the Company
<b>HC:</b>	Health Canada, the federal government department which among other responsibilities regulates the use and sale of therapeutic drug products in Canada
<b>Immune system:</b>	the totality of organs and cells involved in the body's immunologic response to foreign antigens and malignant tissue
<b>IND:</b>	investigational new drug
<b><i>In vitro</i>:</b>	in the test tube; referring to chemical reactions, fermentation, etc., occurring therein e.g. in cell-free extracts
<b><i>In vivo</i>:</b>	in the living body; referring to chemical processes occurring within cells, etc., as distinguished from those occurring in cell-free extracts ( <i>in vitro</i> )
<b>LD<sub>50</sub>:</b>	the measure (quantity) of a drug that, when administered to experimental animals in acute toxicity studies, is lethal to 50 percent of such animals
<b>Macrophage:</b>	a large scavenger white blood cell that engulfs and digests invading micro-organisms and cell debris, and also participates in many complex immunologic processes
<b>Malignant/malignancy:</b>	describes a tumor that is cancerous. Two important qualities of malignancies are the tendency to invade surrounding tissues and to break off and spread elsewhere (metastasis)
<b>MAP Kinase Pathway:</b>	the pathway of mitogenic signal transduction through the cascade of mitogen-activated protein (MAP) kinases which ultimately lead to alteration in regulatory events such as cell proliferation, differentiation and apoptosis.
<b>Metabolism:</b>	the overall biochemical reactions that take place in a living organism including the building up of complex molecules or breakdown of molecules to provide energy
<b>Metabolic:</b>	of, or relating to, the metabolism
<b>Metastasis:</b>	the process by which tumor cells are spread to other parts of the body
<b>Monocyte:</b>	a large white blood cell with finely granulated chromatin dispersed throughout the nucleus that is formed in the bone marrow, enters the blood, and migrates into the connective tissue where it differentiates into a macrophage
<b>mRNA:</b>	messenger, or mRNA, is a copy of the information carried by a gene on the DNA. The role of mRNA is to move the information contained in DNA to the translation machinery.



<b>NDA:</b>	new drug application, the application to obtain marketing approval filed with the FDA or BCD after completion of human clinical trials
<b>NDS:</b>	new drug submission, the application to obtain marketing approval filed with the HC after completion of human clinical trials
<b>NuChem:</b>	NuChem Pharmaceuticals Inc., a subsidiary of the Company
<b>NuChem Analogs:</b>	analogs of CLT licensed by the Company for anti-cancer indications
<b>Nucleic acid:</b>	DNA and RNA, each of which are formed by the combination of nucleotides; it is found in all living cells and contains the genetic code required to transfer genetic information from one generation to the next
<b>Nucleotide:</b>	a compound consisting of a purine or pyrimidine base, a pentose sugar and a phosphoric acid; they are the building blocks from which nucleic acids (DNA or RNA) are constructed
<b>Oligonucleotides:</b>	oligonucleotides are short chains of nucleotides, which are the building blocks of DNA and RNA
<b>Pharmacokinetics:</b>	the action of drugs in the body over a period of time, including the process of absorption, distribution, localization in tissues, biotransformation and excretion
<b>Pre-clinical testing:</b>	testing that is conducted in the laboratory (chemistry and pharmacology) and with animals to help determine a product's chemical, pharmacological and pharmaceutical characteristics (including mechanism of action), toxicity, efficacy and side effects
<b>Proteins:</b>	large molecules composed of long chains of sub-units of amino acids
<b>R1 and R2:</b>	components of ribonucleotide reductase
<b>Ribonucleic acid (RNA):</b>	a nucleic acid found in both the nucleus and the cytoplasm of all cells. It carries genetic information from the nucleus to the cytoplasm, where it also reacts as a template in association with ribosomes to synthesize proteins
<b>SSA:</b>	Secretaria de Salud (the Ministry of Health for Mexico)
<b>Stage IV cancer:</b>	distant metastatic cancer spread
<b>Toxicity:</b>	a condition that results from exposure to a substance at levels causing deleterious side effects which may be harmful to an organism
<b>Tumor:</b>	an abnormal swelling or lump in the body caused by the growth of new tissues which differ in structure from the part of the body in which they are growing. A tumor may be benign or malignant
<b>Tumor necrosis:</b>	tumor deterioration and death
<b>Xenograft:</b>	an implant of a foreign substance



**SCHEDULE A**

**CHARTER OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS  
OF  
LORUS THERAPEUTICS INC.**

**I. PURPOSE**

The Audit Committee is a committee of the Board of Directors of the Company. The primary function of Audit Committee is to assist the Board in fulfilling its oversight responsibilities. The Audit Committee's primary duties and responsibilities are to:

1. serve as an independent and objective party to monitor the integrity of the Company's financial statements, financial reporting process and systems of internal controls regarding finance, accounting, and legal compliance;
2. identify and monitor the management of the principal risks that could impact the financial reporting of the Company;
3. appoint, approve compensation, and monitor the independence and performance of the Company's independent auditors;
4. monitor the compliance by the Company with legal and regulatory requirements;
5. provide an avenue of communication among the independent auditors, management, and the Board; and
6. encourage continuous improvement of, and foster adherence to, the Company's policies, procedures and practices at all levels.

The Audit Committee has the authority to conduct any investigation appropriate to fulfilling its responsibilities, and it has direct access to the independent auditors as well as anyone in the organization. The Audit Committee may retain, at the Company's expense, special legal, accounting, or other consultants or experts it deems necessary in the performance of its duties.

**II. COMPOSITION AND MEETINGS**

***Composition***

Audit Committee members shall meet the independence and experience requirements of any governmental or regulatory authority having jurisdiction over the Company.

The Audit Committee shall be comprised of three or more directors as determined by the Board, none of whom shall be an officer or employee of the Company and each of whom shall be an independent non-executive director free from any relationship that, in the opinion of the Board, would interfere with the exercise of his or her independent judgment as a member of the Committee. All members of the Committee shall have a basic understanding of finance and accounting and be able to read and understand



fundamental financial statements, and at least one member of the Committee shall have accounting or related financial management expertise which results in the individual's financial sophistication.

### ***Appointment***

Audit Committee members shall be appointed by the Board. Audit Committee members may be replaced by the Board at any time. The Board shall fill any vacancy if the membership of the Committee is less than three directors.

The members of the Committee shall be entitled to receive such remuneration for acting as members of the Committee as the Board of Directors may from time to time determine.

### ***Meetings***

The Committee shall meet as often as it determines and as many times as is necessary to carry out its responsibilities, but on at least a quarterly basis. Meetings may be called by the Chair of the Committee or any two of its Members. The Audit Committee Chair shall prepare and/or approve an agenda to be circulated to Committee members in advance of each meeting.

The time at which and the place where the meetings of the Committee shall be held, the calling of meetings and the procedure in all respects of such meetings shall be determined by the Committee, unless otherwise provided for in the by-laws of the Corporation or otherwise determined by resolution of the Board of Directors. Every attempt should be made for the Committee to meet in person when possible, rather than through teleconference facilities.

If an Audit Committee Chair is not designated or present, the members of the Committee may designate a Chair by majority vote of the Committee membership.

The Committee may ask members of management or others to attend meetings and provide pertinent information as necessary. The Committee shall meet privately in executive session periodically. The Committee shall also meet at least annually with management, the independent auditors, and as a Committee, in separate executive sessions, to discuss any matters that the Committee or each of these groups believe should be discussed. The Committee may request any officer or employee of the Company or the Company's outside counsel or independent auditors to attend a meeting of the Committee or to meet with any members of, or consultants to, the Committee. In addition, the Committee shall communicate with management at least quarterly to review the Company's financial statements.

No business may be transacted by the Committee except at a meeting of its members at which a quorum of the Committee is present or by a resolution in writing signed by all the members of the Committee. A majority of the members of the Committee shall constitute a quorum, provided that if the number of members of the Committee is an even number one half of the number of members plus one shall constitute a quorum.



The Committee may appoint one of its members to act as Chair of the Committee. The Chair will appoint a secretary who will keep minutes of all meetings (the "Secretary"). The Secretary does not have to be a member of the Committee or a director and can be changed by simple notice from the Chair.

The Committee shall have access to such officers and employees of the Corporation, its auditors, legal counsel and to such information respecting the Corporation as it considers necessary or advisable in order to perform its duties and responsibilities.

The Chair of the Committee shall report to the Board from time to time as considered appropriate, but not less frequently than quarterly.

It is understood that in order to properly carry out its responsibilities, the Committee may retain outside consultants at the expense of the Corporation if it considers it to be necessary.

### **III. RESPONSIBILITIES AND DUTIES**

The Committee, to the extent it deems necessary or appropriate, shall:

#### **A. Financial Statement and Disclosure Matters**

1. Review the Company's annual audited financial statements and related financial reporting, including disclosures made in management's discussion and analysis and financial press releases, and recommend to the Board whether they should be approved, prior to filing or distribution. Consider the independent auditors' judgments about the quality and appropriateness, not just the acceptability, of the Company's accounting principles and financial disclosure practices, as applied in its financial reporting and press releases, particularly about the degree of aggressiveness or conservatism of its accounting principles and underlying estimates and whether those principles are common practices or are minority practices.
2. Consider and approve, if appropriate, major changes to the Company's accounting principles and practices as suggested by the independent auditors or management and assure that the reasoning is described in determining the appropriateness of changes in accounting principles and disclosures.
3. In consultation with the management and the independent auditors, consider the integrity of the Company's financial reporting processes and controls. Discuss significant financial risk exposures and the steps management has taken to monitor, control, and report such exposures. Review significant findings prepared by the independent auditors together with management's responses.
4. Review any significant disagreements among management and the independent auditors in connection with the preparation of the financial statements.
5. Review with financial management and the independent auditors the Company's quarterly financial results and related financial reporting, including disclosures made in management's discussion and analysis and financial press releases, prior to the release of such information, the operation of internal controls or material weaknesses therein and any



fraud involving management or other employees who have a significant role in the Company's internal controls.

6. Discuss with management the Company's earnings press releases, including the use of "pro forma" or "adjusted" non-GAAP information, as well as financial information and earnings guidance provided to analysts and rating agencies. Such discussion may be done generally (consisting of discussing the types of information to be disclosed and the types of presentations to be made).
7. Discuss with management and the independent auditor the effect of regulatory and accounting initiatives as well as off-balance sheet structures on the Company's financial statements.
8. Discuss with the independent auditor matters relating to the conduct of the audit including any difficulties encountered in the course of the audit work, any restrictions on the scope of activities or access to requested information, and any significant disagreements with management.
9. Review disclosures made to the Audit Committee by the Company's CEO and CFO during any required certification process about any significant deficiencies in the design or operation of internal controls or material weaknesses therein and any fraud involving management or other employees who have a significant role in the Company's internal controls.
10. Review and discuss quarterly reports from the independent auditors on:
  - (a) all critical accounting policies and practices to be used;
  - (b) all alternative treatments of financial information within generally accepted accounting principles for policies and practices related to material items that have been discussed with management, including the ramifications of the use of such alternative disclosures and treatments, and the treatment preferred by the independent auditors; and
  - (c) other material written communications between the independent auditor and management, such as any management letter or schedule of unadjusted differences.

**B. Oversight of the Company's Relationship with the Independent Auditor**

1. The Committee shall have the sole authority to recommend the independent auditor of the Company, subject to shareholder approval. The Audit Committee shall review the independence and performance of the auditors and annually recommend to the Board of Directors the appointment and retention of the independent auditors or approve any discharge of auditors when circumstances warrant.
  2. The independent auditors are directly accountable to the Audit Committee and the Board of Directors. The Committee shall be directly responsible for the compensation, such compensation to be paid by the Company, and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent
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auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or performing other audit, review or attest services.

3. The Committee shall pre-approve all audit fees and terms and all non-audit services provided by the independent auditor, and consider whether these services are compatible with the auditors' independence. Any member of the Committee may approve additional proposed non-audit services that arise between Committee meetings provided that the decision to pre-approve the services is presented and approved at the next scheduled Committee meeting. The approval of all non-audit services will be evidenced by the completion and approval by the Committee of a Non-Audit Services Request Form, a copy of which is attached to this Charter as Schedule "A".
4. On a regular basis, but at least annually, the Committee shall review and discuss with the independent auditors all relationships that the independent auditors and their affiliates have with the Company and its affiliates in order to determine the auditors' independence, including:
  - (a) requesting, receiving and reviewing, on a periodic basis, a formal written statement from the independent auditors delineating all relationships between the independent auditors and the Company, consistent with applicable laws;
  - (b) discussing with the independent auditors any disclosed relationships or services that may impact the objectivity and independence of the independent auditors; and
  - (c) recommending that the Board take appropriate actions to oversee and satisfy itself of the independent auditors' independence.
5. Prior to the commencement of the audit the Committee shall review the independent auditors' audit plan and discuss scope, staffing, locations, reliance upon management and general audit approach with the independent auditors.
6. The Committee shall consider the independent auditors' judgments about the quality and appropriateness of the Company's accounting principles as applied in its financial reporting.
7. Prior to releasing the year-end results, discuss the results the Committee shall of the audit with the external auditors. Discuss certain matters required to be communicated to audit committees in accordance with the standards established by the Canadian Institute of Chartered Accountants.
8. The Company shall provide for appropriate funding, as determined by the Committee, for payment of compensation to the independent auditor for the purpose of rendering or issuing an audit report and to any advisors employed by the Committee.
9. Review with financial management and the independent auditors the Company's quarterly financial results prior to the release of earnings and/or the Company's quarterly financial statements prior to filing or distribution.
10. Discuss any significant changes to the Company's accounting principles.
11. Obtain and review a report from the independent auditor at least annually regarding:



- (a) the independent auditor's internal quality-control procedures,
  - (b) any material issues raised by the most recent internal quality-control review, or peer review, of the firm, or by any inquiry or investigation by governmental or professional authorities within the preceding five years respecting one or more independent audits carried out by the firm,
  - (c) any steps taken to deal with any such issues, and
  - (d) all relationships between the independent auditor and the Company.
12. Evaluate the qualifications, performance and independence of the independent auditor, including considering whether the auditor's quality controls are adequate and the provision of permitted non-audit services is compatible with maintaining the auditor's independence, and taking into account the opinions of management and internal auditors. The Audit Committee shall present its conclusions with respect to the independent auditor to the Board.
  13. Ensure the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law. Consider whether, in order to assure continuing auditor independence, it is appropriate to adopt a policy of rotating the independent auditing firm on a regular basis. Review and evaluate the lead partner of the independent auditor team.
  14. Recommend to the Board policies for the Company's hiring of employees or former employees of the present or former independent auditor who participated in any capacity in the audit of the Company.
  15. Obtain confirmation from the independent auditors that the Audit Committee has received from such auditors all reports required by law.

**C. Oversight of the Company's Internal Audit Function**

1. Review the appointment and replacement of the senior internal auditing executive.
  2. Review the significant reports to management prepared by the internal auditing department and management's responses.
  3. Discuss with the independent auditor and management adequacy and effectiveness of the internal control and management information systems and procedures, the internal audit department responsibilities, budget and staffing and any recommended changes in the planned scope of the internal audit and determine whether the Company is in compliance with applicable legal and regulatory requirements.
  4. Review with the Chief Executive Officer, the President and the Vice President, Finance and Chief Financial Officer of the Corporation and the independent auditors: (i) all significant deficiencies and material weaknesses in the design or operation of the Company's internal controls and procedures for financial reporting which could adversely affect the Company's ability to record, process, summarize and report financial information required to be disclosed by the Company in the reports that it
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files or submits under applicable securities laws within the required time periods, and (ii) any fraud, whether or not material, that involves management of Provident or other employees who have a significant role in the Trust's internal controls and procedures for financial reporting;

5. Discuss with management and the external auditors the effect of regulatory and accounting directives on the Company's financial statements; and
6. Discuss generally with management the Company's earnings press releases, including the use of "pro forma" or "adjusted" non-GAAP information, as well as financial information provided to analysts and rating agencies.

**D. Compliance Oversight Responsibilities**

1. Establish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters.
2. Discuss with management and the independent auditor any correspondence with regulators or governmental agencies and any published reports which raise material issues regarding the Company's financial statements or accounting policies.
3. On at least an annual basis, review with the Company's counsel any legal matters that could have a significant impact on the organization's financial statements, the Company's compliance with applicable laws and regulations, and inquiries received from regulators or governmental agencies.
4. Annually conduct self-assessment of Committee performance including a review and discussion of the Committee roles and responsibilities, seeking input from senior management, the full Board and others if needed.
5. Perform any other activities consistent with this Charter, the Company's by-laws, and governing law, as the Committee or the Board deems necessary or appropriate.

**E. Other Audit Committee Responsibilities**

1. Create an agenda for the ensuing year.
  2. Describe in the Company's annual report the Committee's composition and responsibilities and how they were discharged.
  3. Submit the minutes of all meetings of the Committee to the Board of Directors.
  4. Review and reassess the adequacy of this Charter at least annually and recommend any proposed changes to the Board for approval.
  5. Report to the Board on a regular basis on the activities of the Committee.
  6. Annually review policies and procedures as well as audit results associated with
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directors' and officers expense accounts and perquisites. Review with management and independent auditors and oversee, as deemed necessary, any director and officers' related party transactions and potential conflicts of interest with directors and officers or any affiliated parties of the Company.

**F. Limitation of Audit Committee's Role**

While the Audit Committee has the responsibilities and powers set forth in this Charter, it is not the duty of the Audit Committee to plan or conduct audits or to determine that the Company's financial statements and disclosures are complete and accurate and are in accordance with generally accepted accounting principles and applicable rules and regulations. These are the responsibilities of management and the independent auditor.



**Schedule "A"**

Non-Audit Services Request Form

**LORUS THERAPEUTICS INC.  
NON-AUDIT SERVICES REQUEST FORM**

The Audit Committee approves all audit fees and terms and all non-audit services provided by the independent auditor and consider whether these services are compatible with the auditor's independence. Any member of the Committee, subject to appropriate delegation, may approve additional proposed non-audit services that arise between Committee meetings provided that the decision to approve the service is presented at the next scheduled Committee meeting. This form documents the member's approval of the non-audit service in a form suitable for distribution at meetings of the audit committee.

**REQUEST MADE BY**

Name, Title, Date:

**Detailed Description of Non-Audit Service Requested** *(including a general description of the nature of the services that may make up the project)*

**ENGAGEMENT FEE OR RANGE OF FEES FOR THIS SERVICE**

**PROHIBITED SERVICES**

*In this section please confirm that these services are not "prohibited services" under section 201 of the Sarbanes-Oxley Act of 2002 and other related rules or regulations.(see Exhibit 1)*

These services would not be considered prohibited services



*Issues considered in forming the conclusion above that should be considered by the audit committee*

**COMPATIBILITY WITH AUDITORS' INDEPENDENCE**

*In this section please state whether these services are compatible with the auditors' independence.*

These services are compatible with the auditors' independence

*Issues considered in forming the conclusion above that should be considered by the audit committee*

**Management Approval**

This form must be reviewed and approved by one authorized member of management (either the CEO, CFO, CAO, Controller, Director of Internal Audit, In-House Counsel— tailor as needed) before submitting this form to an Audit Committee member for final approval.

Name, Title, Date:

**AUDIT COMMITTEE MEMBER APPROVAL**

Name, Date:



Exhibit 1

Services Independent Auditors are Precluded

from Providing to Public Audit Clients

**The following is a listing of the types of services for which the audit committee may not retain their external auditors. The examples in this document are for illustration only and may not include every service that would be prohibited. Regulation in this area is still being developed by the SEC and other regulators and this list should be periodically updated.**

*SERVICES PROHIBITED UNDER SECTION 201 OF THE SARBANES-OXLEY ACT OF 2002*

**Bookkeeping or other services related to the accounting records or financial statements**

Examples include:

- Bookkeeping
  - Authorize or approve transactions
  - Prepare or originate source documents or data
  - Prepare or maintain accounting records
  
- **Payroll and Other Disbursements**
  - Authorize payment of client funds
  - Accept responsibility to sign or co-sign client checks
  - Maintain a client's bank account or otherwise have custody of a client's funds or make credit or banking decisions for the client
  - Sign payroll tax return on behalf of client management
  - Approve vendor invoices for payment
  - Prepare or maintain payroll records for the client

**Financial information systems design and implementation**

Examples include:



- Supervise client personnel in the daily operation of a client's information system
- Manage a client's local area network system

**Appraisal or valuation services, fairness opinions, or contribution-in-kind reports**

Examples include:

- Prepare an appraisal or valuation report
- Provide fairness opinions or contribution-in-kind reports

**Actuarial services**

Examples include:

- Prepare an actuarial report for an insurance company used to establish their reserves

**Internal audit outsourcing services**

Examples include:

- Outsourcing of the internal audit function
- Outsourcing of the management of the internal audit function

**Management functions and human resources**

Examples include:

- **Benefit Plan Administration**
- Make policy decisions on behalf of client management
- Make disbursements on behalf of the plan
- Have custody of assets of the plan
- Serve a plan as a fiduciary (as defined by ERISA)

- **Human Resources**

- **Executive or employee searches**
- Negotiate employee compensation or benefits



- Hire or terminate client employees
- Recommend the hiring of a specific individual for a specific position

**Broker or dealer, investment adviser, or investment banking services**

Examples include:

- Broker Dealer services

- **Investment – Advisory or Management**

- Make investment decisions
- Execute buy or sell transactions
- Have custody of client assets

- **Corporate Finance – Consulting or Advisory**

- Negotiate on behalf of the client or its owners, with potential investors and capital resources
- Distribute private placement memoranda or offering documents to potential investors
- Act as an underwriter, broker, agent, distributor, or guarantor with respect to client securities
- Solicit investors or promote client securities
- Maintain custody of client securities
- Market research studies – recommending a specific location for a business or project, conclude on the feasibility of a project, or assist in the preparation of prospective financial information or assumptions
- Forecasts and projections – involvement in developing assumptions, gathering the data, processing the data, or permitting the client to use either the firm’s computer hardware or software

**Legal services and expert services unrelated to the audit**

Examples include:

- Legal services (including, but not limited to, corporate secretarial services)
- Acting as an expert witness in legal, regulatory, or administrative filings or proceedings



*SERVICES GENERALLY PROHIBITED UNDER OTHER PROFESSIONAL STANDARDS*

- Performing ongoing monitoring or quality control activities for a client's operations
- Making decisions regarding internal controls
- Reporting to the board of directors or audit committee on behalf of management
- Authorizing, executing, or consummating transactions
- Preparing source documents on transactions or originating data
- Having custody of assets.
- Approving or being responsible for the overall internal audit work plan
- Acting as a member of client management or as an employee

## MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL REPORTING

The accompanying consolidated financial statements and all information in this annual report have been prepared by management and have been approved by the Board of Directors of the Company.

The financial statements have been prepared in accordance with Canadian generally accepted accounting principles and include amounts that are based on the best estimates and judgments of management. Financial information presented in accordance with Canadian generally accepted accounting principles elsewhere in the annual report is consistent with that in the financial statements.

In discharging its responsibility for the integrity and fairness of the financial statements, management maintains a system of internal controls designed to provide reasonable assurance that transactions are authorized, assets are safeguarded and proper records are maintained. Management believes that the internal controls provide reasonable assurance that financial records are reliable and form a proper basis for the preparation of the consolidated financial statements, and that assets are properly accounted for and safeguarded. The internal control process includes management's communication to employees of policies that govern ethical business conduct.

The Board of Directors, through an Audit Committee, oversees management's responsibilities for financial reporting. This committee, which consists of three independent directors, reviews the audited consolidated financial statements, and recommends the financial statements to the Board for approval. Other key responsibilities of the Audit Committee include reviewing the adequacy of the Company's existing internal controls, audit process and financial reporting with management and the external auditors.

These financial statements have been audited by KPMG LLP, who are independent auditors appointed by the shareholders of the Company upon the recommendation of the Audit Committee. Their report follows. The independent auditors have free and full access to the Audit Committee with respect to their findings concerning the fairness of financial reporting and the adequacy of internal controls



Jim A. Wright, Chief Executive Officer July 16, 2004



Paul Van Damme, Chief Financial Officer

## AUDITORS' REPORT TO THE SHAREHOLDERS

We have audited the consolidated balance sheets of Lorus Therapeutics Inc. as at May 31, 2004 and 2003 and the consolidated statements of loss and deficit and cash flows for each of the years in the three-year period ended May 31, 2004 and the related consolidated statements of loss and deficit and cash flows for the period from inception on September 5, 1986 to May 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

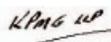
We conducted our audits in accordance with Canadian generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence 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.

In our opinion, these consolidated financial statements present fairly, in all material respects, the financial position of the Company as at May 31, 2004 and 2003 and the results of its operations and its cash flows for each of the years in the three-year period ended May 31, 2004 and for the period from inception on September 5, 1986 to May 31, 2004 in accordance with Canadian generally accepted accounting principles.

Canadian generally accepted accounting principles vary in certain significant respects from accounting principles generally accepted in the United States of America. Information relating to the nature and effect of such differences is presented in note 14 to the consolidated financial statements.

We did not audit the consolidated financial statements of Lorus Therapeutics Inc. for the period from inception on September

5, 1986 to May 31, 1994. Those consolidated financial statements were audited by other auditors who issued a report without reservation on July 8, 1994.



Chartered Accountants, Toronto, Canada  
July 16, 2004, except as to note 13 which is as of October 5, 2004

## CONSOLIDATED BALANCE SHEETS (amounts in 000's) (Canadian dollars)

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On behalf of the Board:

As at May 31	2004	2003
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 1,071	\$ 905
Short-term investments	25,657	24,219
Prepaid expenses and amounts receivable	1,697	1,104
<b>Total current assets</b>	<u>28,425</u>	<u>26,228</u>
Fixed assets (note 3)	1,471	1,507
Goodwill	606	
Acquired research and development (note 4)	3,922	5,669

Deferred financing costs

	-	245
	<u>\$ 34,424</u>	<u>\$ 34,255</u>

LIABILITIES AND SHAREHOLDERS' EQUITY

**Current liabilities**

Accounts payable	\$ 2,429	\$ 1,318
Accrued liabilities	<u>3,396</u>	<u>4,042</u>
Total current liabilities	<u>5,825</u>	<u>5,360</u>

**Shareholders' equity**

Share capital (note 5)		
Common shares		
Authorized: unlimited number of shares;		
Issued and outstanding (000's):		
May 31, 2004 - 171,794		
May 31, 2003 - 145,285	144,673	120,441
Warrants	4,325	-
Compensation options (note 5(d))	1,405	-
Deferred stock-based compensation	-	(43)
Deficit accumulated during development stage	<u>(121,804)</u>	<u>(91,503)</u>
<b>Total shareholders' equity</b>	<u>28,599</u>	<u>28,895</u>
	<u>\$ 34,424</u>	<u>\$ 34,255</u>

Commitments and Guarantees (note 9)

Subsequent event (note 13)

Canada and United States accounting policy differences (note 14)

See accompanying notes to consolidated financial statements



Director



Director

**CONSOLIDATED STATEMENTS OF LOSS AND DEFICIT**

(amounts in 000's except for per common share data) (Canadian dollars)

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	Years Ended May 31			Period from
	2004	2003	2002	inception Sept. 5, 1986 to May 31, 2004
<b>Revenue</b> (note 12)	\$ 608	\$ 66	\$ -	\$ 674
<b>Operating expenses</b>				
Cost of sales	28	55	-	83
Research and development (note 7)	26,785	12,550	8,659	85,844
General and administrative	4,915	4,290	4,867	37,793
Depreciation and amortization	420	960	1,956	8,781
<b>Operating expenses</b>	<u>32,148</u>	<u>17,855</u>	<u>15,482</u>	<u>132,501</u>
Interest and other income	(1,239)	(1,155)	(1,995)	(10,023)
<b>Loss for the period</b>	30,301	16,634	13,487	121,804
Deficit, beginning of period	91,503	74,869	61,382	-
<b>Deficit, end of period</b>	<u>\$ 121,804</u>	<u>\$ 91,503</u>	<u>\$ 74,869</u>	<u>\$ 121,804</u>
<b>Basic and diluted loss per common share</b> (note 2)	<u>\$ 0.18</u>	<u>\$ 0.12</u>	<u>\$ 0.09</u>	
<b>Weighted average number of common shares outstanding used in the calculation of basic and diluted loss per share</b>	<u>171,628</u>	<u>144,590</u>	<u>143,480</u>	

See accompanying notes to consolidated financial statements

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(amounts in 000's)(Canadian dollars)

	Years Ended May 31			Period from inception
	2004	2003	2002	Sept. 5, 1986 to May 31, 2004
<b>OPERATING ACTIVITIES</b>				
Loss for the period	\$ (30,301)	\$ (16,634)	\$ (13,487)	\$ (121,804)
Add items not requiring a current outlay of cash:				
Depreciation and amortization	2,166	2,033	3,407	16,127
Stock-based compensation	(43)	674	296	1,293
Other	245	-	-	745
Net change in non-cash working capital balances related to operations (note 8)	(129)	2,019	(2,124)	3,220
<b>Cash used in operating activities</b>	<b>(28,062)</b>	<b>(11,908)</b>	<b>(11,908)</b>	<b>(100,419)</b>
<b>INVESTING ACTIVITIES</b>				
Sale (purchase) of short-term investments, net	(1,438)	12,438	9,378	(25,657)
Acquisition, net of cash received	-	-	-	(539)
Acquired research and development	-	-	-	(715)
Additions to fixed assets	(383)	(1,260)	(477)	(5,375)
Cash proceeds on sale of fixed assets	-	-	-	348
<b>Cash provided by (used in) investing activities</b>	<b>(1,821)</b>	<b>11,178</b>	<b>8,901</b>	<b>(31,938)</b>
<b>FINANCING ACTIVITIES</b>				
Issuance of warrants	4,537	-	-	36,414
Issuance of common shares	25,512	715	1,389	97,259
Additions to deferred financing costs	-	(245)	-	(245)
<b>Cash provided by financing activities</b>	<b>30,049</b>	<b>470</b>	<b>1,389</b>	<b>133,428</b>
<b>Increase (decrease) in cash and cash equivalents during the period</b>	<b>166</b>	<b>(260)</b>	<b>(1,618)</b>	<b>1,071</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>905</b>	<b>1,165</b>	<b>2,783</b>	<b>-</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 1,071</b>	<b>905</b>	<b>\$ 1,165</b>	<b>\$ 1,071</b>

See accompanying notes to consolidated financial statements

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended May 31, 2004, 2003 and 2002

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### 1. DESCRIPTION OF BUSINESS

Lorus Therapeutics Inc. ("Lorus" or "the Company") is a biopharmaceutical company specializing in the research, development and commercialization of pharmaceutical products and technologies for the management of cancer. With products in all stages of evaluation, from pre-clinical through to Phase III trials, Lorus develops therapeutics that seek to manage cancer with efficacious low-toxicity compounds that improve patients' quality of life.

The Company has not earned substantial revenues from its drug candidates and is therefore considered to be in the development stage.

The continuation of the Company's research and development activities and the commercialization of the targeted therapeutic products is dependent upon the Company's ability to successfully complete its research and development programs and finance its cash requirements through a combination of equity financing and payments from strategic partners. The Company's current level of cash and short-term investments and the additional funds available under a convertible debenture entered into on October 1, 2004 (note 13) is sufficient to execute the Company's current planned expenditures for the next twelve months.

2. SIGNIFICANT ACCOUNTING POLICIES

**Basis of Presentation**

The consolidated financial statements include the accounts of Lorus, its 80% owned subsidiary NuChem Pharmaceuticals Inc. ("NuChem"), and its wholly-owned subsidiary GeneSense Technologies Inc. ("GeneSense"). The results of operations for acquisitions are included in these consolidated financial statements from the date of acquisition. All significant intercompany balances and transactions have been eliminated on consolidation.

The consolidated financial statements have been prepared by management in accordance with accounting principles generally accepted in Canada and comply in all material respects with accounting principles generally accepted in the United States, except as disclosed in note 14 "Canada and United States Accounting Policy Differences."

**Revenue Recognition**

Revenue includes product sales revenue, license revenue and royalty revenue.

The Company recognizes revenue from product sales when title has passed and collection is reasonably assured, which typically is upon delivery to the distributor.

License fees are comprised of initial fees and milestone payments derived from a worldwide exclusive license agreement. Non-refundable license fees are recognized when the Company has no further involvement or obligation to perform under the arrangement, the fee is fixed and determinable and collection of the amount is deemed probable. Future non-refundable milestone payments receivable upon the achievement of third party performance are recognized upon the achievement of specified milestones when the milestone payment is substantive in nature, the achievement of the milestone was not reasonably assured at the inception of the agreement and the Company has no further significant involvement or obligation to perform under the arrangement.

The Company earns royalties from its distributor. Royalties from the distribution agreement are recognized when the amounts are reasonably determinable and collection is reasonably assured.

**Cash Equivalents and Short-Term Investments**

Lorus invests in high quality fixed income government (2004 - \$3,811,000, 2003 - \$4,214,000) and corporate (2004 - \$21,846,000, 2003 - \$20,005,000) instruments with low credit risk. Cash equivalents consist of highly liquid investments with a maturity of three months or less at the time of purchase.

Short-term investments, which consist of fixed income securities with a maturity of three months or more, are recorded at their accreted value as they are held to maturity instruments.

**Inventory**

The Company purchases drugs for resale and for research and clinical development. Drugs purchased for use in research and clinical development are expensed as purchased. Drugs purchased for resale are recorded as inventory and valued at the lower of cost and net realizable value.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
For the years ended May 31, 2004, 2003 and 2002

## Fixed Assets

Fixed assets are recorded at cost less accumulated depreciation and amortization. The Company records depreciation and amortization at rates which are expected to charge operations with the cost of the assets over their estimated useful lives as follows:

Furniture and equipment	straight-line over three to five years
Leasehold improvements	straight-line over the lease term

## Research and Development

Research costs are charged to expense as incurred. Development costs, including the cost of drugs for use in clinical trials, are expensed as incurred unless they meet the criteria under generally accepted accounting principles for deferral and amortization. No development costs have been deferred to date.

## Goodwill and Intangible Assets

Goodwill is not amortized but tested for impairment at least annually. Intangible assets with finite lives acquired in a business combination or other transaction are amortized over their estimated useful lives which have been assessed as seven years.

Goodwill represents the excess of the purchase price over the fair value of net identifiable assets acquired in the GeneSense business combination. Goodwill acquired in a business combination is tested for impairment on an annual basis and at any other time if an event occurs or circumstances change that would indicate that an impairment may exist. When the carrying value of a reporting unit's goodwill exceeds its fair value, an impairment loss is recognized in an amount equal to the excess.

The Company capitalized the cost of acquired research and development assets, comprised of patents and licences, on the acquisitions of GeneSense and the NuChem compounds. The nature of this asset is such that it is categorized as an intangible asset with a finite life. The carrying value of acquired research and development assets does not necessarily reflect its present or future value. The amount recoverable is dependent upon the continued advancement of the drugs through research, clinical trials and ultimately to commercialization. It is not possible to predict the outcome of future research and development programs.

No impairment relating to goodwill and intangible assets has been identified by the Company for 2004 and 2003.

## Impairment of Long-Lived Assets

Effective June 1, 2003, the Company adopted the new standard in CICA Handbook Section 3063, "Impairment or Disposal of Long-Lived Assets." Under the new standard the Company performs an impairment assessment of long-lived assets held for use whenever events or changes in circumstances indicated that the carrying amount of the assets may not be recoverable. If the sum of the undiscounted expected future cash flows expected to result from the use and eventual disposition of an asset is less than its carrying amount, it is considered to be impaired. An impairment loss is measured at the amount by which the carrying amount of the asset exceeds its fair value, which is estimated as the expected future cash flows discounted at a rate commensurate with the risks associated with the recovery of the asset. Prior to June 1, 2003 the Company periodically assessed and measured impairment by comparing the carrying amount to the undiscounted future cash flows the long-lived assets were expected to generate.

## Stock-Based Compensation

Stock options granted to employees are accounted for using the intrinsic value method. Under the intrinsic value method, compensation cost is recorded if, on the measurement date of the grant, the fair value of an underlying common share exceeds the exercise price per share. For options with contingent vesting criteria, the option is treated as a variable award and is revalued, using the intrinsic value method of accounting, at the end of each reporting period until the final measurement date. Deferred stock-based compensation is recognized as an expense over the vesting period of the option.

Options issued to consultants and other non-employees are accounted for using the fair value method and are recognized as an expense over the period which the services are performed or options earned using the Black-Scholes option pricing model.

The Company also has a deferred share unit plan that provides directors the alternative to receive payment for their current services in the form of share units rather than common shares or cash. Share units entitle the holder to receive, in the future, either an equivalent number of common shares or the cash equivalent of the shares at the date the units are exercised. As the award entitles the holder to settle the award through the receipt of cash, the value of the share units are recorded as a liability and the share units are revalued each reporting date with any increase or decrease in value being recorded in the consolidated statements of loss.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended May 31, 2004, 2003 and 2002

## Investment Tax Credits

The Company is entitled to Canadian federal and provincial investment tax credits, which are earned as a percentage of eligible research and development expenditures incurred in each taxation year. Investment tax credits are accounted for as a reduction of the related expenditure for items of a current nature and a reduction of the related asset cost for items of a long-term nature, provided that the Company has reasonable assurance that the tax credits will be realized.

## Income Taxes

Income taxes are reported using the asset and liability method. Under this method future tax assets and liabilities are recorded for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of assets and liabilities and their respective tax bases, and operating loss and research and development expenditure carry forwards. Future tax assets and liabilities are measured using enacted or substantially enacted tax rates expected to apply when the asset is realized or the liability is settled. The effect on future tax assets and liabilities of a change in tax rates is recognized in income in the period that substantive enactment or enactment occurs. A valuation allowance is recorded for the portion of the future tax assets where the realization of any value is uncertain.

## Loss Per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the year. Diluted net loss per common share is calculated by dividing the net loss by the sum of the weighted average number of common shares outstanding and the dilutive common equivalent shares outstanding during the year. Common equivalent shares consist of the shares issuable upon exercise of stock options and warrants calculated using the treasury stock method. Common equivalent shares are not included in the calculation of the weighted average number of shares outstanding for diluted net loss per common share when the effect would be anti-dilutive.

## Segmented Information

The Company is organized and operates as one operating segment, the research and development of cancer therapies. Substantially all of the Company's identifiable assets as at May 31, 2004 and 2003 are located in Canada.

## Foreign Currency Translation

Foreign currency transactions are translated into Canadian dollars at rates prevailing on the transaction dates. Monetary assets and liabilities are translated into Canadian dollars at the rates on the balance sheet dates. Gains or losses resulting from these transactions are accounted for in the loss for the period and are not significant.

## Use of Estimates

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the years. Actual results could differ from those estimates.

## Recent Canadian Accounting Pronouncements

In September 2003, the Canadian Institute of Chartered Accountants ["CICA"] revised Handbook Section 3870 "Stock-Based Compensation and Other Stock-Based Payments" to require that, effective June 1, 2004, the fair value method of accounting for stock options be recognized in the consolidated financial statements. The Company intends to apply these provisions retroactively without restatement for the year commencing June 1, 2004. The cumulative compensation cost of options on common shares of the Company, using the Black-Scholes option pricing model, will be charged to deficit with a corresponding increase to contributed surplus at June 1, 2004.

In November 2003, the CICA issued Accounting Guideline AcG-15, "Consolidation of Variable Interest Entities", to provide guidance for applying the principles in Handbook Section 1590, "Subsidiaries", to certain entities. Although the CICA is contemplating amendments to the Guideline, it is effective for the fiscal years beginning on or after November 1, 2004. Although the Company is currently reviewing AcG-15, the impact of the Guideline, if any, on the Company's consolidated financial statements has not been determined.

In March 2003, the CICA issued Handbook Section 3110, "Asset Retirement Obligations", which establishes standards for the recognition, measurement and disclosure of asset retirement obligations and the related asset retirement costs. This new Section is effective for June 1, 2004 for the Company and harmonizes Canadian requirements with existing United States GAAP. There will be no material impact on the consolidated financial statements resulting from the adoption of Section 3110 either in the current or prior years presented.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended May 31, 2004, 2003 and 2002

3.	FIXED ASSETS		
	As at May 31 (amounts in 000's)	<b>2004</b>	2003
	Furniture and equipment	\$ 1,977	\$ 1,603
	Leasehold improvements	907	898
		<u>2,884</u>	<u>2,501</u>
	Accumulated depreciation and amortization	(1,413)	(994)
		<u>\$ 1,471</u>	<u>\$ 1,507</u>
4.	ACQUIRED RESEARCH AND DEVELOPMENT		
	As at May 31 (amounts in 000's)	<b>2004</b>	2003
	Cost	\$ 12,228	\$ 12,228
	Accumulated amortization	(8,306)	(6,559)
		<u>\$ 3,922</u>	<u>\$ 5,669</u>

5. SHARE CAPITAL

**(a) Continuity of common shares and warrants**

(amounts and units in 000's)

	Common Shares		Warrants	
	Number	Amount	Number	Amount
Balance at May 31, 2001	142,411	\$ 117,150	1,242	\$ 729
Exercise of compensation warrants	(b) 476	265	(476)	(70)
Expiry of compensation warrants	-	659	(766)	(659)
Exercise of stock options	(e) 1,525	1,194	-	-
Stock-based compensation	(f) -	(100)	-	-
Balance at May 31, 2002	144,412	119,168	-	-
Exercise of stock options	(e) 873	715	-	-
Stock-based compensation	(f) -	558	-	-
Balance at May 31, 2003	145,285	\$ 120,441	-	\$ -
<b>Share issuance</b>	(d) 26,220	24,121	13,110	4,325
<b>Exercise of stock options</b>	(e) 289	171	-	-
<b>Stock-based compensation</b>	(f) -	(88)	-	-
<b>Other</b>	-	28	-	-
<b>Balance at May 31, 2004</b>	171,794	\$ 144,673	13,110	\$ 4,325

**(b) October 1999 Private Placement of Special Warrants**

In connection with the October 27, 1999 special warrants offering the Company issued 2,824,849 compensation warrants (stated capital \$0.147 per warrant) for services in connection with the completion of the offering. Each compensation warrant entitles the holder to acquire one common share for \$0.41 at any time prior to October 27, 2001. During fiscal year 2002, 475,700 compensation warrants were exercised.

**(c) Alternate Compensation Plans**

In 2000, the Company established a compensation plan for directors and officers, which allows the Company, in certain circumstances, to issue common shares to pay directors' fees or performance bonuses of officers in lieu of cash. The number of common shares reserved for issuance under this plan is 2,500,000. Since inception, 71,000 shares have been issued under this plan.

The Company also established a deferred share unit plan that provides directors the option of receiving payment for their services in the form of share units rather than common shares or cash. Share units entitle the director to elect to receive, on termination of their services to the Company, an equivalent number of common shares, or the cash equivalent of the market value of the common shares at that future date. The share units are granted based on the market value of the common shares on the date of issue. As of May 31, 2004, 68,183 deferred share units have been issued (2003 - 45,964, 2002 - 83,057), with a cash value of \$57,000 (2003 - \$58,000, 2002 - \$62,000) being recorded in accrued liabilities.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

For the years ended May 31, 2004, 2003 and 2002

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**(d) Share Issuance**

On June 11, 2003, the Company raised gross proceeds of \$32,775,000 by way of a public offering of 26,220,000 units at a price of \$1.25 per unit. Each unit consists of one common share and one-half of one purchase warrant. Each whole warrant entitles the holder to purchase a common share at a price of \$1.75 at any time on or before December 10, 2004. In addition, the Company issued 1,835,400 compensation options with a fair value of \$1,468,000 for services in connection with the completion of the offering. Each compensation option entitles the holder to acquire one unit for \$1.27 at any time on or before December 10, 2004. The Company incurred expenses of \$4,392,000 for the issuance, which include the non-cash charge of \$1,468,000 being the fair value of the compensation option. The Company allocated \$4,325,000 of the net proceeds to the warrants, \$1,405,000 to the compensation option and \$24,121,000 to share capital.

**(e) Stock Option Plan**

Under the Company's stock option plan, options may be granted to directors, officers, employees and consultants of the Company to purchase up to 20,582,081 common shares. Options are granted at the fair market value of the common shares on the date of grant. Options vest at various rates and have a term of five years to ten years. Stock option transactions for the three years ended May 31, 2004 are summarized as follows:

	2004		2003		2002	
	Options (000's)	Weighted- average exercise price	Options (000's)	Weighted- average exercise price	Options (000's)	Weighted- average exercise price
Outstanding at beginning of year	5,378	\$ 1.05	5,425	\$ 1.17	4,144	\$ 1.19

Granted	2,629	\$ 1.16	2,613	\$ 0.72	3,188	\$ 0.98
Exercised	(289)	0.59	(873)	\$ 0.83	(1,525)	\$ 0.78
Forfeited	(1,346)	1.29	(1,787)	\$ 1.01	(382)	\$ 1.39
Outstanding at end of year	6,372	\$ 1.05	5,378	\$ 1.05	5,425	\$ 1.17
Exercisable at end of year	3,542	\$ 1.01	2,921	\$ 1.26	2,183	\$ 1.32

The following table summarizes information about stock options outstanding at May 31, 2004:

Range of Exercise prices	Options outstanding			Options exercisable	
	Options outstanding (000's)	Weighted-average remaining		Options exercisable (000's)	Weighted-average exercise price
		contractual life (years)	Weighted-average exercise price		
\$ 0.33 to \$0.49	552	1.01	\$ 0.39	552	\$ 0.39
\$ 0.50 to \$0.99	2,767	2.79	\$ 0.80	2,085	\$ 0.79
\$ 1.00 to \$1.99	2,588	5.04	\$ 1.21	440	\$ 1.37
\$ 2.00 to \$3.63	465	1.44	\$ 2.41	465	\$ 2.41
	6,372	3.45	\$ 1.05	3,542	\$ 1.00

#### (f) Deferred Stock-based Compensation

The Company issues performance based options to employees which give rise to stock option expense based on the intrinsic value of the option on the date the performance is met. The Company also issues options to non-employees for services which are fair valued and expensed over the performance period.

The Company recorded a deferred stock-based compensation recovery relating to options issued under the Company's stock option plan amounting to \$88,000 for the year ended May 31, 2004 (2003 - - charge \$558,000 and 2002 -recovery \$100,000). Amortization of deferred stock-based compensation was a recovery of \$43,000 for the year ended May 31, 2004 (2003 - - charge of \$674,000 and 2002 - charge of \$296,000).

#### (g) Pro forma disclosure for Employee Stock Based Compensation

The Company accounts for its stock options granted to employees using the intrinsic value method. CICA Section 3870 requires companies not using the fair value method to disclose pro forma net earnings and earnings per share information as if the company had accounted for employee stock options under the fair value method. The Company has elected to disclose pro forma net loss and pro forma net loss per share as if the Company had accounted for its options since 1995 under the fair value method.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended May 31, 2004, 2003 and 2002

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A summary of the pro forma impact on the statement of loss is presented in the table below.

(amounts in 000's)	2004	2003	2002
Loss for the year	\$30,301	\$16,634	\$13,487
Compensation expenses related to the fair value of stock options	1,580	1,929	1,574
Employee stock-based compensation expense as recorded	43	(511)	(296)
Pro forma loss for the period	\$31,924	\$18,052	\$14,765
Pro forma basic and diluted loss per common share	\$ 0.19	\$ 0.12	\$ 0.10

The fair value of each option granted or modified has been estimated at the date of grant or modification using the Black-Scholes option pricing model with the following assumptions used for options granted in the years ended May 31, 2004, 2003 and 2002: (i) dividend yield of 0%; (ii) expected volatility of 89% (2003 - - 110%, 2002 - 80%) (iii) risk free interest rates ranging from 2.25% to 3.05% (2003 - - 3.2-3.5%, 2002 - 3.6%) and (iv) expected lives of 5 years. The Company has assumed no forfeiture rate as adjustments for actual forfeitures are made in the year they occur. The weighted-average grant date fair values of options issued in the years ended May 31, 2004, 2003 and 2002 were \$0.74, \$0.75 and \$0.71 respectively.

#### 6. INCOME TAXES

Income tax recoveries attributable to losses from operations differ from the amounts computed by applying the combined Canadian federal and provincial income tax rates to pretax income from operations primarily as a result of the provision of a valuation allowance on net future income tax benefits.

Significant components of the Company's future tax assets are as follows:

As at May 31 (amounts in 000's)	2004	2003
Non-capital loss carryforwards	\$ 19,746	\$ 9,824
Research and development expenditures	17,613	12,905
Book over tax depreciation	1,307	1,576
Other	1,345	492

Future tax assets	40,011	24,797
Valuation allowance	40,011	24,797
	<u>\$ -</u>	<u>\$ -</u>

In assessing the realizable benefit from 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 on the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers projected future taxable income, uncertainties related to the industry in which the Company operates, and tax planning strategies in making this assessment. Due to the Company's stage of development and operations, and uncertainties related to the industry in which the Company operates, the tax benefit of the above amounts has been completely offset by a valuation allowance.

Research and development expenditures can be carried forward indefinitely. To the extent that the non-capital loss carryforwards are not used, they expire as follows:

Year of expiry (amounts in 000's)	Non-capital losses
2005	\$ 2,159
2006	3,468
2007	4,626
2008	4,985
2009	6,525
2010	8,248
2011	1,028
2012	-
2013	-
2014	22,206
	<u>\$ 53,245</u>

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
FOR THE YEARS ENDED MAY 31, 2004, 2003 AND 2002

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7. RESEARCH AND DEVELOPMENT PROGRAMS

The Company's cancer drug research and development programs focus primarily on the following technology platforms:

**(a) Immunotherapy**

This clinical approach stimulates the body's natural defenses against cancer. The Company's lead drug Virulizin<sup>®</sup> is currently in a Phase III clinical trial for the treatment of pancreatic cancer and has been sold in the private market in Mexico for malignant melanoma.

**(b) Antisense**

Antisense drugs are genetic molecules that inhibit the production of disease-causing proteins. GTI-2040 and GTI-2501, the Company's lead antisense drugs, have shown pre-clinical anti-cancer activity across a broad range of cancers and are currently in a total of seven different Phase II clinical trials.

**(c) Small Molecules**

Anti-cancer activity was discovered with an anti-fungal agent Clotrimazole ("CLT"). Based on the structural feature found to be responsible for the anti-cancer effect of CLT, chemical analogues of CLT have been designed and tested. Our library of clotrimazole analogs has been licensed to Cyclacel Limited as described in note 12.

Lorus scientists discovered novel low molecular weight compounds with anti-cancer and anti-bacterial activity in pre-clinical investigations. Of particular interest were compounds that inhibit the growth of human tumor cell lines including hepatocellular carcinoma, pancreatic carcinoma, ovarian carcinoma, breast adenocarcinoma and metastatic melanoma. These compounds also demonstrated activity against multi-drug resistant bacteria which are responsible for a number of life-threatening infections.

In addition to the above Lorus has a number of other technologies under pre-clinical development including a tumor suppressor or gene therapy approach to inhibiting the growth of tumors.

(amounts in 000's)	Years ended May 31			Period from
	2004	2003	2002	Sept. 5, 1986 to May 31, 2004
Research and Development				
Immunotherapy				
Expensed	\$ 19,944	\$ 7,433	\$ 4,612	\$ 56,865
Acquired	-	-	-	-
Antisense				
Expensed	6,666	4,911	3,410	24,875
Acquired	-	-	-	11,000
Small Molecules				
Expensed	175	206	637	4,104
Acquired	-	-	-	1,228
Total expensed	<u>\$ 26,785</u>	<u>\$ 12,550</u>	<u>\$ 8,659</u>	<u>\$ 85,844</u>
Total acquired	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 12,228</u>

8. SUPPLEMENTARY CASH FLOW INFORMATION

Changes in non-cash working capital balances for each of the periods ended are summarized as follows:

(amounts in 000's)	Years ended May 31			Period from inception Sept. 5, 1986 to May 31, 2004
	2004	2003	2002	
<b>(Increase) decrease</b>				
Prepaid expenses and amounts receivable	\$ (593)	\$ 91	\$ 309	\$ (1,120)
<b>Increase (decrease)</b>				
Accounts payable	1,111	876	(2,686)	1,185
Accrued liabilities	(647)	1,052	253	3,155
	<u>\$ (129)</u>	<u>\$ 2,019</u>	<u>\$ (2,124)</u>	<u>\$ 3,220</u>

During the year ended May 31, 2004, the Company received interest of \$1,151,000 (2003 - \$1,679,000 and 2002 - \$2,488,000).

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
For the years ended May 31, 2004, 2003 and 2002

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9. COMMITMENTS AND GUARANTEES

**(a) Operating lease commitments**

The Company has entered into operating leases for premises and office equipment under which it is obligated to make minimum annual payments of approximately \$110,000 in 2005.

During the year ended May 31, 2004, operating lease expenses were \$141,000 (2003 - \$122,000 and 2002 - \$118,000).

**(b) Other contractual commitments**

In December 1997, the Company acquired certain patent rights and a sub-license to develop and commercialize the anti-cancer application of certain compounds in exchange for:

- (i) A 20% share interest in NuChem;
- (ii) A payment of US\$350,000 in shares of Lorus, and
- (iii) Up to US\$3,500,000 in cash.

To date the Company has made cash payments of US\$500,000. The remaining balance of up to US\$3,000,000 remains payable upon the achievement of certain milestones based on the commencement and completion of clinical trials. Additional amounts paid will be classified as acquired research and development and will be amortized over the estimated useful life of the licensed asset.

The Company holds an exclusive world-wide license from the University of Manitoba (the "University") and Cancer Care Manitoba ("CCM") to certain patent rights to develop and sub-license certain oligonucleotide technologies. In consideration for the exclusive license of the patent rights, the University and CCM are entitled to an aggregate of 1.67% of the net sales received by the Company from the sale of products or processes derived from the patent rights and 1.67% of all monies received by the Company from sub-licenses of the patent rights. Any and all improvements to any of the patent rights derived in whole or in part by the Company after the date of the license agreement, being June 20, 1997, are not included within the scope of the agreement and do not trigger any payment of royalties. To date the Company has not paid any royalties pursuant to the license agreement.

**(c) Guarantees**

The Company entered into various contracts whereby contractors perform certain services for the Company. The Company indemnifies the contractors against costs, charges and expenses in respect of legal actions or proceedings against the contractors in their capacity of servicing the Company. The maximum amounts payable from these guarantees cannot be reasonably estimated. Historically, the Company has not made significant payments related to these guarantees.

The Company contracts with Clinical Research Organizations to facilitate some of our clinical trials. These contracts may be terminated upon sixty days written notice.

10. RELATED PARTY TRANSACTIONS

During the year ended May 31, 2004, consulting fees of nil were paid to a company which is controlled by a director of the Company (2003 - \$48,874 and 2002 - \$68,000). These transactions are in the normal course of operations and are measured at the exchange amount of consideration established and agreed to by the related parties.

The amount payable to related parties as at May 31, 2004 was nil (2003 - nil and 2002 - \$46,000).

11. FINANCIAL INSTRUMENTS

The carrying values of cash and cash equivalents, short-term investments, amounts receivable, accounts payable and accrued liabilities approximate their fair values due to the short-term nature of these instruments.

Fair value estimates are made at a specific point in time, based on relevant market information and information about the financial instrument. These estimates are subjective in nature and involve uncertainties and matters of significant judgment and, therefore, cannot be determined with precision. Changes in assumptions could significantly affect the estimates.

Financial instruments potentially exposing the Company to a concentration of credit risk consist principally of cash equivalents and short-term investments. The Company mitigates this risk by investing in high grade fixed income securities.

12 REVENUE

During the year, the Company recorded license revenue of \$546,000 (2003 - nil, 2002 - nil) in connection with a worldwide exclusive license agreement entered into with Cyclacel Limited in the United Kingdom for the out-licensing of the Company's library of clotrimazole analogs. Additional license fees of up to \$11.6 million may be earned if Cyclacel achieves certain defined research and development milestones. Under the agreement the Company will also receive royalties on the sale of any products.

Revenue also includes product and royalty revenue from the sale of Virulizir<sup>®</sup> to Mayne Pharma, the Company's distribution partner for the Mexico market.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

For the years ended May 31, 2004, 2003 and 2002

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13 SUBSEQUENT EVENT

On October 5, 2004, subsequent to the 2004 fiscal year-end, we entered into an agreement to raise aggregate net proceeds of \$14.4 million through the issuance of \$15 million of secured convertible debentures. The debentures are secured by a first charge over all of the assets of the Company. We received \$4.4 million on October 5, 2004, and will receive \$5.0 million on January 15, 2005 and on April 15, 2005. The debentures will expire on October 1, 2009 and interest will accrue and be paid monthly at a rate of prime + 1% until the Company's share price reaches \$1.75 for 60 consecutive trading days, at which time interest will no longer accrue. Interest is to be payable in common shares of Lorus until such shares trade at a price of \$1.00 or more after which interest will be payable in cash or common shares at the option of the debenture holder. Common shares issued in payment of interest will be issued at a price equal to the weighted average trading price of such shares for the ten trading days immediately preceding their issue in respect of each interest payment. The \$5.0 million principal amount of debentures issued on October 5, 2004 is convertible at the holder's option into common shares of the Company with an exercise price per share of \$1.00. The \$10.0 million principal amount of debentures issued thereafter is convertible at an exercise price per share equal to the greater of \$1.00 and the weighted average trading price of our common shares for the twenty trading days prior to the investment of the funds, less any discount permitted by the Toronto Stock Exchange. The agreement also provides for the issuance of up to 4 million warrants, with a life of five years, to buy common shares at a price per share of \$1.00.

14 CANADA AND UNITED STATES ACCOUNTING POLICY DIFFERENCES

These consolidated financial statements have been prepared in accordance with generally accepted accounting principles as applied in Canada ("Canadian GAAP"). In certain respects, generally accepted accounting principles as applied in the United States ("United States GAAP") differ from those applied in Canada. There are no material measurement differences between Canadian GAAP and United States GAAP that apply to the consolidated financial statements.

**(a) SFAS 130 Reporting Comprehensive Income**

SFAS No. 130 establishes standards for reporting and presentation of comprehensive income. This standard defines comprehensive income as the changes in equity of an enterprise except those resulting from shareholder transactions. Comprehensive loss for the periods presented in these consolidated financial statements equaled the loss for the period.

**(b) Recent United States Accounting Pronouncements**

United States GAAP, Statement of Financial Accounting Standards No. 143, "Accounting for Asset Retirement Obligations" ["FAS 143"], was adopted by the Company effective June 1, 2003. The standard requires the Company to estimate and accrue for the present value of its obligations to restore leased premises at the end of the lease. At lease inception, the present value of this obligation would be recognized as other long-term liabilities with a corresponding amount recognized in fixed assets. The fixed asset amount would be amortized, and the liability amount would be accreted, over the period from lease inception to the time the Company expects to vacate the premises resulting in both depreciation and interest charges in the consolidated statements of income. There is no material impact on the consolidated financial statements resulting from the adoption of FAS 143 either in the current or prior years presented.

In December 2003, the Financial Accounting Standards Board ["FASB"] amended Interpretation No. 46, "Consolidation of Variable Interest Entities" ["FIN 46R"]. FIN 46R requires that a variable interest entity ["VIE"] be consolidated by a company if that company is subject to a majority of the risk of loss from the VIE's activities and/or is entitled to receive a majority of the VIE's residual returns. For the Company, the requirements of FIN 46R apply in 2003 for all VIE's created after January 31, 2003. For VIE's created before January 31, 2003, the requirements of FIN 46 apply as of May 31, 2005 for a VIE that does not meet the definition of a special-purpose entity ["SPE"] and as of June 1, 2004 for a VIE that is an SPE. The application of this Interpretation will not have an effect on the Company's financial statements.

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## MANAGEMENT 'S DISCUSSION AND ANALYSIS

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The following discussion should be read in conjunction with the audited consolidated financial statements for the year ended May 31, 2004 and the accompanying notes (the "Financial Statements") set forth elsewhere in this report. The Financial Statements and all financial information discussed below have been prepared in accordance with Canadian generally accepted accounting principles ("GAAP"). Significant differences between Canadian and United States GAAP are identified in Note 14 to the Financial Statements. All amounts are expressed in Canadian dollars unless otherwise noted. In this Management's Discussion and Analysis, "Lorus", the "Company", "we", "us" and "our" each refers to Lorus Therapeutics Inc.

### OVERVIEW

Lorus Therapeutics Inc. is a life sciences company focused on the research, development and commercialization of effective anti-cancer therapies with high safety. Lorus has worked diligently to establish a diverse, marketable anti-cancer product pipeline, with products in various stages of development ranging from pre-clinical to a global Phase III clinical trial which has reached full enrollment. This product pipeline is supported by a growing intellectual property portfolio.

Our success is dependent upon several factors, including establishing the efficacy and safety of our products in clinical trials, obtaining the necessary regulatory approvals to market our products and maintaining sufficient levels of funding through public and/or private financing. Lorus has not commercially marketed any product other than Virulizin<sup>®</sup>, which is being sold in the private market in Mexico.

We believe that the future of cancer treatment and management lies in drugs that are effective, safe and have minimal side effects and therefore improve a patient's quality of life. Many of the drugs currently approved for the treatment and management of cancer are toxic with severe side effects and we therefore believe that a product development plan based on effective and safe drugs could have broad applications in cancer treatment. Lorus' strategy is to continue the development of our product pipeline using several therapeutic approaches. Each therapeutic approach is dependent on different technologies, thereby mitigating the development risks associated with a single technology platform. We evaluate the merits of each product throughout the clinical trial process and consider commercialization. The most advanced anti-cancer drugs in our pipeline, each of which flow from different platform technologies, are:

Immunotherapeutics (Virulizin<sup>®</sup>); Antisense (GTI compounds); small molecule and Tumor Suppressor Technology.

Our net loss for 2004 totaled \$30.3 million (\$0.18 per share) compared to a net loss of \$16.6 million (\$0.12 per share) in 2003. Research and development expenses in 2004 increased to \$26.8 million from \$12.6 million in 2003. The Virulizin<sup>®</sup> Phase III clinical trial expansion, that resulted in full enrollment in June 2004, increased manufacturing and compliance activities and the procurement of drug supply for the U.S. NCI-sponsored Phase II clinical trial programs for GTI-2040 contributed to the increase in net loss in 2004. We utilized cash of \$28.1 million in our operating activities in 2004 compared with \$11.9 million in 2003; the higher utilization was necessary to support our expanded research and development activities. At the end of 2004 we had cash and cash equivalents and short-term investments of \$26.7 million compared to \$25.1 million at the end of 2003.

As products progress through clinical trials, the size of the trials and cost of these development activities increase dramatically. The Company completed enrollment in its Virulizin<sup>®</sup> Phase III clinical trial shortly after the fiscal year end. A substantial amount of the costs of the trial were incurred in the year and particularly in the fourth quarter of fiscal 2004. We anticipate lower quarterly clinical trial costs in fiscal 2005.

### CRITICAL ACCOUNTING POLICIES

The Company periodically reviews its financial reporting and disclosure practices and accounting policies to ensure that they provide accurate and transparent information relative to the current economic and business environment. As part of this process, the Company has reviewed its selection, application and communication of critical accounting policies and financial disclosures. Management has discussed the development and selection of the critical accounting policies with the Audit Committee of the Board of Directors and the Audit Committee has reviewed the disclosure relating to critical accounting policies in this Management's Discussion and Analysis. Other important accounting policies are described in Note 2 of the Financial Statements.

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## MANAGEMENT 'S DISCUSSION AND ANALYSIS

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### Drug Development Costs

We incur costs related to the research and development of pharmaceutical products and technologies for the management of cancer. These costs include internal and external costs for pre-clinical research and clinical trials, drug costs, regulatory compliance costs and patent application costs. All research costs are expensed as incurred as required under GAAP.

Development costs, including the cost of drugs for use in clinical trials, are expensed as incurred unless they meet the criteria under GAAP for deferral and amortization. The Company continually assesses its activities to determine when, if ever, development costs may qualify for capitalization. By expensing the research and development costs as required under GAAP, the value of the product portfolio is not reflected in the Company's Financial Statements.

### RESULTS OF OPERATIONS

#### Revenues

Revenues for the year increased to \$608 thousand, representing an increase of \$542 thousand over 2003 sales of \$66 thousand and nil in 2002. The increase results from a licensing agreement Lorus entered into during the year with Cyclacel Ltd. in connection with the out-licensing of our clotrimazole analog library of anti-cancer drug candidates. The agreement included an initial license fee of \$546 thousand with the potential of additional license fees of up to \$11.6 million that may be earned if Cyclacel achieves certain defined research and development milestones. We do not expect that any of these milestones will be achieved in the next 12 months. The balance of the revenue earned during 2004 relates to product and royalty revenues from the sale of Virulizin<sup>®</sup> to our distributor in the Mexican market, Mayne Pharma. The Company processed a change in the formulation of Virulizin<sup>®</sup> for sale in Mexico in order to increase the shelf life of the product, however, as this change in formulation was not approved by the Mexican Minister of Health until subsequent to year end, there were no sales of Virulizin<sup>®</sup> in Mexico during the last five months of the fiscal year. We do not anticipate product revenue in fiscal 2005 from any of our other anti-cancer drugs currently under development.

#### Research and Development

Research and development expenditures totaled \$26.8 million in 2004 compared to \$12.6 million in 2003 and \$8.7 million in 2002. The significant increase in 2004 expenditures is primarily the result of two factors. First, we incurred increased costs associated with the expanded pivotal Phase III global clinical trial of Virulizin<sup>®</sup> for the treatment of advanced pancreatic cancer, including personnel, drug manufacturing and testing, combination drug purchases and contract research organization costs. Second, we incurred expenditures related to the upfront procurement of the GTI-2040 drug for the five U.S. National Cancer Institute ("NCI") sponsored Phase II clinical trials initiated during 2004 for patients with Acute Myeloid Leukemia ("AML"), breast cancer, non-small cell lung cancer, solid tumors and advanced unresectable colon cancer. Research and development costs in 2003 were higher than 2002 primarily due to: (i) the initial expansion of the Phase III Virulizin<sup>®</sup> clinical trial; (ii) the expansion of the Phase II clinical trial of GTI-2040 in renal cell carcinoma to more than 8 major oncology centres in the U.S.; and (iii) the preparation for the National Cancer Institute sponsored GTI-2040 Phase II clinical trial programs.

Of the total research and development expenditures incurred during the year, Virulizin<sup>®</sup> accounted for \$19.9 million or 74% of total spending. As discussed above, our lead drug Virulizin<sup>®</sup> is undergoing a Phase III clinical trial for which full enrollment was reached shortly after year end. During fiscal 2005 we expect our research and development costs to decrease, as no further start-up costs associated with this trial will be incurred.

#### General and Administrative

General and administrative expenses totaled \$4.9 million in 2004 compared to \$4.3 million in 2003 and \$4.9 million in 2002. The increase in 2004 of \$600 thousand compared to 2003 is due to higher professional and filing fees related to regulatory changes and changes to the option plan, as well as a one time non-cash charge of \$245 thousand to write-off financing costs no longer deemed to have future value. The decrease in 2003 compared to 2002 resulted mainly from lower legal and advisory service fees.

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## MANAGEMENT'S DISCUSSION AND ANALYSIS

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#### Depreciation and Amortization

Depreciation and amortization expenses totaled \$420 thousand in 2004 compared to \$1.0 million in 2003 and \$2.0 million in 2002. The decrease in 2004 over 2003 is due primarily to the amortization of stock-based compensation that was a recovery of \$43 thousand in 2004 and an expense of \$700 thousand in 2003 due to a decline in Lorus' use of the compensation tool during 2004. The decrease in 2003 over 2002 is related primarily to the adoption of the new accounting pronouncement for goodwill and other intangible assets whereby the Company ceased amortizing goodwill on June 1, 2002 upon adoption of CICA Handbook section 3062 "Goodwill and other intangible assets". Amortization of goodwill totaled \$1.5 million in 2002. Amortization of stock-based compensation in 2003 totaled \$700 thousand as compared to \$300 thousand in 2002.

#### Interest and Other Income

Interest income totaled \$1.2 million in 2004 and in 2003 and \$2.0 million in 2002. Interest income was unchanged between 2004 and 2003 despite higher average cash and short-term investment balances in 2004 because of lower market interest rates in 2004 compared with 2003. The decrease in 2003 interest income compared to 2002 was due to a lower average cash and short-term investment balance in 2003 and the general decline in market interest rates.

#### Loss for the Period

The loss for the year totaled \$30.3 million or \$0.18 per share in 2004 compared to \$16.6 million or \$0.12 per share in 2003 and \$13.5 million or \$0.09 per share in 2002. The increase in net loss in 2004 compared to 2003 is primarily due to the significant increase in clinical trial activities to support the expanded Phase III Virulizin<sup>®</sup> clinical trial. The increase in net loss in 2003 compared to 2002 relates primarily to increased clinical trial activities, which was partially offset by lower administrative costs and the discontinuance of amortization of goodwill in accordance with the adoption of the new CICA accounting pronouncement described above. On a comparative basis, the loss for the year ended May 31, 2002 would have been \$12.0 million or \$0.08 per share after adjustment to remove the amortization of goodwill.

## LIQUIDITY AND CAPITAL RESOURCES

Since its inception, Lorus has financed its operations and technology acquisitions primarily from equity financing, the exercise of warrants and stock options, and interest income on funds held for future investment. We expect to continue to finance the costs of the global Virulizin<sup>®</sup> Phase III clinical trial from internal resources until its anticipated completion in Q1 of fiscal 2006. The costs of the five GTI-2040 Phase II clinical trials will continue to be borne by the NCI in the United States. We believe that our available cash, cash equivalents and short-term investments, and the interest earned thereon, together with the post year-end convertible debenture financing discussed below, will be sufficient to finance our operations and capital needs for at least the next 12 months.

#### Financing

On June 11, 2003, Lorus raised net proceeds of \$29.9 million by way of a public offering of 26,220,000 units at a price of \$1.25 per unit, each unit consisting of one common share and one-half of one share purchase warrant. In addition during fiscal 2004, Lorus issued common shares on the exercise of stock options for proceeds of \$200 thousand. In 2003, Lorus issued common shares on the exercise of stock options for proceeds of \$700 thousand. In 2002, Lorus issued common shares on the exercise of warrants and stock options for proceeds of \$1.4 million.

On October 5, 2004, subsequent to the 2004 fiscal year-end, we entered into an agreement to raise aggregate net proceeds of \$14.4 million through the issuance of \$15 million of secured convertible debentures. The debentures are secured by a first charge over all of the assets of the Company. We received \$4.4 million on October 5, 2004, and will receive \$5.0 million on January 15, 2005 and on April 15, 2005. The debentures will expire on October 1, 2009 and interest will accrue and be paid monthly at a rate of prime + 1% until the Company's share price reaches \$1.75 for 60 consecutive trading days, at which time interest will no longer accrue. Interest is to be payable in common shares of Lorus until such shares trade at a price of \$1.00 or more after which interest will be payable in cash or common shares at the option of the debenture holder. Common shares issued in payment of interest will be issued at a price equal to the weighted average trading price of such shares for the ten trading days immediately preceding their

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## MANAGEMENT 'S DISCUSSION AND ANALYSIS

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issue in respect of each interest payment. The \$5.0 million principal amount of debentures issued on October 5, 2004 is convertible at the holder's option into common shares of the Company with an exercise price per share of \$1.00. The \$10.0 million principal amount of debentures issued thereafter is convertible at an exercise price per share equal to the greater of \$1.00 and the weighted average trading price of our common shares for the twenty trading days prior to the investment of the funds, less any discount permitted by the Toronto Stock Exchange. The agreement also provides for the issuance of up to 4 million warrants, with a life of five years, to buy common shares at a price per share of \$1.00.

### Use of Proceeds

In our prospectus dated June 3, 2003 we indicated that the proceeds to be received from that financing would be used as follows: \$12.0 million for the product development of our immunotherapy platform, \$11 million for the product development of our antisense platform and \$2.0 million for pre-clinical and discovery programs. It was anticipated that the balance of funding would be used for working capital and general purposes. During fiscal 2004 we incurred \$19.9 million in research and development expenses on our immunotherapy platform, \$6.7 million on our antisense platform, and \$200 thousand on pre-clinical and discovery programs. The additional spending on our immunotherapy platform was funded through cash and short-term investments held by the Company prior to the 2003 offering and is the direct result of the expansion of the Virulizin<sup>®</sup> Phase III clinical trial. The spending anticipated in the 2003 prospectus on our antisense platform and pre-clinical and discovery programs was to be incurred over a number of years, not solely in 2004. We have sufficient funds available at the end of 2004 to fund the remaining \$4.3 million to be spent on our antisense platform and \$1.8 million to be spent on pre-clinical and discovery programs.

### Operating Cash Requirements

Lorus utilized cash in operating activities of \$28.1 million in 2004 compared to \$11.9 million in 2003 and in 2002. The cash used in operating activities in 2004 is higher than the prior year due to higher expenditures throughout the year to support the Virulizin<sup>®</sup> Phase III clinical trial. The cash used in operating activities in 2003 was comparable with that experienced in 2002 despite a higher net loss in 2003 due primarily to changes in the timing of payments of accounts payable and accrued liabilities.

We expect the cash used in operating activities to decrease in 2005 from the amount experienced in 2004 as our major clinical trial with Virulizin<sup>®</sup> will be underway and no further initiation costs associated with this trial will be incurred in 2005.

### Cash Position

At May 31, 2004, Lorus had cash and cash equivalents and short-term investments totaling \$26.7 million compared to \$25.1 million at the end of 2003. The Company invests in highly rated and liquid debt instruments. Investment decisions are made in accordance with an established investment policy administered by senior management and overseen by the Board of Directors. Working capital (representing primarily cash and cash equivalents and short-term investments) at May 31, 2004 was \$22.6 million as compared to \$20.9 million in 2003. As discussed above, subsequent to the year-end, we entered into an agreement to issue \$15 million in convertible debentures for net proceeds of \$14.4 million. Cash and short-term investments will therefore increase by \$14.4 million (gross proceeds of issuance net of issuance costs). The Company does not expect to generate a positive cash flow from operations for the next few years due to substantial additional research and development costs, including costs related to drug discovery, pre-clinical testing, clinical trials, manufacturing costs and operating expenses associated with supporting these activities. Negative cash flow will continue until such time, if ever, that we receive regulatory approval to commercialize any of our products under development and revenue from any such products exceeds expenses.

We may seek to access the public or private equity markets from time to time, even if we do not have an immediate need for additional capital at that time. Lorus intends to use its resources to fund its existing drug development programs and develop new programs from its portfolio of pre-clinical research technologies. The amounts actually expended for research and drug development activities and the timing of such expenditures will depend on many factors, including the progress of the Company's research and drug development programs, the results of pre-clinical and clinical trials, the timing of regulatory submissions and approvals, the impact of any internally developed licenses or acquired technologies, the impact from technological advances, determinations as to the commercial potential of the Company's compounds and the timing and development status of competitive products.

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## MANAGEMENT 'S DISCUSSION AND ANALYSIS

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### CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET FINANCING

At May 31, 2004, we had contractual obligations requiring annual payments as follows:

(amounts in 000's)	Less than 1 year	1-3 years	4-5 years	5+ years	Total
Operating leases	110	–	–	–	110
Contract Research Organizations <sup>1</sup>	2,585	2,213	–	–	4,798

Off-balance sheet financing arrangements are limited to operating lease contracts in respect of office equipment, and a building lease.

<sup>1</sup> Contract Research Organization expenditures relate to our Phase III Virulizin<sup>®</sup> clinical trial

### OUTSTANDING SHARE DATA

As at August 30, 2004 the Company had 171,804,989 common shares issued and outstanding. In addition, the Company had 8,235,998 stock options issued and outstanding, 1,835,400 compensation options issued and outstanding with an exercise price of \$1.27 and warrants to purchase 13,110,000 common shares of Lorus at an exercise price of \$1.75 per share.

## SELECTED ANNUAL FINANCIAL DATA

The following selected consolidated financial data has been derived from, and should be read in conjunction with the accompanying audited consolidated financial statements for the year ended May 31, 2004 which are prepared in accordance with Canadian GAAP.

### Consolidated Statements of Loss and Deficit

(amounts in 000's except for per common share data) (Canadian dollars)

	Years Ended May 31		
	2004	2003	2002
Revenues	\$608	\$ 66	\$ –
Operating expenses			
Cost of sales	28	55	–
Research and development	26,785	12,550	8,659
General and administrative	4,915	4,290	4,867
Depreciation and amortization	420	960	1,956
Operating loss	31,540	17,789	15,482
Interest and other income	(1,239)	(1,155)	(1,995)
Loss for the year	30,301	16,634	13,487
Basic and fully diluted loss per common share	\$0.18	\$ 0.12	\$ 0.09
Total assets	34,424	34,255	47,572

## QUARTERLY RESULTS OF OPERATIONS

The following table sets forth certain unaudited consolidated statements of operations data for each of the eight most recent fiscal quarters that, in management's opinion, have been prepared on a basis consistent with the audited consolidated financial statements contained elsewhere in this annual report and include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the information presented.

During Q3 2003, we began selling Virulizin<sup>®</sup> for the treatment of malignant melanoma through our distributor, Mayne Pharma, in the Mexican private market. Sales continued to Q2 2004 when Lorus filed a change in formulation with the Mexican Minister of Health which was not approved until subsequent to year end. Sales through Mayne Pharma include both product sales and royalty revenue. Revenue increased significantly in Q2 2004 due to the initial license fee from Cyclacel Ltd. discussed above.

Research and development expenses increased significantly throughout 2004 in comparison to 2003 due

## MANAGEMENT'S DISCUSSION AND ANALYSIS

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to the expansion of the Phase III Virulizin<sup>®</sup> clinical trial. Research and development payments fluctuated during 2004 primarily due to the timing of milestone payments to our Contract Research Organizations, as well as the manufacturing of our study drugs (Virulizin<sup>®</sup> and GTI-2040) and the purchase of the study combination drug.

	Fiscal 2004 Quarter Ended				Fiscal 2003 Quarter Ended			
	Aug 31 2003	Nov 30 2003	Feb 29 2004	May 31 2004	Aug 31 2002	Nov 30 2002	Feb 28 2003	May 31 2003
Revenue	\$29	\$ 575	\$ 2	\$ 2	\$ –	\$ –	\$ 27	\$ 39
Cost of Sales	–	26	1	1	–	–	27	28
Research and development	7,263	5,586	7,340	6,596	3,047	3,323	2,876	3,304
General and administrative	1,231	1,176	1,010	1,498	1,304	796	960	1,230
Depreciation and amortization	99	99	108	114	95	164	224	477
Operating loss	8,564	6,312	8,457	8,207	4,446	4,283	4,060	5,000
Interest and other income		(393)	(314)	(298)	(234)	(370)	(314)	(213)
Loss for the period	8,171	5,998	8,159	7,973	4,076	3,969	3,802	4,787

Basic and fully diluted loss per common share	\$0.05	\$0.03	\$0.05	\$0.05	\$0.03	\$0.03	\$0.02	\$0.04
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## RISKS AND UNCERTAINTIES

Lorus has not produced or commercially marketed any product other than Virulizin<sup>®</sup>, which has been approved for sale and is being sold in the private market in Mexico. Although we have commenced commercial sales of Virulizin<sup>®</sup>, there can be no assurance that the Company will realize future revenues from the product. In addition, there can be no assurance that we will ever realize revenues from any of our products in development, or that we will ever be profitable.

Lorus' products are in various stages of development. There can be no assurance that we will have funds available to permit the successful commercialization of our products. The Company's funding needs may vary depending on many factors including: the progress and number of research and drug development programs; costs associated with clinical trials and the regulatory process; costs related to maintaining drug manufacturing sources; costs of prosecuting or enforcing patent claims and other intellectual property rights; collaborative and license agreements with third parties; and opportunities to in-license or acquire new products. In order to commercialize our products, we must obtain regulatory approvals. Regulatory approvals can take a number of years and involve substantial expenditures. There can be no assurance that the Company will ever obtain necessary approvals or licenses for any of its products; that the Company will not encounter difficulties or excessive costs in its efforts to secure necessary approvals and licenses; or that the Company will be able to obtain sufficient funds to meet the necessary expenditures associated with obtaining regulatory approvals. Even if our product candidates receive all necessary regulatory approvals and clearances, they may not gain market acceptance. Physicians, patients, third party payors and the medical community may not accept or utilize our products, and if our products do not achieve significant market acceptance our business and financial condition will be materially adversely affected. In addition, market acceptance is affected by the extent to which reimbursement for the cost of such products will be available from government health administration authorities, private health coverage insurers and other organizations.

Lorus relies upon third parties to provide certain key services, including contract manufacturers to manufacture its products and independent investigators and contract research organizations to assist it in conducting its clinical trials. These third parties may encounter difficulties in meeting regulatory requirements and in maintaining quality control and quality assurance to meet Lorus' clinical development needs. If these third party service providers are unable to meet regulatory requirements or maintain quality control and quality assurance, or we are unable to retain such suppliers or obtain new third party suppliers, we may not be able to effectively conduct clinical trials or ultimately commercialize our products.

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## MANAGEMENT'S DISCUSSION AND ANALYSIS

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We currently hold licenses from third parties for certain technologies, including in respect of our antisense platform. We cannot assure you that these licenses will not terminate or that they will remain in good standing. Our strategy is to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of our products. There can be no assurance, however, that we will be able to establish such additional collaborations on favourable terms, if at all, or that our current or future collaborative arrangements will be successful or may not be terminated by our partners. We do not have any sales, marketing or distribution capabilities. In order to commercialize our products, if any are approved, we must either acquire or internally develop sales, marketing and distribution capabilities or make arrangements with third parties to perform these services for us. The inability to market our products could have a material adverse effect on our business and financial condition.

The sale and use of the products we develop could carry the risk of product liability proceedings. While we currently maintain limited product liability insurance, we cannot assure you that product liability insurance will continue to be available to us on commercially reasonable terms. Product liability claims might also exceed the amounts of such coverage.

Our discovery and development processes involve the controlled use of hazardous and radioactive materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by local laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Our interest income is subject to fluctuations of interest rates in our investment portfolio of debt securities. Investments are held to maturity and have staggered maturities to minimize interest rate risk. There can be no assurance that interest income fluctuations will not have an adverse impact on Lorus' financial condition. The Company maintains its accounts in Canadian dollars, but its revenues and a portion of its expenditures are in foreign currencies. Lorus does not currently engage in hedging its foreign currency requirements to reduce exchange rate risk.

Our success depends in part on our ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. We cannot assure that our pending patent applications will result in patents being granted, that we will be able to develop additional proprietary products that are patentable, that patents already granted to us will provide us with any competitive advantage, or that patents of others will not have an adverse effect on our ability to do business.

Our success depends in large part upon our ability to attract and retain highly qualified scientific and management personnel. We face competition for such personnel from other companies, academic institutions, government entities and other organizations. We cannot assure you that we will retain our current personnel and will be able to continue to attract qualified personnel.

## RECENT ACCOUNTING PRONOUNCEMENTS

Effective June 1, 2003, the Company adopted Statement of Financial Accounting Standards No. 143, "Accounting for Asset Retirement Obligations" ["FAS 143"]. The standard requires us to estimate and accrue for the present value of our obligations to restore leased premises at the end of the lease. At lease inception, the present value of this obligation would be recognized as other long-term liabilities with a corresponding amount recognized in fixed assets. The

fixed asset amount would be amortized, and the liability amount would be accreted, over the period from lease inception to the time the Company expects to vacate the premises resulting in both depreciation and interest charges in the consolidated statements of income. There is no material impact on the consolidated financial statements resulting from the adoption of FAS 143 either in the current or prior years presented.

In December 2003, the Financial Accounting Standards Board ["FASB"] amended Interpretation No. 46, "Consolidation of Variable Interest Entities" ["FIN 46R"]. FIN 46R requires that a variable interest entity ["VIE"] be consolidated by a company if that company is subject to a majority of the risk of loss from the VIE's activ-

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## MANAGEMENT 'S DISCUSSION AND ANALYSIS

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ities and/or is entitled to receive a majority of the VIE's residual returns. For the Company, the requirements of FIN 46R apply in 2003 for all VIE's created after January 31, 2003. For VIE's created before January 31, 2003, the requirements of FIN 46R apply as of May 31, 2005 for a VIE that does not meet the definition of a special-purpose entity ["SPE"] and as of June 1, 2004 for a VIE that is an SPE. The application of this Interpretation will not have an effect on our consolidated financial statements.

In September 2003, the Canadian Institute of Chartered Accountants ["CICA"] revised Section 3870 'Stock-Based Compensation and Other Stock-Based Payments' to require that, effective June 1, 2004, the fair value method of accounting for stock options be recognized in the consolidated financial statements. The Company intends to apply these provisions retroactively without restatement for the year commencing June 1, 2004. The cumulative compensation cost of options on common shares of the Company, using the Black-Scholes option pricing model, will be charged to deficit with a corresponding increase to contributed surplus at June 1, 2004. In November 2003, the CICA issued Accounting Guideline AcG-15, "Consolidation of Variable Interest Entities", to provide guidance for applying the principles in Handbook Section 1590, "Subsidiaries", to certain entities. Although the CICA is contemplating amendments to the Guideline, it is effective for fiscal years beginning on or after November 1, 2004. Although the Company is currently reviewing AcG-15, the impact of the Guideline, if any, on the Company's consolidated financial statements has not been determined. In March 2003, the CICA issued Handbook Section 3110, "Asset Retirement Obligations", which establishes standards for the recognition, measurement and disclosure of asset retirement obligations and the related asset retirement costs. This new Section is effective June 1, 2004 for the Company and harmonizes Canadian requirements with existing United States GAAP. There will be no material impact on the consolidated financial statements resulting from the adoption of Section 3110 either in the current or prior years presented.

### FORWARD LOOKING STATEMENTS

Statements contained herein that are not based on historical fact, including without limitation statements containing the words "believes," "may," "likely," "plans," "will," "estimate," "continue," "anticipates," "intends," "expects" and similar expressions, constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such factors include, without limitation, changing market conditions, our ability to obtain patent protection and protect our intellectual property rights, commercialization limitations imposed by intellectual property rights owned or controlled by third parties, intellectual property liability rights and liability claims asserted against us, the successful and timely completion of clinical studies, the impact of competitive products and pricing, new product development, uncertainties related to the regulatory approval process, product development delays, our ability to attract and retain business partners and key personnel, future levels of government funding, our ability to obtain the capital required for research, operations and marketing and other risks detailed from time-to-time in the Company's ongoing quarterly filings, annual information forms and annual reports.

### ADDITIONAL INFORMATION

Additional information relating to Lorus, including Lorus' annual information form and other disclosure documents, is available on SEDAR at [www.sedar.com](http://www.sedar.com).

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