

ONCOLYTICS BIOTECH INC  
Form 6-K  
November 05, 2008

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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 November 2008

Commission File Number 000-31062

**Oncolytics Biotech Inc.**

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*(Translation of registrant's name into English)*

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

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*(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.

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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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**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: November 5, 2008

By: /s/ Doug Ball

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Doug 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 2008 Third Quarter Results**

**CALGARY, AB, November 4, 2008** Oncolytics Biotech Inc. (TSX:ONC, NASDAQ:ONCY) (Oncolytics or the Company) today announced its financial results for the three and nine-month periods ended September 30, 2008.

**Recent Pivotal Trial Decision**

Oncolytics made a decision in early November to pursue a pivotal (Phase II/III) randomized trial using the combination of REOLYSIN<sup>®</sup> with paclitaxel/carboplatin in refractory patients with head and neck cancers. The decision was made following a review of results by the Company's Board of Directors from the Company's ongoing U.K. Phase I and Phase II combination REOLYSIN<sup>®</sup> and paclitaxel/carboplatin clinical trials. The results were presented November 1, 2008 at the International Society for Biological Therapy of Cancer (iSBTc) annual meeting in San Diego, CA.

**Selected Third Quarter Highlights:**

Treatment of the 200<sup>th</sup> patient in clinical studies with REOLYSIN<sup>®</sup>;

Completion of patient enrolment in the dose escalation portion of its U.K. clinical trial to evaluate the anti-tumour effects of systemic administration of REOLYSIN<sup>®</sup> in combination with docetaxel (Taxotere<sup>®</sup>) in patients with advanced cancers including bladder, prostate, lung and upper gastro-intestinal;

The U.S. National Cancer Institute (NCI), part of the National Institutes of Health, started enrolment in a Phase II clinical trial for patients with metastatic melanoma using systemic administration of REOLYSIN<sup>®</sup>;

The start of patient enrolment in a U.S. Phase II clinical trial using intravenous administration of REOLYSIN<sup>®</sup> in combination with paclitaxel and carboplatin in patients with advanced head and neck cancers;

Initiation of a U.S. Phase II clinical trial using intravenous administration of REOLYSIN<sup>®</sup> in combination with paclitaxel and carboplatin in patients with NSCLC with K-RAS or EGFR-activated tumours;

The grant of the Company's 2<sup>nd</sup> U.S. patent which covers methods of purifying reassorted reovirus from an FDA-approved cell line.

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### **Latest Highlights**

Subsequent to quarter end, the Company announced:

Eight of nine refractory head and neck cancer patients treated to date have experienced either a partial response or stabilization of disease in our Phase I and Phase II U.K. combination REOLYSIN<sup>®</sup> and carboplatin/paclitaxel trials;

Nine of eleven evaluable patients have experienced stable disease or better for at least four cycles in our U.K. combination REOLYSIN<sup>®</sup> and docetaxel trial;

The selection of refractory head and neck cancers for the Company's first pivotal trial;

Results of two preclinical studies which demonstrated synergy *in vitro* and *in vivo* with the combination of REOLYSIN<sup>®</sup> and chemotherapy;

Results of a preclinical study demonstrating that a single IV administration of ReoT3D can result in substantial tumor growth delay in melanoma-bearing nude mice;

The grant of the Company's 2<sup>nd</sup> U.S. patent, which covers methods of selectively removing cancer cells *ex vivo* from blood stem cells and other organs using reovirus; and,

Successful completion of initial scale-up of its manufacturing process for REOLYSIN<sup>®</sup> to the 100L commercial scale from the current 40L level.

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**Oncolytics Biotech Inc.**  
**CONSOLIDATED BALANCE SHEETS**  
*(unaudited)*

As at,

|   | <b>September<br/>30, 2008</b> | <b>December 31,<br/>2007</b> |
|---|-------------------------------|------------------------------|
|   | \$                            | \$<br><i>[Restated]</i>      |
| <b>ASSETS</b>                                       |                               |                              |
| <b>Current</b>                                      |                               |                              |
| Cash and cash equivalents                           | <b>12,680,162</b>             | 6,715,096                    |
| Short-term investments                              | <sup>3/4</sup>                | 18,498,733                   |
| Accounts receivable                                 | <b>47,891</b>                 | 80,085                       |
| Prepaid expenses                                    | <b>307,697</b>                | 260,300                      |
|   | <b>13,035,750</b>             | 25,554,214                   |
| <b>Property and equipment</b>                       | <b>235,542</b>                | 201,103                      |
| <b>Intellectual property</b>                        | <b>271,125</b>                | 542,250                      |
|   | <b>13,542,417</b>             | 26,297,567                   |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY</b>          |                               |                              |
| <b>Current</b>                                      |                               |                              |
| Accounts payable and accrued liabilities            | <b>2,800,857</b>              | 2,821,227                    |
| <b>Shareholders equity</b>                          |                               |                              |
| Share capital                                       |                               |                              |
| Authorized: unlimited number of common shares       |                               |                              |
| Issued: 41,180,748 (December 31, 2007 - 41,180,748) | <b>92,759,665</b>             | 92,759,665                   |
| Warrants  | <b>5,346,260</b>              | 5,346,260                    |
| Contributed surplus                                 | <b>10,431,917</b>             | 10,376,962                   |
| Deficit   | <b>(97,796,282)</b>           | (85,006,547)                 |
|   | <b>10,741,560</b>             | 23,476,340                   |
|   | <b>13,542,417</b>             | 26,297,567                   |

**Oncolytics Biotech Inc.**  
**CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS**  
*(unaudited)*

|   | <b>Three Month<br/>Period<br/>Ending<br/>September<br/>30, 2008<br/>\$</b> | <b>Three Month<br/>Period<br/>Ending<br/>September<br/>30,<br/>2007<br/>\$<br/>[Restated]</b> | <b>Nine Month<br/>Period<br/>Ending<br/>September<br/>30, 2008<br/>\$</b> | <b>Nine Month<br/>Period<br/>Ending<br/>September<br/>30, 2007<br/>\$<br/>[Restated]</b> | <b>Cumulative<br/>from inception<br/>on April 2,<br/>1998 to<br/>September 30,<br/>2008<br/>\$<br/>[Restated]</b> |
|---|--|---|---|--|---|
| <b>Revenue</b>                                      |  |   |   |  |   |
| Rights revenue                                      | ¾  | ¾   | ¾   | ¾  | 310,000   |
|   | ¾  | ¾   | ¾   | ¾  | 310,000   |
| <b>Expenses</b>                                     |  |   |   |  |   |
| Research and development                            | <b>3,210,294</b>   | 3,134,340   | <b>9,650,595</b>  | 9,621,760  | 70,750,311  |
| Operating   | <b>880,438</b>   | 812,939   | <b>3,250,830</b>  | 2,711,962  | 23,856,466  |
| Stock based compensation                            | <b>17,339</b>  | 38,909  | <b>54,955</b>   | 142,878  | 4,759,760   |
| Foreign exchange loss/gain                          | <b>29,026</b>  | 18,917  | <b>(20,059)</b>   | 2,829  | 637,651   |
| Amortization intellectual property                  | <b>90,375</b>  | 90,375  | <b>271,125</b>  | 271,125  | 3,343,875   |
| Amortization property and equipment                 | <b>11,853</b>  | 10,197  | <b>35,233</b>   | 30,061   | 483,630   |
|   | <b>4,239,325</b>   | 4,105,677   | <b>13,242,679</b>   | 12,780,615   | 103,831,693   |
| <b>Loss before the following:</b>                   | <b>4,239,325</b>   | 4,105,677   | <b>13,242,679</b>   | 12,780,615   | 103,521,693   |
| <b>Interest income</b>                              | <b>(98,493)</b>  | (319,221)   | <b>(452,944)</b>  | (946,826)  | (6,467,693)   |
| <b>Gain on sale of BCY LifeSciences Inc.</b>        | ¾  | ¾   | ¾   | ¾  | (299,403)   |
| <b>Loss on sale of Transition Therapeutics Inc.</b> | ¾  | ¾   | ¾   | ¾  | 2,156,685   |
| <b>Loss before income taxes</b>                     | <b>4,140,832</b>   | 3,786,456   | <b>12,789,735</b>   | 11,833,789   | 98,911,282  |
| <b>Future income tax recovery</b>                   | ¾  | ¾   | ¾   | ¾  | (1,115,000)   |

|  |                   |            |                   |            |            |
|--|-------------------|------------|-------------------|------------|------------|
| <b>Net loss and comprehensive loss for the period</b>        | <b>4,140,832</b>  | 3,786,456  | <b>12,789,735</b> | 11,833,789 | 97,796,282 |
| <b>Basic and diluted loss per share</b>                      | <b>0.10</b>       | 0.09       | 0.31              | 0.29       |            |
| <b>Weighted average number of shares (basic and diluted)</b> | <b>41,180,748</b> | 41,120,748 | <b>41,180,748</b> | 40,181,777 |            |

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**Oncolytics Biotech Inc.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(unaudited)*

|  | <b>Three Month<br/>Period<br/>Ending<br/>September<br/>30, 2008<br/>\$</b> | <b>Three Month<br/>Period<br/>Ending<br/>September<br/>30,<br/>2007<br/>\$<br/>[Restated]</b> | <b>Nine Month<br/>Period<br/>Ending<br/>September<br/>30, 2008<br/>\$</b> | <b>Nine Month<br/>Period<br/>Ending<br/>September<br/>30, 2007<br/>\$<br/>[Restated]</b> | <b>Cumulative<br/>from inception<br/>on April 2,<br/>1998 to<br/>September 30,<br/>2008<br/>\$<br/>[Restated]</b> |
|--|--|---|---|--|---|
| <b>OPERATING<br/>ACTIVITIES</b>            |  |   |   |  |   |
| Net loss for the period                    | (4,140,832)  | (3,786,456)   | (12,789,735)  | (11,833,789)   | (97,796,282)  |
| Deduct non-cash items                      |  |   |   |  |   |
| Amortization intellectual property         | 90,375   | 90,375  | 271,125   | 271,125  | 3,343,875   |
| Amortization property and equipment        | 11,853   | 10,197  | 35,233  | 30,061   | 483,630   |
| Stock based compensation                   | 17,339   | 38,909  | 54,955  | 142,878  | 4,759,760   |
| Other non-cash items                       | <sup>3</sup> / <sub>4</sub>  | <sup>3</sup> / <sub>4</sub>   | <sup>3</sup> / <sub>4</sub>   | <sup>3</sup> / <sub>4</sub>  | 1,383,537   |
| Net changes in non-cash working capital    | (1,217,916)  | 316,534   | (35,573)  | (46,262)   | 2,445,269   |
|  | <b>(5,239,181)</b>   | <b>(3,330,441)</b>  | <b>(12,463,995)</b>   | <b>(11,435,987)</b>  | <b>(85,380,211)</b>   |
| <b>INVESTING<br/>ACTIVITIES</b>            |  |   |   |  |   |
| Capital assets                             | (10,927)   | (11,386)  | (69,672)  | (49,691)   | (771,839)   |
| Purchase of short-term investments         | (62,435)   | (255,688)   | (314,631)   | (742,853)  | (49,383,594)  |
| Redemption of short-term investments       | 9,813,364  | <sup>3</sup> / <sub>4</sub>   | 18,813,364  | <sup>3</sup> / <sub>4</sub>  | 48,965,110  |
| Investment in BCY LifeSciences Inc.        | <sup>3</sup> / <sub>4</sub>  | <sup>3</sup> / <sub>4</sub>   | <sup>3</sup> / <sub>4</sub>   | <sup>3</sup> / <sub>4</sub>  | 464,602   |
| Investment in Transition Therapeutics Inc. | <sup>3</sup> / <sub>4</sub>  | <sup>3</sup> / <sub>4</sub>   | <sup>3</sup> / <sub>4</sub>   | <sup>3</sup> / <sub>4</sub>  | 2,532,343   |
|  | <b>9,740,002</b>   | <b>(267,074)</b>  | <b>18,429,061</b>   | <b>(792,544)</b>   | <b>1,806,622</b>  |
| <b>FINANCING<br/>ACTIVITIES</b>            |  |   |   |  |   |

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|   |                   |                    |                   |                  |                   |
|---|-------------------|--------------------|-------------------|------------------|-------------------|
| Proceeds from exercise of warrants and stock options                      | ¾                 | ¾                  | ¾                 | ¾                | 15,259,468        |
| Proceeds from private placements  | ¾                 | ¾                  | ¾                 | ¾                | 38,137,385        |
| Proceeds from public offerings  | ¾                 | ¾                  | ¾                 | 12,063,394       | 42,856,898        |
|   | ¾                 | ¾                  | ¾                 | 12,063,394       | 96,253,751        |
| <b>Increase (decrease) in cash and cash equivalents during the period</b> | <b>4,500,821</b>  | <b>(3,597,515)</b> | <b>5,965,066</b>  | <b>(165,137)</b> | <b>12,680,162</b> |
| <b>Cash and cash equivalents, beginning of the period</b>                 | <b>8,179,341</b>  | <b>6,923,889</b>   | <b>6,715,096</b>  | <b>3,491,511</b> | <b>¾</b>          |
| <b>Cash and cash equivalents, end of the period</b>                       | <b>12,680,162</b> | <b>3,326,374</b>   | <b>12,680,162</b> | <b>3,326,374</b> | <b>12,680,162</b> |

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**To view the 2008 Third Quarter Report which includes the Consolidated Financial Statements, related Notes to Consolidated Financial Statements, and Management's Discussion and Analysis, please see the Company's third quarter filings which will be available on [www.sedar.com](http://www.sedar.com) and on [www.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com).**

**About Oncolytics Biotech Inc.**

Oncolytics is a Calgary-based biotechnology company focused on the development of oncolytic viruses as potential cancer therapeutics. Oncolytics' clinical program includes a variety of Phase I/II and Phase II human trials using REOLYSIN<sup>®</sup>, its proprietary formulation of the human reovirus, alone and in combination with radiation or chemotherapy. For further information about Oncolytics please visit [www.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com)

*This press release 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<sup>®</sup> as a cancer therapeutic; the Company's expectations as to the success of its research and development programs in 2008 and beyond, the Company's planned operations, the value of the additional patents and intellectual property; the Company's expectations related to the applications of the patented technology; the Company's expectations as to adequacy of its existing capital resources; the design, timing, success of planned clinical trial programs; and other statements related to anticipated developments in the Company's business and technologies 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<sup>®</sup> as a cancer treatment, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize REOLYSIN<sup>®</sup>, 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, except as required by applicable laws.*

**FOR FURTHER INFORMATION PLEASE CONTACT:**

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