ONCOLYTICS BIOTECH INC
Form 6-K
August 07, 2003

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer

Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

For August 7, 2003

Commission File Number 000-31062

Oncolytics Biotech Inc.

(Translation of registrant s name into English)

Suite 210, 1167 Kensington Crescent NW
Calgary, Alberta, Canada T2N 1X7

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F þ Form 40-F o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): o

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): o

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant s home country), or under the rules of the home country exchange on which the registrant s securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant s security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes o No þ

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-____

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Oncolytics Biotech Inc.
(Registrant)

Date August 7, 2003

By: /s/ Douglas A. Ball

Douglas A. Ball
Chief Financial Officer

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Second Quarter Report 2003

LETTER TO SHAREHOLDERS

For the quarter ended June 30, 2003

In the second quarter of 2003, Oncolytics significantly increased its working capital by $8.7 million through a combination of completing a private placement ($5.8 million), selling a non-core asset ($2.6 million) and the exercise of warrants ($0.3 million). These transactions bring the Company s total cash position as of June 30, 2003 to approximately $13.5 million.

The Company also added two important patents to its intellectual property portfolio during the second quarter of 2003. The Company was granted its seventh and eighth U.S. patents within the quarter, significantly broadening the Company s intellectual property portfolio, particularly within the area of co-treatment with other therapies. Allowed claims in our seventh U.S. patent cover co-administration of the virus with immune suppressing agents such as Cyclosporin. Additional allowed claims cover the use of the virus in combination with conventional therapeutic agents and treatments such as surgery, chemotherapy, and radiation therapy. The eighth U.S. patent covers the use of combinations of reovirus strains for the treatment of Ras-mediated tumours and is the first patent to include composition of matter claims.

Oncolytics also announced in the quarter that Health Canada had approved amendments to our Phase I/II recurrent malignant glioblastoma clinical trial, allowing the trial to resume enrolling patients.

Management feels the Company is now well-positioned to further advance the clinical development of REOLYSIN®.

Thank you for your continued encouragement and support.

Brad Thompson, PhD
Chairman, President and CEO

Management s Discussion and Analysis

This discussion and analysis should be read in conjunction with the unaudited financial statements of Oncolytics Biotech Inc. (Oncolytics or the Company) as at and for the three and six months ended June 30, 2003 and 2002, and should also be read in conjunction with the audited financial statements and Management s Discussion and Analysis (MD&A) contained in Oncolytics annual report for the year ended December 31, 2002. The financial statements have been prepared in accordance with Canadian generally accepted accounting principles (GAAP).

SECOND QUARTER HIGHLIGHTS

Through a combination of a private placement ($5.8 million), the sale of a non-core asset ($2.6 million), and the exercise of warrants ($0.3 million), the Company increased its working capital by a total of $8.7 million.

Received approval from Health Canada for the amendments to the glioma study;

Received seventh and eighth U.S. patents covering the use of combinations of reovirus strains for the treatment of Ras-mediated tumours and co-administration of reovirus with immune suppressing agents such as Cyclosporin.

CAPITAL EXPENDITURES

The Company continues to expand and protect its intellectual property. Oncolytics has received three U.S. patents during the first half of 2003. In the second quarter of 2003 the Company received its seventh and eighth U.S. patents covering the use of combinations of reovirus strains for the treatment of Ras-mediated tumours and co-administration of reovirus with immune suppressing agents such as Cyclosporin. As a result of its established patent base and the required filing fees, Oncolytics expended an additional $135,487 for professional fees associated with its patent portfolio in the second quarter of 2003 compared to $197,056 in the second quarter of 2002. Total patent costs incurred in 2003 were $595,147 compared to $346,186 in 2002.

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INVESTMENTS

Transition Therapeutics Inc. (TTH)

In the second quarter of 2003, the Company took advantage of an opportunity to monetize its investment in TTH. On June 6, 2003, Oncolytics sold all of its 6.89 million common shares in TTH for net cash proceeds of $2.6 million. The sale of TTH has provided the Company with additional operating capital that will allow Oncolytics to continue its development of REOLYSIN®. As a result of the sale, an accounting loss of $2.2 million was recorded ($0.10 per share).

BCY Lifesciences (BCY)

The Company continues to hold its ownership in BCY Lifesciences (BCY) which represents less than 8% ownership of the issued and outstanding share capital of BCY. As at June 30, 2003 the book value of the investment in BCY was $0.30 million with a market value of $0.45 million.

FINANCING ACTIVITIES

On June 19, 2003 the Company closed a private placement raising net proceeds of $5.8 million. The Company issued 2,120,000 units for $3.00 per unit. Each unit consisted of one common share and one-half of one common share purchase warrant. Each whole common share purchase warrant entitles the holder to purchase an additional common share for $4.00 per share until December 19, 2004.

Also, during the second quarter of 2003, there were 113,325 common share purchase warrants related to earlier private placements that were exercised for proceeds of $0.3 million. As at June 30, 2003 there were 513,675 common share purchase warrants outstanding with an exercise price of $3.00 and 1,272,000 common share purchase warrants outstanding with an exercise price of $4.00.

LIQUIDITY AND CAPITAL RESOURCES

The Company s cash and working capital positions at the end of the second quarter of 2003 were $13,486,096 and $13,033,348 respectively compared to cash and working capital positions as at December 31, 2002 of $8,319,244 and $7,184,699 respectively. The increase in cash for the second quarter of 2003 reflects cash inflows from the private placement, the exercise of common share purchase warrants and the sale of the TTH shares. Cash outflows during the period arose primarily from research and development expenses, operational expenses and legal costs required to broaden the Company s patent portfolio. As at July 31, 2003 the Company had 24,524,109 common shares issued and outstanding.

Management believes that its existing capital resources are adequate to fund its current plans for research and development activities into the second quarter of 2005. In the event that the Company chooses to alter its present plans, or seek additional capital, the Company will look to fund additional capital requirements primarily through the issue of additional equity. The Company recognizes the challenges and uncertainty inherent in the capital markets and the potential difficulties it might face in today s environment. Market prices for securities in biotechnology companies are volatile and the ability to raise funds will be dependent on a number of factors, including the progress of R&D and availability of clinical trial information.

RESULTS OF OPERATIONS

For the three month period ended June 30, 2003

Research and Development Expenses (R&D)

During the second quarter of 2003, the Company incurred R&D expenses of $848,721 compared to $753,200 in the second quarter of 2002. The increase in R&D expenses relates to costs associated with the production of REOLYSIN® as the Company continues activities in support of its commercial manufacturing process and prepares for a systemic clinical trial. As a result, the Company continues to incur costs associated with the production, quality and stability testing of REOLYSIN®. The Company also continues to study the toxicology of REOLYSIN® as it prepares to expand its clinical trial program. Pre-clinical toxicology studies were performed focusing on the systemic delivery of REOLYSIN® in the second quarter of 2003. Finally, the Company continues to advance its malignant glioma Phase I/II trial. On May 6, 2003 the malignant glioma trial was given approval to re-commence from Health Canada after protocol amendments were submitted following a planned interim safety assessment of the study in December of 2002.

Operating Expenses

During the second quarter of 2003, the Company incurred operating expenses of $826,894 compared to $601,495 in the second quarter of 2002. Operating expenses for the second quarter of 2003 increased due to additions to Oncolytics staff, increased professional fees and filing costs associated with public company filing requirements, an increase in liability insurance premiums and non-cash compensation associated with stock based compensation paid to third parties.

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Loss on Sale of Investment in TTH

As a result of the sale of the Company s ownership in TTH a loss of $2,156,685 was recorded. The loss represents the difference of the cash proceeds received on the sale of its TTH shares and the cost value ascribed to the investment when it was acquired through a share exchange in 2002.

For the six month period ended June 30, 2003

Research and Development Expenses (R&D)

During the first six months of 2003, the Company incurred R&D expenses of $1,328,356 compared to $1,574,718 in the first six months of 2002. The Company continues to incur R&D expenses related to its T2 prostate and malignant glioma Phase I clinical trials, the development of a commercial manufacturing process and continued toxicology studies related to the systemic delivery of REOLYSIN®. The reduction in R&D expenses compared to June 30, 2002 corresponds to the substantial completion of the development of a commercial manufacturing process which occurred in the fourth quarter of 2002.

Operating Expenses

During the first six months of 2003, the Company incurred operating expenses of $1,348,919 compared to $1,140,973 in the first six months of 2002. Operating expenses for the first six months of 2003 increased due to additions to Oncolytics staff in 2002 and 2003, the increased professional fees and filing costs associated with public company filing requirements, an increase in liability insurance premiums and non-cash compensation associated with stock based compensation.

Future Income Taxes

The Company accrued $1,230 during the first six months of 2003 relating to its estimate of capital taxes compared to a future tax recovery of $317,295 in the first six months of 2002. The future tax recovery in 2002 related to the reversal of the Company s future tax liability as its future tax assets relating to non-capital losses, scientific research and development pools and other tax pools exceeded the value of the future tax liability.

Net Loss

The Company incurred a net loss for the first six months of 2003 of $5,069,604 compared to a net loss of $2,559,419 for the first six months of 2002. Basic and diluted loss per common share increased to $0.23 in the first six months of 2003 compared to $0.13 for 2002. The increase in the Company s net loss and net loss per share is mainly due to the loss from the sale of its TTH shares of $2,156,685 or $0.10 per share.

The Company continued its dialogue with regulatory authorities regarding interim results and protocol amendments with respect to its T2 prostate and glioma clinical trials in the second quarter. As well, Oncolytics is moving towards its goal of commencing a systemic human trial with the completion of a commercial manufacturing process for REOLYSIN® and the completion of its toxicology study examining systemic delivery of REOLYSIN®.

FUTURE OUTLOOK

The Company presently expects to continue its clinical development of REOLYSIN® during 2003, including:

- Continuing and completing the Phase I component of the Phase I/II Malignant Glioma Study;
- Progressing into Phase II of the Malignant Glioma Study;
- Initiating a Phase I/II systemic administration study;
- Completing the T2 prostate cancer study; and
- Broadening clinical trial activities into other jurisdictions.

FORWARD-LOOKING STATEMENTS

The MD&A contains forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including the Company s belief as to the potential of REOLYSIN® as a cancer therapeutic and the Company s expectations as to the success of its research and development programs in 2003 and beyond, involve known and unknown risks and uncertainties, which could cause the Company s actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue research and development projects, the efficacy of REOLYSIN® as a cancer treatment, the success and timely completion of clinical studies and trials, the Company s ability to successfully commercialize REOLYSIN®, uncertainties related to the research and development of pharmaceuticals, uncertainties related to the regulatory process and general changes to the economic environment. Investors should consult the Company s quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements.

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Balance Sheets

	Unaudited June 30, 2003	Audited December 31, 2002
ASSETS		
Current assets:		
Cash	**$ 13,486,096**	$ 8,319,244
Accounts receivable	**58,844**	48,536
Prepaid expenses	**150,413**	77,158
	13,695,353	8,444,938
Capital assets	**4,822,106**	4,516,813
Investments *(note 3)*	**297,123**	5,006,503
	$ 18,814,582	$ 17,968,254
LIABILITIES		
Accounts payable and accrued liabilities	**$ 662,005**	$ 1,260,239
Alberta Heritage Foundation Loan	**150,000**	150,000
Contingency *(note 4)*		
Shareholders equity:		
Share capital *(note 2)*	**36,707,418**	30,305,858
Contributed surplus	**2,815,324**	2,702,718
Deficit	**(21,520,165)**	(16,450,561)
	18,002,577	16,558,015
	$ 18,814,582	$ 17,968,254

See accompanying notes

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Statement of Loss and Deficit

	6 Months Ended June 30, 2003	6 Months Ended June 30, 2002	3 Months Ended June 30, 2003	3 Months Ended June 30, 2002	Cumulative From Inception On April 2, 1998
Revenue					
Rights revenue	**$**	**$**	**$**	$	$ 310,000
Interest income	**84,526**	111,617	**41,356**	54,437	1,857,204
	84,526	111,617	**41,356**	54,437	2,167,204
Expenses					
Research and development	**1,328,356**	1,574,718	**848,721**	753,200	14,905,237
Operating	**1,348,919**	1,140,973	**826,894**	601,495	6,155,992
Amortization	**318,940**	272,640	**163,716**	141,027	1,565,506
	2,996,215	2,988,331	**1,839,331**	1,495,722	22,626,735
Loss before the following:	**2,911,689**	2,876,714	**1,797,975**	1,441,285	20,459,531
Loss on sale of investment in Transition Therapeutics Inc. *(note 3)*	**2,156,685**		**2,156,685**		2,156,685
Loss before income tax	**5,068,374**	2,876,714	**3,954,660**	1,441,285	22,616,216
Capital tax	**1,230**	6,514	**630**	6,218	18,949
Future income tax recovery		(323,809)		(161,904)	(1,115,000)
Net loss for the period	**5,069,604**	2,559,419	**3,955,290**	1,285,599	21,520,165
Deficit, beginning of the year	**16,450,561**	10,359,075	**17,564,875**	11,632,895	
Deficit, end of period	**$21,520,165**	$12,918,494	**$21,520,165**	$12,918,494	$ 21,520,165
Per share amounts					
Loss from operations per share	**$ 0.13**	$ 0.15	**$ 0.08**	$ 0.07	
Loss on sale of Transition Therapeutics Inc. per share	**$ 0.10**	$	**$ 0.10**	$	
Basic and diluted loss per common share	**$ 0.23**	$ 0.13	**$ 0.18**	$ 0.07	
Weighted average number of shares	**22,396,218**	19,360,577	**22,569,011**	19,527,902	

See accompanying notes

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Statement of Cash Flows

	6 Months Ended June 30, 2003	6 Months Ended June 30, 2002	3 Months Ended June 30, 2003	3 Months Ended June 30, 2002	Cumulative From Inception On April 2, 1998
OPERATING ACTIVITIES					
Net loss for the period	**$ (5,069,604)**	$ (2,559,419)	**$ (3,955,290)**	$ (1,285,599)	$ (21,520,165)
Deduct non-cash items					
Loss on sale of investment	**2,156,685**		**2,156,685**		2,156,685
Amortization	**318,940**	272,640	**163,716**	141,027	1,565,506
Future income tax recovery		(323,809)		(161,904)	(1,115,000)
Non-cash compensation	**112,606**		**112,135**		145,324
Net changes in non-cash working capital	**(669,452)**	(1,748,470)	**(412,316)**	(407,076)	395,918
	(3,150,825)	(4,359,058)	**(1,935,070)**	(1,713,552)	(18,371,732)
INVESTING ACTIVITIES					
Intellectual property expenditures	**(595,147)**	(346,186)	**(135,487)**	(197,056)	(2,214,104)
Equipment and other	**(41,431)**	(176,912)	**(40,809)**	(18,587)	(501,674)
Proceeds on sale of Transition Therapeutics Inc.	**2,552,695**		**2,552,695**		2,552,695
Investment in Transition Therapeutics Inc.					(20,352)
Investment in BCY Lifesciences Inc.		(125,000)		(125,000)	(127,123)
	1,916,117	(648,098)	**2,376,399**	(340,643)	(310,558)
FINANCING ACTIVITIES					
Alberta Heritage Loan					150,000
Proceeds from exercise of warrants and options	**339,975**		**339,975**		3,100,078
Proceeds from private placement	**6,061,585**		**5,817,414**		12,735,105
Proceeds from public offering					16,183,203
	6,401,560		**6,157,389**		32,168,386
Increase *(decrease)* in cash during period	**5,166,852**	(5,007,156)	**6,598,718**	(2,054,195)	13,486,096
Cash, beginning of period	**8,319,244**	14,970,756	**6,887,378**	12,017,795	
Cash, end of period	**$ 13,486,096**	$ 9,963,600	**$ 13,486,096**	$ 9,963,600	$ 13,486,096

See accompanying notes

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Notes to Financial Statements

For the three and six months ended June 30, 2003 (Unaudited)

1. ACCOUNTING POLICIES

These unaudited interim financial statements do not include all of the disclosures included in the Company s annual financial statements. Accordingly, these unaudited interim financial statements should be read in conjunction with the Company s most recent annual financial statements.

The accounting policies used in the preparation of these unaudited interim financial statements conform with those used in the Company s most recent annual financial statements.

2. SHARE CAPITAL

Authorized: Unlimited number of common shares

Issued

	Number of Common Shares	Amount $
Balance, December 31, 2002	22,145,284	30,305,858
Issued for cash pursuant to February 10, 2003 private placement (a)	140,000	280,000
Issued for cash pursuant to June 19, 2003 private placement (b)	2,120,000	6,360,000
Exercise of warrants	113,325	339,975
Share issue costs		(578,415)
Balance, June 30, 2003	24,518,609	36,707,418

(a) Pursuant to a private placement, 140,000 common shares were issued at an issue price of $2 per share net of issue costs of $35,829. Each common share had an associated one-half of one common share purchase warrant for a total of 70,000 warrants. Each whole common share purchase warrant will entitle the holder to acquire one common share in the capital of the Company upon payment of $3 per share until August 10, 2004.

In addition, the company issued 7,000 common share purchase warrants on the same terms to the brokerage firm assisting with the transaction.

(b) Pursuant to a private placement, 2,120,000 common shares were issued at an issue price of $3 per share net of issue costs of $542,586. Each common share had an associated one-half of one common share purchase warrant for a total of 1,060,000 warrants. Each whole common share purchase warrant will entitle the holder to acquire one common share in the capital of the Company upon payment of $4 per share until December 19, 2004.

In addition, the company issued 212,000 common share purchase warrants on the same terms to the brokerage firms assisting with the transaction.

Options and Warrants As at June 30, 2003, the Company has outstanding stock options of 2,703,500 with a weighted average exercise price of $4.35. During the six month period ended June 30, 2003 the Company issued 50,000 options with an exercise price of $1.65 per share and there were no options exercised or surrendered.

As at June 30, 2003, the Company has 1,785,675 warrants with a weighted average exercise price of $3.67.

Pro Forma Disclosures Pro forma compensation expense, net loss and loss per share relating to the options granted are as follows:

	6 Months Ended June 30, 2003	6 Months Ended June 30, 2002
Reported net loss	$ 5,069,604	$ 2,559,419
Compensation expense	(20,775)	116,936
Pro forma net loss	5,048,829	2,676,355
Reported basic and diluted net loss per share	0.23	0.13
Pro forma basic and diluted net loss per share	0.23	0.14

	3 Months Ended June 30, 2003	3 Months Ended June 30, 2002
Reported net loss	$ 3,955,290	$ 1,285,599
Compensation expense	(32,296)	116,936
Pro forma net loss	3,922,994	1,402,535
Reported basic and diluted net loss per share	0.18	0.07
Pro forma basic and diluted net loss per share	0.17	0.07

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The estimated fair value of the stock options issued during the three and six months ended June 30, 2003 was determined using the Black-Scholes Model using the following weighted average assumptions resulting in a weighted average fair value of $0.55 per option.

	2003
Risk-free interest rate	3.56%
Expected hold period to exercise	2 years
Volatility in the price of the corporation s shares	56.8%
Dividend yield	0%

3. LOSS ON SALE OF INVESTMENT IN TRANSITION THERAPEUTICS INC.

On June 14, 2002, the Company acquired 6,890,000 common shares of Transition Therapeutics Inc. (TTH), a public company, through the issuance of 1,913,889 common shares of the Company from treasury. The investment was recorded at $4,709,380 (including acquisition costs of $20,352) based on the trading price of the Company s shares. On June 6, 2003, the Company sold all of its 6,890,000 common shares of Transition Therapeutics Inc. (TTH) for net cash proceeds of $2,552,695 recording a loss on sale of investment of $2,156,685.

4. CONTINGENCIES

During 1999, the Company assumed certain obligations in connection with a Share Purchase Agreement (the Agreement) between SYNSORB Biotech Inc. and the former shareholders of the Company to make milestone payments and royalty payments.

As of June 30, 2003, a milestone payment was still outstanding for $1.0 million, due within 90 days of the first receipt, in any country, from an Appropriate Regulatory Authority, for marketing approval to sell REOLYSIN® to the public or the approval of a new drug application for REOLYSIN®.

This milestone payment, when payable, will be accounted for as research and development expense and will not be deductible for tax purposes.

In addition to the milestone payment, payments may have become due and payable in accordance with the Agreement upon realization of sales of REOLYSIN®. During and subsequent to the period ended June 30, 2003, the Company completed amendments and revisions to the contingent obligations to its five founding shareholders. The amendments and revisions reduced the amount and clarified the determination of potential obligations of the Company to these shareholders arising from the Agreement and Assumption Agreement entered into in 1999. If the Company receives royalty payments or other payments as a result of entering into partnerships or other arrangements for the development of the reovirus technology, the Company is obligated to pay to the founding shareholders, 14.25% (December 31, 2002 20%) of the royalty payments and other payments received. Alternatively, if the Company develops the reovirus treatment to the point where it may be marketed at a commercial level, the payments referred to in the foregoing sentence will be amended to a royalty payment of 2.85% (December 31, 2002 4%) of Net Sales received by the Company for such products.

SHAREHOLDER INFORMATION

For annual and quarterly reports, news releases and other investor information, please contact:
Doug Ball, CFO, Oncolytics Biotech Inc Suite 210, 1167 Kensington Cres NW Calgary, Alberta Canada T2N 1X7

Officers

Bradley Thompson, PhD
Chairman, President and Chief Executive Officer

Doug Ball, CA
Chief Financial Officer

George M Gill, MD
Senior Vice President, Clinical and Regulatory Affairs

Wayne Schnarr, PhD, MBA
Vice President, Corporate Development

Directors

Bradley Thompson, PhD
Chairman, President & CEO, Oncolytics Biotech Inc.

Doug Ball, CA
CFO, Oncolytics Biotech Inc.

George Masters
Biotech Consultant

Tony Noujaim, PhD
President & CEO of Virexx Research Inc.

Bob Schultz, FCA
Chairman of Rockwater Capital Corporation.

Fred Stewart, QC
President of Fred Stewart & Associates

William A Cochrane, OC, MD Inc.
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Matt Coffey, PhD
Vice President, Product Development