

ONCOLYTICS BIOTECH INC

Form 6-K

May 03, 2004

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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 the month of May 2004

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

Form 40-F

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):

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):

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

No

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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PRESS RELEASE

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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: May 3, 2004

By: /s/ Douglas A. Ball

Douglas A. Ball
Chief Financial Officer

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210, 1167 Kensington Cr. N.W.
Calgary, Alberta
Canada T2N 1X7

FOR IMMEDIATE RELEASE

Oncolytics Biotech Inc. Announces 2004 First Quarter Results

CALGARY, AB, May 3, 2004 Oncolytics Biotech Inc. (Oncolytics) (TSX:ONC, NASDAQ:ONCY) today announced its financial results for the three-month period ending March 31, 2004.

First Quarter Highlights:

Received approval to commence a Phase I systemic (intravenous) administration clinical trial at the Royal Marsden Hospital, Surrey, U.K.

Provided a final update on the T2 prostate cancer clinical trial

Strengthened the Board of Directors with the addition of Mr. Jim Dinning

Added an 11th U.S. patent covering manufacturing of REOLYSIN®

Announced a \$6.73 million private placement with a European institutional investor

During the quarter, we made a number of significant advancements in the development of REOLYSIN® as a potential cancer therapeutic, said Dr. Brad Thompson, President and CEO of Oncolytics.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 months ended March 31, 2004 and 2003, and should also be read in conjunction with the audited financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) contained in Oncolytics annual report for the year ended December 31, 2003. The financial statements have been prepared in accordance with Canadian generally accepted accounting principles (GAAP).

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FORWARD-LOOKING STATEMENTS

The following discussion 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, the Company's expectation regarding the adequacy of its existing capital resources, and the Company's expectations as to the success of its research and development programs in 2004 and beyond, future financial position, business strategy and plans for future operations, and statements that are not historical facts, 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 competition, changes in technology, 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. Forward looking statements are based on assumptions, projections, estimates and expectations of management at the time such forward looking statements are made, and such assumptions, projections, estimates and/or expectations could change or prove to be incorrect or inaccurate. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements.

OVERVIEW

Oncolytics Biotech Inc. is a Development Stage Company

Since its inception in April of 1998, Oncolytics Biotech Inc. (the Company) has been a development stage company and has focused its research and development efforts on the development of REOLYSIN®, its potential cancer therapeutic. The Company has not been profitable since its inception and expects to continue to incur substantial losses from its research and development. The Company does not expect to generate significant revenues until, if and when, its cancer product becomes commercially viable.

General Risk Factors

Prospects for biotechnology companies in the research and development stage should generally be regarded as speculative. It is not possible to predict, based upon studies in animals, or early studies in humans, whether a new therapeutic will ultimately prove to be safe and effective in humans, or whether necessary and sufficient data can be developed through the clinical trial process to support a successful product application and approval.

If a product is approved for sale, product manufacturing at a commercial scale and significant sales to end users at a commercially reasonable price may not be successful. There can be no assurance that the Company will generate adequate funds to continue development, or will ever achieve significant revenues or profitable operations. Many factors (e.g. competition, patent protection, appropriate regulatory approvals) can influence the revenue and product profitability potential.

In developing a product for approval, the Company will rely upon its employees, contractors, consultants and collaborators and other third party relationships, including the ability to obtain appropriate product liability insurance. There can be no assurance that these reliances and relationships will continue as required.

In addition to developmental and operational considerations, market prices for securities of biotechnology companies generally are volatile, and may or may not move in a manner consistent with the progress being made by the Company.

Table of Contents**Highlights**

During the first quarter of 2004, the Company's net loss was \$2,676,236 compared to \$1,114,314 for the first quarter of 2003. The increase in the net loss primarily reflects the increased manufacturing costs incurred by the Company in preparation for its planned clinical trial program and other supporting activities. Also, the Company took action to further diminish its economic dependence related to having only one manufacturer of REOLYSIN® by entering into a manufacturing contract with a second supplier and incurred costs in the quarter associated with the transfer of its manufacturing process to the additional supplier. In addition, the Company's clinical trial, pre-clinical trial, and research collaboration expenses increased compared to the first quarter of 2003.

Recent Developments

On April 7, 2004, the Company sold 1,077,100 units, pursuant to a private placement, at an average price of \$6.25 per unit. Net cash proceeds after issue costs were approximately \$6,206,875. The units are comprised of 1,077,100 common shares and 538,550 common share purchase warrants. Each whole common share purchase warrant entitles the holder to acquire one common share of the capital of the Company upon payment of \$7.75 per share until October 7, 2005. In addition, the Company issued 107,710 common share purchase warrants to its adviser entitling the holder to acquire one common share of the capital of the Company upon payment of \$7.00 per share until October 7, 2005. The Company will use the proceeds from this financing for general corporate purposes.

RESULTS OF OPERATIONS

Net loss for the three month period ended March 31, 2004 was \$2,676,236 compared to \$1,114,314 for 2003. The increase in the Company's net loss was due to the following:

Research and Development Expenses (R&D)

| | <u>2004</u> | <u>2003</u> |
|--|-------------------|-------------------|
| | \$ | \$ |
| Manufacturing and process expenses | 1,376,430 | 66,108 |
| Clinical trial expenses | 125,645 | 10,643 |
| Pre-clinical trial and research collaboration expenses | 178,960 | 57,826 |
| Other R&D expenses | 273,362 | 345,058 |
| | <u> </u> | <u> </u> |
| Research and development expenses | 1,954,397 | 479,635 |
| | <u> </u> | <u> </u> |

For the first quarter of 2004, R&D increased to \$1,954,397 compared to \$479,635 for the first quarter of 2003. The increase in R&D was due to the following:

Manufacturing & Related Process Development

During the first quarter of 2004, the Company continued to focus on the production of REOLYSIN® in order to supply its R&D activity. Approximately 75% of the manufacturing and process development costs incurred in the first quarter of 2004 relate to the production of REOLYSIN® compared to nil in the first quarter of 2003. The increase in production costs also relates to technology transfer and set up costs associated with the addition of a second supplier in the first quarter of 2004.

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The majority of the remaining costs incurred in the first quarter of 2004 and all of the costs incurred in the first quarter of 2003 relate to process development expenses. The increase in process development expenses is due to the continued development of the Company's viral and cell banks which did not occur in 2003.

For the remainder of 2004, the Company expects that it will continue to produce REOLYSIN® and that a majority of these costs will relate directly to manufacturing.

Clinical Trial Programs

The Company's clinical trial expenses increased to \$125,645 in the first quarter of 2004 compared to \$10,643 for the first quarter of 2003. The increase was primarily due to the costs incurred in obtaining the approval to commence a systemic (intravenous) delivery clinical trial in the United Kingdom and continuing enrollment in its recurrent malignant glioma brain cancer study.

Pre-Clinical Trial and Research Collaboration Expenses

During the first quarter of 2004, the Company incurred increased pre-clinical and research collaboration expense that may assist in future clinical trial applications.

Operating Expenses

| | <u>2004</u> | <u>2003</u> |
|---|----------------|----------------|
| | \$ | \$ |
| Salary, insurance and other office expenses | 378,417 | 215,279 |
| Public company and other operating expenses | 322,757 | 306,275 |
| Stock based compensation | 5,426 | 471 |
| | <u>706,600</u> | <u>522,025</u> |

For the first quarter of 2004, the Company's operating expenses increased to \$706,600 compared to \$522,025 for the first quarter of 2003. Specifically, the Company incurred additional salary and insurance costs in the first quarter of 2004 compared to the first quarter of 2003. The increase in salary costs relates to additional staff levels that occurred in the second quarter of 2003 primarily in support of its corporate requirements including those associated with public company requirements. The increase in insurance premiums relates to the increased premiums for Directors' and Officers' liability insurance that began in the second quarter of 2003.

Sale of Investments

| | <u>2004</u> | <u>2003</u> |
|---|-------------|-------------|
| | \$ | \$ |
| Gain on sale of investment in BCY LifeSciences Inc. (BCY) | 47,648 | - |

In the first quarter of 2004, the Company sold 676,945 common shares of BCY for net cash proceeds of \$131,650. This resulted in an accounting gain of \$47,648. As at March 31, 2004, the Company owned 221,000 common shares and 694,995 common share purchase warrants of BCY. The common share purchase warrants were exercisable at \$0.27 and expired out of the money on April 23, 2004.

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Commitments

As at March 31, 2004, the Company has committed to payments totaling \$1,704,102 for activities primarily related to product manufacturing and continued toxicology and process related work. The Company anticipates that these committed payments will occur in 2004. All of these committed payments are considered to be part of the Company's normal course of business.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity

As at March 31, 2004, the Company had cash and cash equivalents, short-term investments and working capital positions of \$2,941,266, \$17,356,874 and \$18,493,690 respectively compared to \$2,641,127, \$18,111,608 and \$20,088,868 as at December 31, 2003. The decrease in the first quarter of 2004 reflects the operating and investing activities of the Company offset by the cash received from the exercise of warrants and options. For the three month period ended March 31, 2004, the Company had received proceeds from the exercise of warrants and options of \$944,745. Cash outflows during the first quarter of 2004 were due to research and development expenses, operational expenses, and intellectual property expenditures.

The Company desires to maintain adequate cash and short-term investment reserves to support its planned activities which include its clinical trial program, production manufacturing, and its intellectual property expansion and protection as well as administrative activities. The Company believes that its existing capital resources, including the recently closed private placement (see *Recent Developments*) are adequate to fund its current plans for research and development activities through 2006 without presuming the further exercise of outstanding warrants and options. In the event that the Company chooses to 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, availability of clinical trial information, and general market conditions.

Capital Expenditures and Commitments

During the first quarter of 2004 the Company spent \$130,540 on intellectual property compared to \$459,660 in the first quarter of 2003. The difference relates to variances in filing fees on existing patent applications.

Investing Activities

Under its Investment Policy, the Company is permitted to invest in short-term instruments with a rating no less than R-1 (DBRS) with terms less than two years. As at March 31, 2004, the Company invested \$17,356,874 under this policy and is currently earning interest at an effective rate of 2.67%.

OTHER MD&A REQUIREMENTS

The Company has 29,010,171 common shares outstanding at April 29, 2004. If all of the Company's warrants and options were exercised the Company would have 35,090,577 common shares outstanding.

Table of Contents**Oncolytics Biotech Inc.****BALANCE SHEETS**

As at,

| | March 31, 2004 | December 31, 2003 |
|--|-------------------|----------------------|
| | \$ (unaudited) | \$ (audited) |
| ASSETS | | |
| Current | | |
| Cash and cash equivalents | 2,941,266 | 2,641,127 |
| Short-term investments | 17,356,874 | 18,111,608 |
| Accounts receivable | 62,305 | 64,224 |
| Prepaid expenses | 129,102 | 156,837 |
| | <u>20,489,547</u> | <u>20,973,796</u> |
| Capital assets | 4,918,494 | 4,965,379 |
| Investments [note 3] | 27,423 | 111,425 |
| | <u>25,435,464</u> | <u>26,050,600</u> |
| LIABILITIES AND SHAREHOLDERS EQUITY | | |
| Current | | |
| Accounts payable and accrued liabilities | 1,995,857 | 884,928 |
| | <u>150,000</u> | <u>150,000</u> |
| Alberta Heritage Foundation loan | 150,000 | 150,000 |
| Shareholders equity | | |
| Share capital [note 2] | | |
| Authorized: unlimited | | |
| Issued: 27,450,389 (2003 27,208,262) | 45,765,630 | 44,712,589 |
| Warrants [note 2] | 1,489,954 | 1,598,250 |
| Contributed surplus | 3,704,851 | 3,699,425 |
| Deficit | (27,670,828) | (24,994,592) |
| | <u>23,289,607</u> | <u>25,015,672</u> |
| | <u>25,435,464</u> | <u>26,050,600</u> |

See accompanying notes

Table of Contents**Oncolytics Biotech Inc.****STATEMENTS OF LOSS AND DEFICIT**

For the three month periods ended March 31,

| | 2004 | 2003 | Cumulative from inception on April 2, 19981 to March 31, 2004 |
|---|-------------------|-------------------|--|
| | \$ (unaudited) | \$ (unaudited) | \$ (unaudited) |
| Revenue | | | |
| Rights revenue | | | 310,000 |
| Interest income | 117,356 | 43,170 | 2,203,339 |
| | <u>117,356</u> | <u>43,170</u> | <u>2,513,339</u> |
| Expenses | | | |
| Research and development | 1,954,397 | 479,635 | 18,845,466 |
| Operating | 706,600 | 522,025 | 8,467,513 |
| Amortization | 179,023 | 155,224 | 2,089,113 |
| | <u>2,840,020</u> | <u>1,156,884</u> | <u>29,402,092</u> |
| Loss before the following: | 2,722,664 | 1,113,714 | 26,888,753 |
| Gain on sale of BCY LifeSciences Inc. [note 3] | (47,648) | | (312,101) |
| Loss on sale of Transition Therapeutics Inc. | | | 2,156,685 |
| | <u>2,675,016</u> | <u>1,113,714</u> | <u>28,733,337</u> |
| Capital tax | 1,220 | 600 | 52,491 |
| Future income tax recovery | | | (1,115,000) |
| | <u>2,676,236</u> | <u>1,114,314</u> | <u>27,670,828</u> |
| Net loss for the period | 2,676,236 | 1,114,314 | 27,670,828 |
| Deficit, beginning of period | 24,994,592 | 16,450,561 | |
| | <u>27,670,828</u> | <u>17,564,875</u> | <u>27,670,828</u> |
| Deficit, end of period | 27,670,828 | 17,564,875 | 27,670,828 |
| Basic and diluted loss per share | 0.10 | 0.05 | |
| Weighted average number of shares | 27,255,740 | 22,221,506 | |

See accompanying notes

Table of Contents**Oncolytics Biotech Inc.****STATEMENTS OF CASH FLOWS**

For the three month periods ended March 31,

| | 2004 | 2003 | Cumulative from inception on April 2, 19981 to March 31, 2004 |
|---|--------------------|--------------------|--|
| | \$ (unaudited) | \$ (unaudited) | \$ (unaudited) |
| OPERATING ACTIVITIES | | | |
| Net loss for the period | (2,676,236) | (1,114,314) | (27,670,828) |
| Deduct non-cash items | | | |
| Amortization | 179,023 | 155,224 | 2,089,113 |
| Non-cash compensation | 5,426 | 471 | 1,034,851 |
| Gain on sale of BCY LifeSciences Inc. | (47,648) | | (312,101) |
| Loss on sale of Transition Therapeutics Inc. | | | 2,156,685 |
| Future income tax recovery | | | (1,115,000) |
| Net changes in non-cash working capital | 1,140,583 | (257,136) | 1,719,783 |
| | <u>(1,398,852)</u> | <u>(1,215,755)</u> | <u>(22,097,497)</u> |
| INVESTING ACTIVITIES | | | |
| Intellectual property | (130,540) | (459,660) | (2,795,366) |
| Other capital assets | (1,598) | (622) | (512,570) |
| Purchase of short-term investments | (245,266) | | (18,356,874) |
| Redemption of short-term investments | 1,000,000 | | 1,000,000 |
| Investment in BCY LifeSciences Inc. | 131,650 | | 454,678 |
| Investment in Transition Therapeutics Inc. | | | 2,532,343 |
| | <u>754,246</u> | <u>(460,282)</u> | <u>(17,677,789)</u> |
| FINANCING ACTIVITIES | | | |
| Alberta Heritage Foundation loan | | | 150,000 |
| Proceeds from exercise of warrants and stock options | 944,745 | | 4,405,730 |
| Proceeds from private placements | | 244,171 | 16,518,220 |
| Proceeds from public offerings | | | 21,642,602 |
| | <u>944,745</u> | <u>244,171</u> | <u>42,716,552</u> |
| Increase (decrease) in cash and cash equivalents during the period | 300,139 | (1,431,866) | 2,941,266 |
| Cash and cash equivalents, beginning of the period | 2,641,127 | 8,319,244 | |
| Cash and cash equivalents, end of the period | 2,941,266 | 6,887,378 | 2,941,266 |

See accompanying notes

Table of Contents**Oncolytics Biotech Inc.****NOTES TO FINANCIAL STATEMENTS**March 31, 2004 and 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 information for the year ended December 31, 2003 has been derived from the Company's audited financial statements for the year then ended.

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:

| | Shares | | Warrants | |
|---|------------|--------------|-----------|--------------|
| | Number | Amount \$ | Number | Amount \$ |
| Balance, December 31, 2002 | 22,145,284 | 30,191,572 | 550,000 | 114,286 |
| Issued for cash pursuant to February 10, 2003 private placement | 140,000 | 265,540 | 77,000 | 16,000 |
| Issued for cash pursuant to June 19, 2003 private placement | 2,120,000 | 5,912,113 | 1,272,000 | 543,287 |
| Issued for cash pursuant to August 21, 2003 private placement | 1,363,900 | 3,801,778 | 813,533 | 349,176 |
| Issued for cash pursuant to October 14, 2003 public offering | 1,200,000 | 5,528,972 | 720,000 | 617,428 |
| Exercise of options | 64,700 | 149,615 | | |
| Exercise of warrants | 174,378 | 593,194 | (174,378) | (41,927) |
| Share issue costs | | (1,730,195) | | |
| Balance, December 31, 2003 | 27,208,262 | 44,712,589 | 3,258,155 | 1,598,250 |
| Exercise of warrants | 235,377 | 1,038,228 | (235,377) | (108,296) |
| Exercise of options | 6,750 | 14,813 | | |
| Balance, March 31, 2004 | 27,450,389 | 45,765,630 | 3,022,778 | 1,489,954 |

Table of Contents**Oncolytics Biotech Inc.****NOTES TO FINANCIAL STATEMENTS**March 31, 2004 and 2003 (*unaudited*)

The following table summarizes the Company's outstanding warrants as at March 31, 2004:

| Exercise Price | Outstanding, Beginning of the Period | Granted During the Period | Exercised During the Period | Outstanding, End of Period | Weighted Average Remaining Contractual Life (years) |
|-----------------------|---|--|--|---------------------------------------|--|
| \$3.00 | 480,755 | | (99,259) | 381,496 | 0.19 |
| \$4.00 | 2,057,400 | | (85,934) | 1,971,466 | 0.79 |
| \$5.00 | 120,000 | | (20,184) | 99,816 | 1.04 |
| \$6.25 | 600,000 | | (30,000) | 570,000 | 1.04 |
| | 3,258,155 | | (235,377) | 3,022,778 | 0.76 |

Stock Option Plan

The Company has issued stock options to acquire common stock through its stock option plan of which the following are outstanding at:

| | March 31, 2004 | | December 31, 2003 | |
|--------------------------------------|--------------------------|--|--------------------------|--|
| | Stock Options | Weighted Average Share Price \$ | Stock Options | Weighted Average Share Price \$ |
| Outstanding at beginning of period | 2,800,800 | 3.87 | 2,653,500 | 4.40 |
| Granted during period | | | 599,000 | 3.71 |
| Cancelled during period | | | (387,000) | 7.97 |
| Exercised during period | (6,750) | 2.19 | (64,700) | 2.31 |
| Outstanding at end of period | 2,794,050 | 3.81 | 2,800,800 | 3.81 |
| Options exercisable at end of period | 2,713,633 | 3.87 | 2,720,383 | 3.87 |

As the Company is following the fair value based method of accounting for employee options, compensation expense of \$5,426 (March 31, 2003 nil) has been recorded for the period with respect to the vesting of employee options issued in prior periods with an offsetting credit to contributed surplus.

3. INVESTMENTS

During the three month period ending March 31, 2004, the Company sold 676,945 of its BCY shares for net cash proceeds of \$131,650 recording a gain on sale of investment of \$47,648. As at March 31, 2004, the Company's remaining ownership in BCY was 221,000 common shares with a book value of \$27,423 and an estimated market value of \$41,990 based on the trading price at March 31, 2004.

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Oncolytics Biotech Inc.

NOTES TO FINANCIAL STATEMENTS

March 31, 2004 and 2003 (*unaudited*)

4. SUBSEQUENT EVENT

On April 7, 2004, the Company sold 1,077,100 units, pursuant to a private placement, at an average price of \$6.25 per unit. Net cash proceeds after share issue costs, including the fees paid to its advisor, were approximately \$6,206,875. The units are comprised of 1,077,100 common shares and 538,550 common share purchase warrants. Each whole common share purchase warrant entitles the holder to acquire one common share of the capital of the Company upon payment of \$7.75 per share until October 7, 2005. In addition, the Company issued 107,710 common share purchase warrants to its adviser entitling the holder to acquire one common share of the capital of the Company upon payment of \$7.00 per share until October 7, 2005.

FOR FURTHER INFORMATION PLEASE CONTACT:

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