



**Message to shareholders,**

**November 13, 2001**

We are pleased to submit this report, for our third quarter ended September 30, 2001. While it was an unusual quarter, with major political and economic setbacks affecting most North American industries following the unfortunate events of September 11, the Company has weathered the storm reasonably well and continues to make progress towards achieving its milestones. Key activities during the quarter are described below:

**Research and Development further strengthens core technologies**

We continue to make rapid progress in the development of our Prostate Secretory Protein (PSP<sup>94</sup>) and the Antinucleosomal Autoantibodies (ANA) technologies. The peptide PCK3145, indicated for the treatment of prostate cancer, has been extensively tested in animal models and is on target to be tested in humans in early January 2002. The peptide has been tested for toxicity, stability and efficacy and is currently being tested for safety in primates. We are on target to file an IND (Investigational New Drug submission) before the end of the year, to conduct Phase I/II human clinical trials on patients who have failed hormonal therapy for prostate cancer.

In addition, we continue to develop the diagnostic/prognostic application of the PSP<sup>94</sup> technology and have now developed specific monoclonal antibodies to the binding protein which binds to PSP<sup>94</sup> in the serum. This will allow for the development of a user-friendly ELISA diagnostic to be used in the assay of hundreds of serum samples that we have access to through our collaborations.

During the quarter we announced the finalization of our agreement with Multiple Peptide Systems (MPS) of California, for the manufacture of cGMP grade PCK3145 to be used for the clinical trials. Manufacturing of the peptide is on target and we have been in receipt of batches of the clinical grade material for initial testing.

In keeping with our corporate strategy, we continue to be active in protecting our intellectual property and have recently filed patents related to the PSP<sup>94</sup> peptides, binding protein and DNA sequence domains.

Together with our development partner Biovation Ltd (U.K.) and our research collaborators at Northeastern University (Boston), we have made substantial progress in the development of our second core technology platform ANA. The chimeric monoclonal antibody (c-2C5) as well as the de-immunized version of the same antibody, prepared by Biovation, are currently undergoing extensive testing in our laboratory, for safety and efficacy.

Our manufacturing partner, Goodwin Biotechnology Inc. (Florida), has made progress in the plans to manufacture cGMP grade monoclonal c-2C5 and has completed the clone selection for large scale production.

We have also developed a bioassay for the efficacy determination and are currently validating it. Our collaborators at Northeastern are making progress in developing an imaging agent for cancer, using a radioactively labelled version of the ANA antibody. Animal tests are planned for later this year.

While our corporate strategy has been aimed at establishing corporate alliances with pharmaceutical companies when our products are in clinical Phase II, due to considerable interest in our core technologies shown by several companies, we have recently initiated preliminary discussions with potential partners and intend to further this activity in coming months.

### **Late Stage Products**

#### ***FIBROSTAT® Clinical Studies in full gear***

The Canadian Phase II clinical studies with our lead product FIBROSTAT® for the treatment and prevention of hypertrophic scarring are going well and enrolment has been completed as of October 25, 2001 with 132 patients on active treatment. The Company is on target to file the IND for clinical Phase III studies in Canada before the end of the year, in partnership with our licensee for Canada, Biovail Corporation. We are currently in advanced discussions for the licensing of FIBROSTAT® for the United States, as well as other foreign jurisdictions.

#### ***COLOPATH® integration into IMI's development plans***

International Medical Innovations Inc. (IMI), our licensee for the development of COLOPATH®, our colorectal cancer screening technology, has made progress in further developing the test together with their ColorectAlert™ and the reader technology. Active discussions are ongoing with potential marketing partners and plans are on track for a major clinical trial in the US in 2002.

As an important part of the corporate strategy, we continue to seek and evaluate new technologies from both universities and other companies, and are in active discussions with some of them.

Signed : "Hans J. Mäder"  
Chairman, President and CEO

## **Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following information should be read in conjunction with our unaudited consolidated financial statements and related notes included herein, together with our audited consolidated financial statements for the six months ended December 31, 2000 and the related notes, which were prepared in accordance with generally accepted accounting principles in Canada.

### **RESULTS OF OPERATIONS**

#### **Quarter ended September 30, 2001 compared with the Quarter ended September 30, 2000**

The Company incurred a net loss for the third quarter of 2001 of \$2,668,013 or \$0.06 per common share, compared with a net loss of \$909,704 or \$0.02 per common share in the same quarter last year.

Revenues for the current quarter were \$95,368, compared with \$240,749 in the third quarter of 2000. The decrease reflected lower interest income in the current quarter as a result of a reduced level of cash and cash equivalents compared with the third quarter of last year, together with the decline in interest rates in the current period.

Research and development expenses for the third quarter of 2001 at \$2,156,602 were \$1,303,341 or 153% higher than in the third quarter of 2000. This increase in spending reflected the Company's continuing commitment to accelerating the progress of its research programs.

General and administrative expenses amounted to \$721,138 in the current quarter, an increase of \$181,672 or 34% over the total of \$539,466 in the corresponding quarter last year. The higher expenses were primarily the result of increased professional fees and investor relations costs, together with higher staffing costs due to the building of a more experienced management team.

Depreciation and amortization expense was at \$113,965 for the third quarter of 2001, compared with \$67,401 in the same quarter last year. The increase resulted from a high level of spending on intellectual property during the past year, particularly in the fourth quarter of 2000.

Spending on research and development represented 72% of total expenses for the current quarter, compared with 58% for the corresponding quarter last year.

#### **Nine months ended September 30, 2001 compared with the Nine months ended September 30, 2000**

A net loss of \$7,173,135 or \$0.16 per common share was incurred in the nine months ended September 30, 2001, compared with a net loss of \$3,410,286 or \$0.09 per common share in the corresponding period in 2000.

Revenues of \$430,230 were generated in the current period, a decrease of \$52,215 from the total of \$482,445 in the first nine months of 2000. This reduction was due to lower interest rates during the current year than in 2000.

Research and development expenses amounted to \$5,516,679 in the first nine months of 2001 compared with \$2,011,254 in the same period last year, an increase of \$3,505,425 or 174%. The increase reflected the significantly faster pace at which the Company is moving its products through the various phases of clinical trials.

General and administrative expenses for the nine months ended September 30, 2001 increased by \$149,949 or 7% to \$2,311,293 from the total of \$2,161,344 in the nine months ended September 30, 2000.

Depreciation and amortization expense at \$318,781 in the current period was \$114,932 higher than in the same period last year, primarily due to a high level of spending in the fourth quarter of 2000 to acquire intellectual property.

During the nine months ended September 30, 2001 research and development expenses comprised 68% of total expenses, compared with 45% in the same period last year.

## **LIQUIDITY AND CAPITAL RESOURCES**

Cash and cash equivalents at September 30, 2001 totaled \$7,990,861 compared with \$14,163,170 at December 31, 2000. The reduction of \$6,172,309 resulted primarily from a cash outflow of \$7,330,265 to finance operating activities for the nine month period, including an amount of \$552,911 to fund an increase in non-cash working capital. A total of \$344,482 was expended in the period for intellectual property and capital assets. The issue of common shares by way of a private placement realized \$959,652, net of issue expenses. The exercise of stock options generated an additional \$180,286. Also, an amount of \$362,500 was derived from the issuance of a convertible debenture associated with the licensing in February 2000 of the Canadian rights to Fibrostat®.

The accelerated spending on research and development during the past year has enabled the Company to successfully advance its research program, while general and administrative expenses have remained relatively stable. Consequently, commencing early in 2002, operating expenses are expected to return to more normal levels. As a result, management believes that it has sufficient funds available to support its activities for at least the next twelve months.

### **Safe Harbour Statement**

Certain matters discussed in this management discussion and analysis of financial condition and results of operations are, by nature, forward-looking. For a number of reasons, actual results could differ materially.

**PROCYON BIOPHARMA INC.**  
**CONSOLIDATED BALANCE SHEETS**

As at	September 30, 2001 (unaudited) \$	December 31, 2000 (audited) \$
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	7,990,861	14,163,170
Accounts receivable	302,852	221,363
Investment tax credits recoverable	813,689	667,000
Prepaid expenses	39,346	25,801
	<b>9,146,748</b>	<b>15,077,334</b>
Fixed assets	522,222	497,788
Intellectual property	4,779,407	4,778,140
Investments	-	1
	<b>14,448,377</b>	<b>20,353,263</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	650,229	1,055,217
Deferred revenue [note 3]	93,800	-
	<b>744,029</b>	<b>1,055,217</b>
Convertible debenture	50,000	50,000
Future income taxes	414,000	414,000
	<b>1,208,029</b>	<b>1,519,217</b>
<b>Shareholders' equity [note 4]</b>		
Share capital	33,598,087	32,458,150
Other paid-in capital	862,000	785,000
Warrants	233,687	233,687
Equity components of convertible debenture	612,500	250,000
Deficit	(22,065,926)	(14,892,791)
	<b>13,240,348</b>	<b>18,834,046</b>
	<b>14,448,377</b>	<b>20,353,263</b>

See accompanying notes

**PROCYON BIOPHARMA INC.**  
**CONSOLIDATED STATEMENTS OF**  
**LOSS AND DEFICIT**  
(unaudited)

	Quarter Ended September 30, 2001	September 30, 2000	Nine months Ended September 30, 2001	September 30, 2000
	\$	\$	\$	\$
		[restated - note 2]		[restated - note 2]
<b>REVENUES</b>				
Sales	-	-	-	3,081
Interest and other income	<b>95,368</b>	240,749	<b>430,230</b>	479,364
	<b>95,368</b>	240,749	<b>430,230</b>	482,445
<b>EXPENSES</b>				
Research and development	<b>2,156,602</b>	853,261	<b>5,516,679</b>	2,011,254
Research and development tax credits	<b>(229,000)</b>	(310,000)	<b>(545,000)</b>	(532,000)
General and administrative	<b>721,138</b>	539,466	<b>2,311,293</b>	2,161,344
Write-down of investment	-	-	-	42,494
Depreciation and amortization	<b>113,965</b>	67,401	<b>318,781</b>	203,849
Interest and bank charges	<b>676</b>	325	<b>1,612</b>	5,790
	<b>2,763,381</b>	1,150,453	<b>7,603,365</b>	3,892,731
<b>Net loss for the period</b>	<b>(2,668,013)</b>	(909,704)	<b>(7,173,135)</b>	(3,410,286)
Adjustment for income taxes	-	-	-	(539,000)
Deficit, beginning of period	<b>(19,397,913)</b>	(11,718,925)	<b>(14,892,791)</b>	(8,679,343)
<b>Deficit, end of period</b>	<b>(22,065,926)</b>	(12,628,629)	<b>(22,065,926)</b>	(12,628,629)
<b>Loss per share</b>	<b>(0.06)</b>	(0.02)	<b>(0.16)</b>	(0.09)
<b>Weighted average number of common shares outstanding</b>	<b>44,956,097</b>	40,636,024	<b>44,259,040</b>	36,890,641

See accompanying notes

**PROCYON BIOPHARMA INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(unaudited)

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
	\$	\$	\$	\$
		[restated - note - 2]		[restated - note - 2]
<b>OPERATING ACTIVITIES</b>				
Net loss for the period	(2,668,013)	(909,704)	(7,173,135)	(3,410,286)
Add non-cash items				
Amortization of capital assets	113,965	67,401	318,781	203,849
Write-down of investment	-	-	-	42,494
Increase in other paid-in capital	-	-	77,000	120,000
	(2,554,048)	(842,303)	(6,777,354)	(3,043,943)
Net change in non-cash working capital balances related to operations	(311,079)	(418,177)	(552,911)	(756,831)
<b>Cash flows related to operating activities</b>	<b>(2,865,127)</b>	<b>(1,260,480)</b>	<b>(7,330,265)</b>	<b>(3,800,774)</b>
<b>INVESTMENT ACTIVITIES</b>				
Intellectual property	(93,322)	(29,851)	(258,298)	(77,179)
Acquisition of capital assets	(15,316)	(51,360)	(86,184)	(148,070)
Disposal of capital assets	-	-	-	18,757
<b>Cash flows related to investment activities</b>	<b>(108,638)</b>	<b>(81,211)</b>	<b>(344,482)</b>	<b>(206,492)</b>
<b>FINANCING ACTIVITIES</b>				
Issue of common shares	12,000	34,292	1,180,288	1,016,223
Share issue expenses	(19,158)	-	(40,350)	(115,026)
Issue of special warrants	-	15,331,407	-	19,933,569
Special warrants issue costs	-	(195,646)	-	(1,700,976)
Repayment of long-term debt	-	-	-	(135,442)
Issuance of convertible debenture	43,750	-	362,500	50,000
<b>Cash flows related to financing activities</b>	<b>36,592</b>	<b>15,170,053</b>	<b>1,502,438</b>	<b>19,048,348</b>
Net increase (decrease) in cash and cash equivalents	(2,937,173)	13,828,362	(6,172,309)	15,041,082
Cash and cash equivalents, beginning of period	10,928,034	3,247,231	14,163,170	2,034,511
<b>Cash and cash equivalents, end of period</b>	<b>7,990,861</b>	<b>17,075,593</b>	<b>7,990,861</b>	<b>17,075,593</b>
<b>Supplemental cash flow information</b>				
Cash paid during the period for interest	-	-	-	2,614

See accompanying notes

## **Procyon Biopharma Inc.**

# **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

September 30, 2001

(unaudited)

### **1. Basis of presentation**

These financial statements have been prepared by management in accordance with Canadian generally accepted accounting principles. The interim financial statements do not include all disclosures required for annual financial statements and should be read in conjunction with the most recent annual financial statements as at and for the period ended December 31, 2000.

### **2. Change in accounting policy**

In December 2000, the Company changed its accounting policy for the amortization of intellectual property to straight-line amortization over an estimated useful life of 15 years from the date of acquisition. Previously amortization was recorded over an estimated useful life of 10 years from the date of commercialization.

This change has been applied retroactively with a charge to the deficit on December 31, 2000 of \$666,000. The impact of this change is to reduce net income for the quarter ended September 30, 2001 by \$92,826 (quarter ended September 30, 2000 - \$49,765) and net income for the nine months ended September 30, 2001 by \$257,031 (nine months ended September 30, 2000 - \$164,467).

### **3. Revenue recognition**

Deferred revenue from licensing or royalty fees is recognized as income on a straight-line basis in accordance with the contractual agreements with third parties.

### **4. Share Capital**

#### **Authorized and issued**

The authorized capital is an unlimited number of common shares.

#### **Common shares**

As at September 30, 2001, 44,969,430 common shares valued at \$33,598,087 were issued and outstanding (43,853,685 valued at \$32,458,150 at December 31, 2000). On June 22, the Company completed a private placement of 980,394 common shares for a cash consideration of \$1,000,002 less expenses of \$40,350. Also, during the nine months ended September 30, 2001 a total of 135,351 common shares were issued for cash on exercise of stock options.

#### **Stock Option Plan**

As at September 30, 2001, 3,818,932 stock options were outstanding compared to 3,858,023 as at December 31, 2000. During the nine months period, 423,750 options were granted, 135,351 options were exercised and 327,490 options were forfeited.

## Warrants

As at September 30, 2001 there were 5,817,398 common shares reserved for issuance upon exercise of common shares compared to 8,536,726 as at December 31, 2000. As part of a private placement completed on June 22, 2001, the two investors who participated in the private placement had the right to purchase an additional 221,530 common shares if within 90 days of closing of the private placement the Company completed a second private placement at a price lower than \$1.02 per common share. This did not occur and consequently these warrants expired during September. Also, 2,719,328 warrants issued in September 1997 to a shareholder, Oxbow Equities Corporation expired on September 29, 2001.

## 5. Segmented Information

Information by geographic segment is as follows:

	<b>Three-month Period ended September 30, 2001</b>	<b>Three-month Period ended September 30, 2000</b>
	\$	\$
<b>Revenue</b>		
Canada	-	-
United States	-	-
	<b>As of September 30, 2001</b>	<b>As of December 31, 2000</b>
<b>Intellectual property and fixed assets</b>		
Canada	3,234,603	3,298,143
United States	2,067,026	1,977,785
	<b>5,301,629</b>	<b>5,275,928</b>