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# Labopharm Inc.

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www.labopharm.com

• quarterly report 2001 •

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## Message to Shareholders

### *Third Quarter, Fiscal 2001*

In the third quarter of fiscal 2001, Labopharm made significant progress on its R & D program which remains on schedule for both partnered and in-house projects. We have intensified our commitment to the in-house development of Tramadol, an analgesic for the treatment of moderate to severe pain, with worldwide sales for existing formulations approaching US\$1 billion. During the quarter, we also completed a first pre-pilot study on Oxybutynin, a drug to treat urinary incontinence and initiated a second clinical study, which is currently underway. In addition, new studies on our once-a-day formulation of Tramadol were initiated following the close of the quarter.

With our collaborative agreements in place



**JAMES R. HOWARD-TRIPP**  
PRESIDENT AND CEO

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with Aventis and Sepracor, and co-development studies underway for Oxybutynin, our emphasis is on developing Tramadol as our highest priority in-house project. We are very enthusiastic about Tramadol's market potential and are aggressively moving towards a registration dossier in the first half of fiscal 2002. We plan to develop this product with our own resources in order to maximize the commercial return for the Company by licensing it out only at a late stage of development.

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### **Financing Completed**

Receipt of the final prospectus related to the distribution of 3,934,500 common shares was completed in the third quarter of fiscal 2001. The CDN\$12 million raised in the placement will be

used to ramp up development of Labopharm's product pipeline – with particular emphasis on the in-house projects – and to fund the acquisition and development of new drug products.

We are pleased to report that while the rate of program development for fiscal 2001 is progressing on schedule, the burn rate for the first nine months is lower than projected. This decline in the burn rate is due to careful monitoring of our expenditures as well as the influx of funds derived from the two new partnership agreements with Aventis which were concluded in August and September 2000.

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### Analyst Coverage Initiated

Shortly after the close of the quarter, analyst coverage of Labopharm was initiated by Research Capital Corporation which accorded the Company a BUY rating with a one-year target price of \$7.00.

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### Research

Research and Development of our product portfolio is progressing on schedule. Great emphasis is being given to our in-house, once-a-day

formulation of Tramadol, incorporating Labopharm's patented controlled release technology Contramid®. A new study, initiated in December 2000, will assess the pharmacokinetic

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profile of two formulations of the drug and will be used to confirm final formulations for a full pivotal study to be initiated midway through fiscal 2002. The Company plans to file for market registration for Tramadol in Europe during 2002. Labopharm is increasing its research efforts on Tramadol with the objective of maximizing the commercial return for the Company by developing the product with

our own resources and licensing it out only at a late stage. Expected worldwide sales for existing formulations of this product are close to US\$1 billion.

Labopharm also completed its first pre-pilot study for Oxybutynin, a generic version of the urinary incontinence drug, Ditropan XL, in late September 2000. The drug is now in Phase I codevelopment with an international pharmaceutical company. The projected sales for Ditropan XL in 2000 are US\$175 million.

After the close of the quarter, Labopharm

completed a Phase II clinical trial on a solid oral dosage (tablet) form of Xopenex™ (levabuterol HCl), for the treatment of asthma and chronic obstructive pulmonary disease (COPD) which is being jointly developed with Sepracor Inc. of Massachusetts. The studies demonstrated efficacy in the treatment of bronchospasm due to asthma when compared to placebo.

Other important products in Labopharm's pipeline that are being concurrently developed include the two Aventis Pharmaceuticals drugs, which cannot be identified for competitive reasons but which had combined brand name sales in excess of US\$1.5 billion for the year 2000.

### Financial Results

For the third quarter ended November 30, 2000, operating revenue was \$745,100 compared to \$888,300 for the same period last year. Research and development contracts generated \$560,300 compared to \$806,800 for the same quarter last year. Interest revenue was \$184,800 in the third quarter, compared to \$81,500 for the same period last year due to the

\$12 million private placement announced in the second quarter. For the first nine months, revenues amounted to \$1,651,400 compared to \$1,319,100 for the corresponding period last year, an increase of 25%.

Research and development costs (net of tax credits) amounted to \$814,200 for the third quarter this year, totalling \$2,525,200 for the

first nine months, representing a 5% increase over the same period last year. This increase is mainly due to an increase in laboratory staff and fees related to patents.

General and administrative expenses were slightly higher, increasing by 5% during the third quarter of fiscal 2001 compared to the same period last year. For the first nine months of fiscal 2001 these expenses are up by 7% due mainly to costs associated with the strengthening of the management team. The costs

of our new special warrants issue were partially absorbed during this last quarter.

The net loss amounted to \$698,100 in the third quarter, compared to \$824,900 for the same period last year. For the first nine months, the net

Labopharm is increasing its research efforts on Tramadol with the objective of maximizing the commercial return for the Company by developing the product with its own resources and licensing it out only at a late stage.

loss decreased by 3% to \$2,810,400 compared to \$2,897,500 a year earlier. This slight variation is mainly due to an increase in revenue from research and development contracts.

Labopharm's cash and cash equivalents rose by \$8,930,700 for the first nine months this year compared to a reduction of \$5,919,900 for the same period last year. This positive variance reflects the net \$11 million obtained through the new special warrants issue. The burn rate was \$2,072,400 for the first nine months of fiscal 2001 compared to \$5,919,900 for the same period last year. In the previous year we had to settle an agreement with our former Contramid® supplier. The total cash position as at November 30th, 2000, amounts to \$14,406,700.

## Outlook

Labopharm will continue to aggressively develop its in-house product portfolio, while maintaining momentum on the development of our partnered drug programs. Particular emphasis is being placed on the rapid development of Tramadol, our in-house formulation for the treatment of moderate to severe pain. We are also continuing to seek out new products for acquisition, with the intention of expanding our in-house product portfolio. With our financing complete and key agreements in place, the Company can focus on intensifying the development of our R & D programs.

January 18, 2001



James R. Howard-Tripp

President and CEO

# \$12 Million Private Placement

## Labopharm Announces Receipt for Final Prospectus from Securities Commissions

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Labopharm announced on November 29, 2000 the issuance of a receipt by the securities commissions in Ontario and Quebec for a final prospectus related to the distribution of 3,934,500 common shares issuable following the exercise of 3,934,500 special warrants. The special warrants were previously issued on August 31, 2000, by way of a private placement, for aggregate consideration of approximately \$12 million. The issue price for the offering was \$3.05 per special warrant. Research Capital Corporation acted as agent for this financing.

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Labopharm has indicated that funds raised under this private placement will be used to further the development of the Company's product pipeline, to fund the acquisition and development of complimentary drug delivery technologies, or to acquire new products as well as for working capital and general corporate purposes.

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# Tramadol

## New Study on Improved Formulations

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Labopharm announced on December 12, 2000 the initiation of a second pilot study on a once-a-day formulation of the analgesic, Tramadol, incorporating Labopharm's patented controlled release technology, Contramid®. The study will assess the pharmacokinetic profile of two improved formulations of this drug, under fed and fasting conditions, compared to a drug currently on the market as a reference. The study will involve 18 healthy volunteers and results are expected in mid-January. They will be used to confirm final formulations for a full pivotal study to be initiated in 2001. Labopharm plans to file for market registration for this drug in Europe during the first half of 2002.

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"Tramadol is our highest priority in-house project at this time," said James R. Howard-Tripp, President and CEO of Labopharm. "A once-a-day formulation of this product, comparable to ours, does not presently exist.

With worldwide sales for existing formulations of this product approaching \$1 billion, our formulations of Tramadol should have significant potential for Labopharm. Our intent is to develop this product with our own resources to registration and only to license it out at late-stage in order to maximize the commercial return for the Company," he added.

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Tramadol hydrochloride is a centrally acting analgesic for the treatment of moderate to severe pain. It is highly prescribed in Europe and the US for the alleviation of acute and chronic pain. A once-a-day formulation of this drug has been difficult to develop and Labopharm's formulations have shown excellent promise.

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# Treatment of Asthma

## Positive Results of Phase II Clinical Trial for Once-a-day Levalbuterol for Asthma

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Labopharm announced on January 9, 2001 positive results following completion of a Phase II clinical trial on solid oral dosage (tablet) forms of XOPENEX<sup>®</sup> (levalbuterol HCl) for the treatment of asthma. The formulation of this drug tablet uses Labopharm's proprietary controlled release technology, Contramid<sup>®</sup>. This trial's objective was to determine the efficacy of oral XOPENEX<sup>®</sup> in dilating the bronchial passages of patients with moderate to moderately-severe asthma. The study demonstrated the following key results: a significant improvement in breathing compared to placebo in both moderate and severe asthmatic patients; efficacy that increases proportionally with dosage; bioequivalence with a product already on the market; as well as pharmacokinetic results that replicated those obtained in an earlier trial using normal, healthy volunteers.

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"We are very encouraged by the results of this Phase II trial," said James R. Howard-Tripp, President and CEO of Labopharm. "An analysis of the study clearly demonstrated that we have a drug that is efficacious in the treatment of bronchospasm due to asthma when compared to placebo. For patients who have difficulty using inhalers, such as the young and the elderly, this drug shows interesting potential," he added.

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The Phase II clinical trial was carried out under an agreement between Sepracor Inc. of Marlborough, Massachusetts, and Labopharm to develop this product jointly.

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**EARNINGS** (unaudited)

(Thousands of dollars except for per share data and number of shares)

For period of:	3 months ending Nov. 30		9 months ending Nov. 30	
	2000	1999	2000	1999
<b>Operating revenue</b>				
Research and development contracts	\$ 560.3	\$ 806.8	\$ 1,351.3	\$ 1,006.8
Investment income	184.8	81.5	300.1	312.3
	745.1	888.3	1,651.4	1,319.1
<b>Operating expenses</b>				
Research and development expenses	814.2	1,116.2	2,525.2	2,398.8
Selling and administrative expenses	624.9	554.4	1,929.0	1,767.0
Finance charges	4.1	42.6	7.6	50.8
	1,443.2	1,713.2	4,461.8	4,216.6
<b>Net loss</b>	\$ (698.1 )	\$ (824.9)	\$ (2,810.4 )	\$ (2,897.5)
<b>Net loss per share*</b>	\$ (0.0342 )	\$ (0.0412)	\$ (0.1387 )	\$ (0.1455)
*Weighted average number of common shares outstanding	20,392,690	20,016,681	20,255,993	19,866,681
Amortization for the period is:	\$ 70.4	\$ 83.0	\$ 234.4	\$ 252.8

**BALANCE SHEET** (unaudited)

(Thousands of dollars)

As at November 30

	2000	1999
<b>Assets</b>		
<b>Current assets</b>		
Property, plant and equipment	\$ 15,679.4	\$ 8,206.5
Intangible assets	1,027.0	1,104.3
Deferred income taxes	1,289.9	939.1
	176.2	176.2
	\$ 18,172.5	\$ 10,426.1
<b>Liabilities</b>		
<b>Current liabilities</b>		
Capital lease obligations	\$ 1,218.9	\$ 1,140.3
	34.7	53.5
	1,253.6	1,193.8
Shareholders' equity	16,918.9	9,232.3
	\$ 18,172.5	\$ 10,426.1

**CASH FLOWS** (unaudited)

(Thousands of dollars)

For period of:	3 months ending Nov. 30		9 months ending Nov. 30	
	2000	1999	2000	1999
<b>Operating activities</b>				
Net loss	\$ (698.1 )	\$ (824.9)	\$ (2,810.4 )	\$ (2,897.5)
Items not affecting cash:				
Amortization	70.4	83.0	234.4	252.8
Loss on disposal of capital assets	0.3	-	6.1	6.3
	(627.4 )	(741.9)	(2,569.9 )	(2,638.4)
Net change in non-cash operating working capital items	856.8	(740.0)	703.4	(2,783.5)
	229.4	(1,481.9)	(1,866.5 )	(5,421.9)
<b>Investing activities</b>				
Acquisition of temporary investments	(11,681.9 )	(1,000.1)	(12,249.3 )	(1,027.0)
Proceeds of temporary investments	865.1	3,083.2	3,405.0	6,992.8
Acquisition of property, plant and equipment	(92.4 )	(83.1)	(164.7 )	(212.9)
Acquisition of intangible assets	(136.8 )	(74.1)	(304.0 )	(139.0)
Proceeds from disposal of capital assets	3.4	-	3.5	12.0
	(11,042.6 )	1,925.9	(9,309.5 )	5,625.9
<b>Financing activities</b>				
Reimbursement of capital lease obligations	(1.4)	(31.2)	(24.3 )	(158.1)
Capital lease obligations	-	-	37.3	-
Proceeds from issuance of capital stock	-	-	246.3	-
Proceeds from issuance of warrants	-	-	12,000.2	-
Warrants issue expenses	(136.8 )	-	(997.1 )	-
	(138.2 )	(31.2)	11,262.4	(158.1)
Increase (decrease) in cash and cash equivalents	(10,951.4 )	412.8	86.4	45.9
Cash at beginning	11,286.5	150.6	248.7	517.5
Cash at end	\$ 335.1	\$ 563.4	\$ 335.1	\$ 563.4

## Officers

Donald Buxton  
Chairman of the Board

James R. Howard-Tripp  
President and CEO

Vincent Lenaerts  
Chief Scientific Officer  
Vice-President, Research and Development

Allan Mandelzys  
Vice-President  
Business Development

Warren Whitehead  
Interim Chief Financial Officer

M<sup>e</sup> Lisane Dostie  
Director  
Corporate Affairs and Secretary

## Head Office

Labopharm Inc.  
1200 Chomedey Blvd.  
Suite 500  
Laval, Québec  
H7V 3Z3

Tel.: (450) 686-1017

Tel.: 1 888 686-1017

Fax: (450) 686-9141

Website: [www.labopharm.com](http://www.labopharm.com)

E-mail: [info@labopharm.com](mailto:info@labopharm.com)

Investor Relations  
James R. Howard-Tripp  
President and CEO

Stock Exchange Listing  
Toronto Stock Exchange  
Trading Symbol: DDS

Transfer Agent  
General Trust of Canada