



TSX:ONC NASDAQ:ONCY

## Investor Presentation

### December 2011

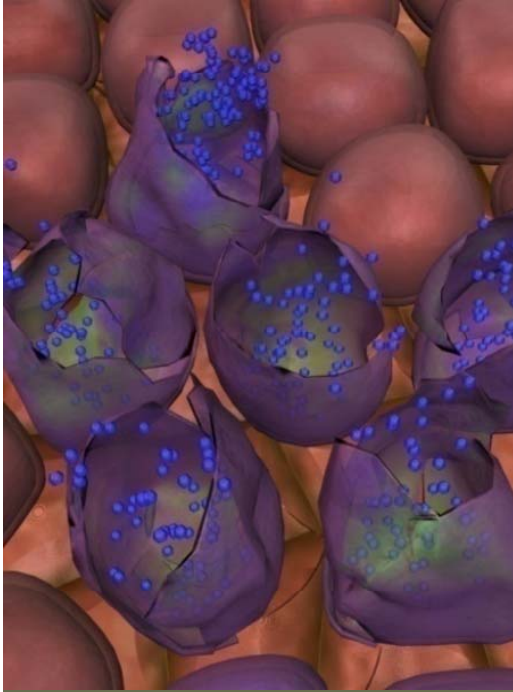


## Forward Looking Statements

Today's presentation contains certain forward looking statements relating to the company's financial results, business prospects and the development and commercialization of REOLYSIN<sup>®</sup>, a therapeutic reovirus. These statements are based on management's current expectations and beliefs and are subject to a number of factors which involve known and unknown risks, delays, uncertainties and other factors not under the company's control which may cause actual results, performance or achievements of the company to be materially different from the results, performance or other expectations implied by these forward looking statements. In any forward looking statement in which Oncolytics Biotech<sup>®</sup> Inc. expresses an expectation or belief as to future results, such expectations or beliefs are expressed in good faith and are believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will be achieved. These factors include results of current or pending clinical trials, risks associated with intellectual property protection, financial projections, market projections, actions by the FDA/HPB/MHRA and those other factors detailed in the company's filings with SEDAR and the Securities and Exchange Commission. Oncolytics does not undertake an obligation to update the forward looking statements, except as required by applicable laws.



# REOLYSIN Overview

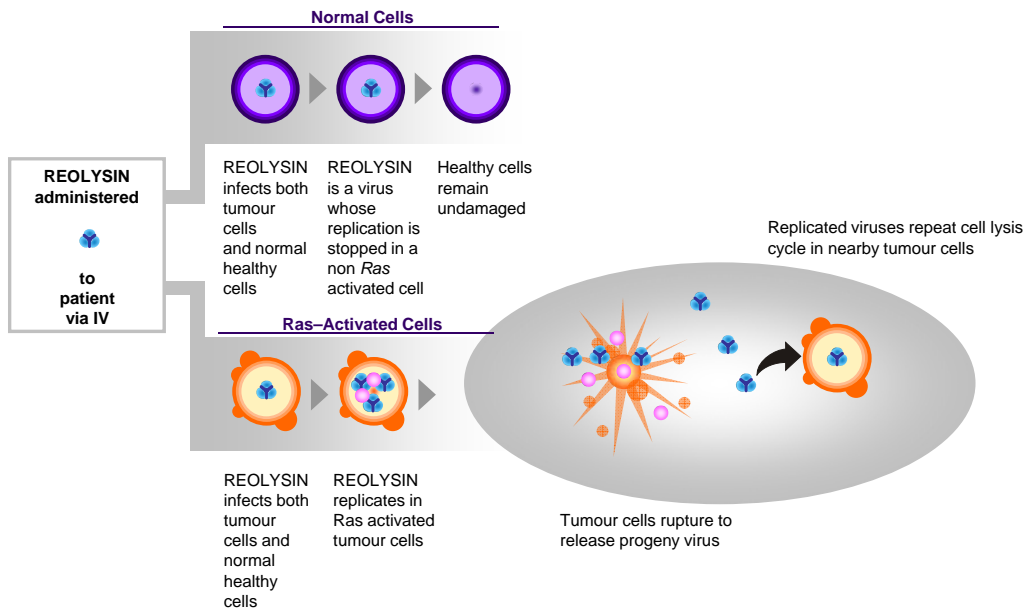


- REOLYSIN is a proprietary isolate of the reovirus, a replication competent virus
- Reovirus is considered safe to humans
- REOLYSIN has been safely administered to patients via intravenous, intratumoural, and intrathecal injection
- **Mechanism of Action:**
  - In *Ras*-activated cancer cells, one of the key cellular defense mechanisms against double stranded RNA viral infection, Protein Kinase-R (PKR), is deactivated
  - This specific vulnerability of constitutive *Ras*-activated cancer cells to the reovirus is the basis of REOLYSIN's activity and specificity
  - Reovirus oncolysis is seen in cancer cells with constitutive *Ras* pathway activation; susceptible cancer cells therefore include those with either:
    1. *EGFR* overexpression or mutation<sup>1</sup> or:
    2. *Ras* mutation which includes *Kras* mutation<sup>2</sup>
  - Both of these mutations lead to activation of the *Ras* pathway

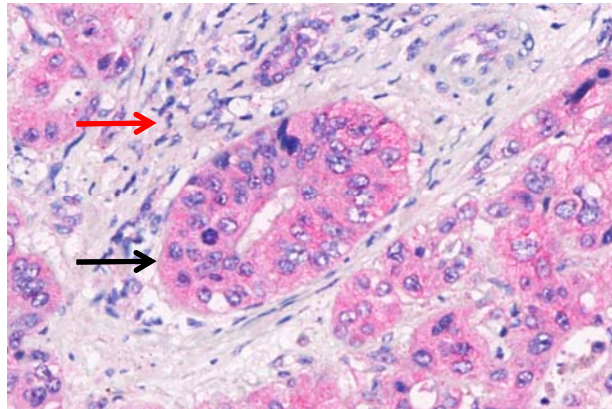
1 - Evidence that the epidermal growth factor receptor on host cells confers reovirus infection efficiency. Strong et al. *Virology* 1993; 197(1): 405

2 - The molecular basis of viral oncolysis: usurpation of the *Ras* signaling pathway by reovirus. Strong et al. *EMBO J* 1998; 17(12): 3351

# REOLYSIN Mechanism of Action



## REOLYSIN Selectivity



- Slide shows positive (red staining) for reovirus in the cancer cells (black arrow), relative to the normal cells (red arrow)
- 9 out of 10 patients showed the same pattern, *i.e.* targeted delivery to metastatic tumour lesions of the liver. Two of the patients had complete tumour necrosis. This demonstrates REOLYSIN specifically accesses and replicates in metastatic CRC

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## Market for Ras Pathway Mediated Cancers

- Estimated current global cancer market (2011) is \$77 billion
- At least 2/3 of carcinomas and more than 90% of metastatic disease has a Ras pathway involvement
- at least 5 million new patients per year are predicted to develop cancers with a *Ras* pathway involvement

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# Pivotal (Phase III) Program for REOLYSIN

## Study Overview

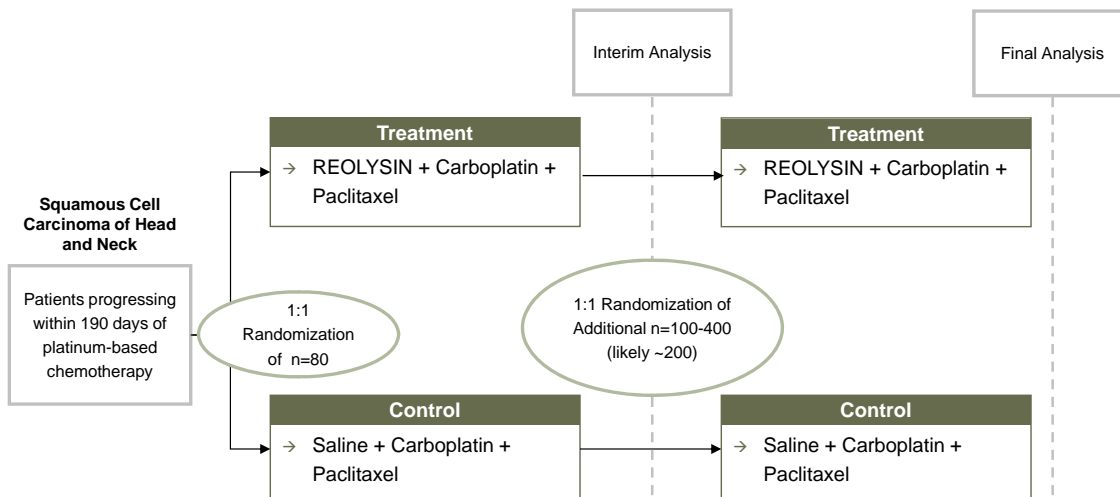
- Phase III trial examining REOLYSIN in combination with paclitaxel/carboplatin in taxane-naïve patients with platinum-refractory head and neck cancers
- Trial and statistical design reviewed by FDA under Special Protocol Assessment (SPA) process
- Randomized, two-arm, double-blind, multicentre, two-stage, adaptive trial
- Study approved in 12 countries in North America and Europe
- Principal investigators:
  - James A Bonner, MD, *University of Alabama at Birmingham*
  - Kevin Harrington, MBBS MRCP FRCR, *The Royal Marsden Hospital, London, UK*
  - Jan Vermorken, MD, PhD, *University Hospital, Antwerp, Belgium*

## End Points

- Primary endpoint: overall survival
- Secondary endpoint: progression-free survival
- Pharmacodynamic endpoints: tumor Ras pathway status and HPV status

# Pivotal (Phase III) Program for REOLYSIN

- Two-stage Phase III trial
  - 80 patients in first stage
  - Adaptive design in second stage allows for detection of a range of increases in overall survival by enrolling from 100 to 400 patients, with the most probable being ~200

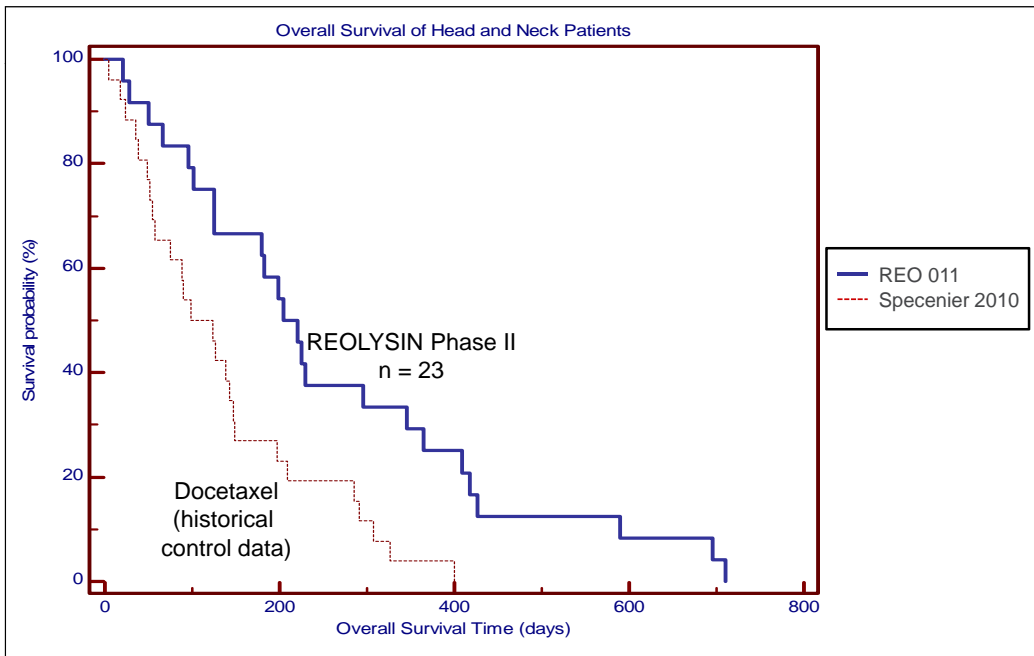


# Interim Results Compared to Historical Controls

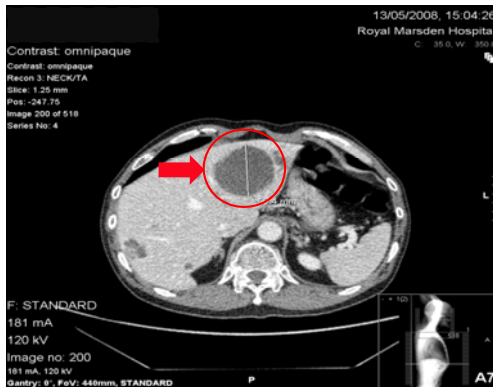
## Second-Line Therapies In Platinum Refractory Head and Neck Patients

Treatment	Reference	Response Rate	Median TTP or PFS (months)	Median Survival (months)
Various Treatments or Best Supportive care	Léon <i>et al.</i> , 2005	2.6%	N/A	3.0
Docetaxel	Specenier <i>et al.</i> , 2010	6.7%	<2.0	4.5
Carboplatin/paclitaxel	Vermorken Estimate	10.0%	2.0	4.5 (refractory)
<b>REOLYSIN + carboplatin/paclitaxel</b>	<b>REO 011 (n=23) Combined taxane naive patients REO 011 and REO 015 (n = 18)</b>	<b>42.0% (REO 011) 50.0% (REO 011 and 015)</b>	<b>N/A</b>	<b>N/A</b>

# Phase II (REO 011) Head and Neck Patients: Overall Survival



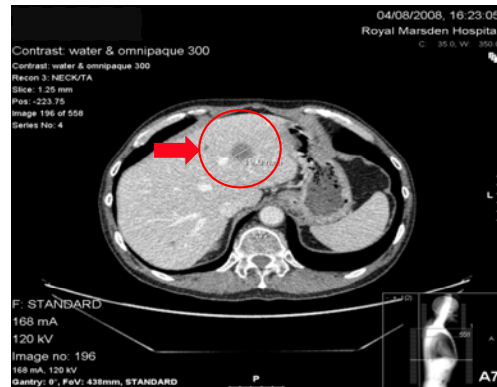
## Phase II REOLYSIN/Paclitaxel/Carboplatin — Metastatic Nasopharyngeal Case Study



**Pre-treatment**

### Prior treatment

- Radiation – 2 cycles
- Cisplatin, gemcitabine/carboplatin, carboplatin/5-FU – 6 cycles
- Docetaxel – 3 cycles



**Post cycle 3**

### Results

- Target lesion – liver metastases
- Baseline – 59.4 mm
- Post cycle 3 – 19 mm
- Response maintained through 8 cycles

## US Phase 2 Ovarian: REOLYSIN/Paclitaxel Combination

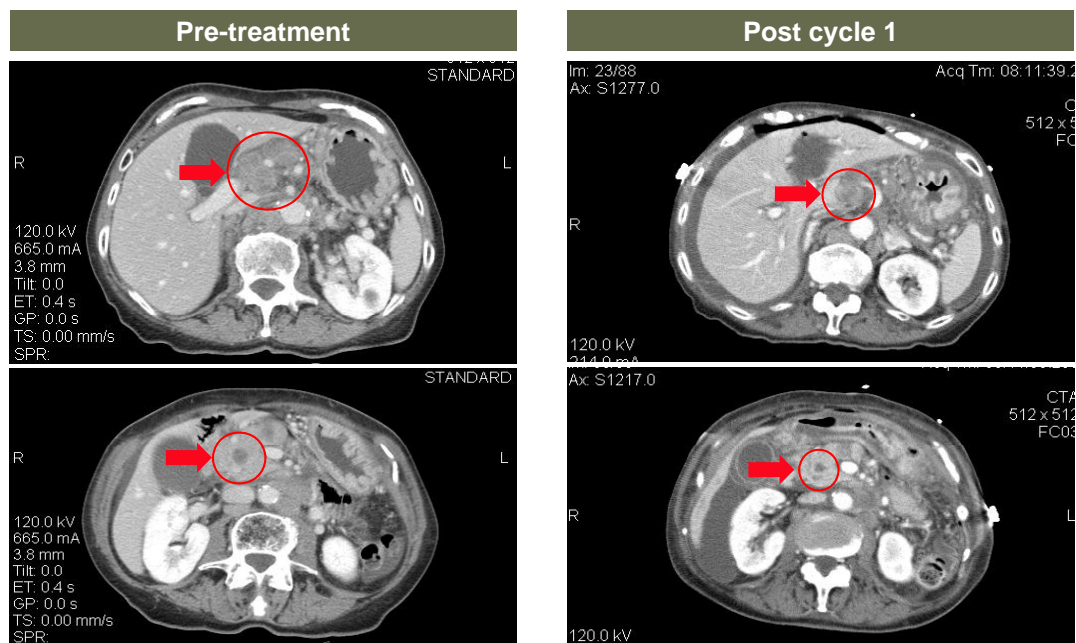
- Phase 2 trial examining REOLYSIN in combination with paclitaxel in the treatment of recurrent or persistent ovarian, fallopian tube or primary peritoneal cancer
- 110 patient randomized, two-arm, multicentre study
- Sponsored by the NCI, under the Gynecologic Oncology Group (GOG)

# Phase 2 Studies of REOLYSIN in Pancreatic Cancer

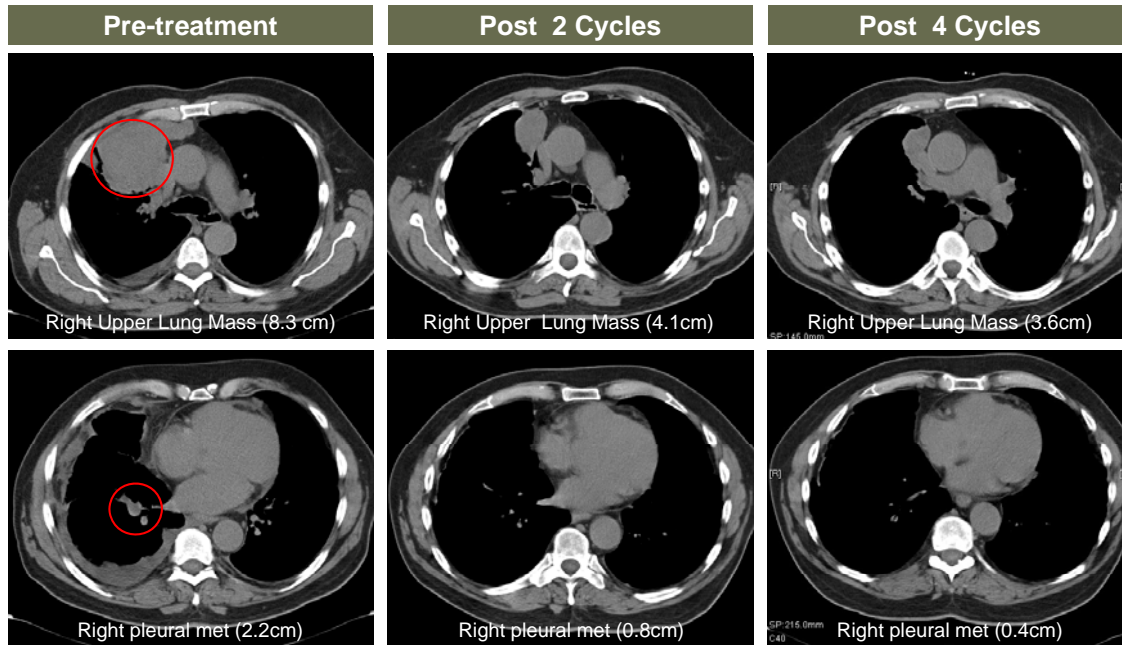
## US Phase 2 Program

- > 90% of pancreatic cancers have *Kras* mutations
- Single arm study examining use of REOLYSIN/gemzar combination in patients with advanced or metastatic pancreatic cancer with measurable disease who have not received any prior chemotherapy or biotherapy
- Primary endpoint (8 or more SD or better in first 33 patients) met in first 13 evaluable patients (1 PR, 8 SD for 12 weeks or greater, 1 SD for 9 weeks).
- Randomized NCI study will examine paclitaxel/carboplatin/REOLYSIN vs paclitaxel/carboplatin in pancreatic patients with recurrent or metastatic disease (70 patients), cross over arm for control to test arm on progression

## Pancreatic Cancer and Ras Pathway Activation - US Phase 2 Pancreatic Cancer REOLYSIN/Gemzar Combination - PR in Hepatic Hilar Lymph Node and Pancreatic Head



## US Phase 2 SCCLC: REOLYSIN/Carbo/Taxol Combination Pt 0001 – Partial Response (PR) in Lung



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## Phase 2 NSCLC and *Kras*/EGFR

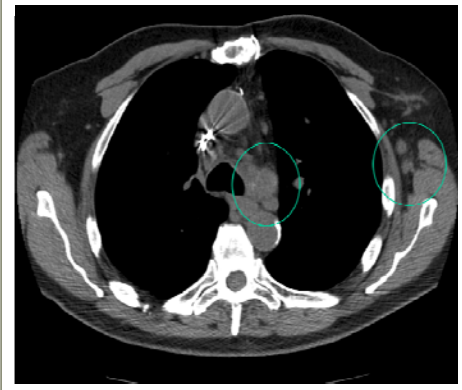
### U.S. Phase 2

- For NSCLC prescreened for *Kras* and EGFR mutation status
- 15 to 20% of NSCLC is *Kras* mutated and up to 50% is EGFR mutated or over expressed
- First line therapy study i.e. patients will be offered REOLYSIN/paclitaxel/carboplatin instead of standard of care if they are *Kras* or EGFR mutated or EGFR over expressed, all of which cause Ras pathway activation
- Current standard of care includes EGFR inhibitors which have been shown to be ineffective in *Kras* mutated patients
- Interim data demonstrated that of 21 evaluable patients (all stage 4 on entry; 8 *Kras* mutated, 13 EGFR mutated or overexpressed and *Kras* wild type), 90.5% were SD or better (6 PR, 13 SD) including all 8 *Kras* mutated patients

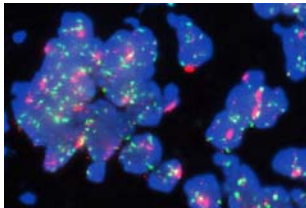
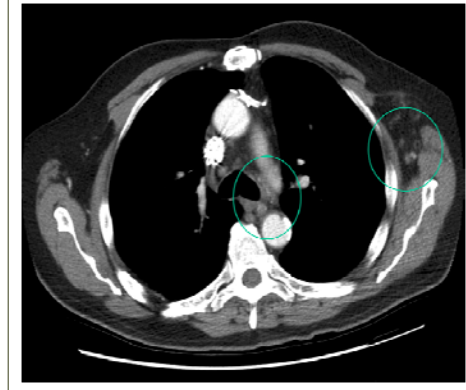
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## US Phase 2 NSCLC: REOLYSIN/Carbo/Taxol Combination – Partial Response (PR) in Lung by CT (EGFR Mutation)

Pre-treatment



Post Cycle 2



- FISH for EGFR (Red) and CEP7 (Green)
- Ex19 18bp in-frame deletion and T790M mutation

## Colorectal Cancer and *Kras*

- Current standard of care for second-line patients also includes EGFR inhibitors
- 45% of second-line colorectal patients have *Kras* mutations
- Phase I study of 12-20 patients using REOLYSIN/FOLFIRI combination in second line patients prescreened for *Kras* mutations

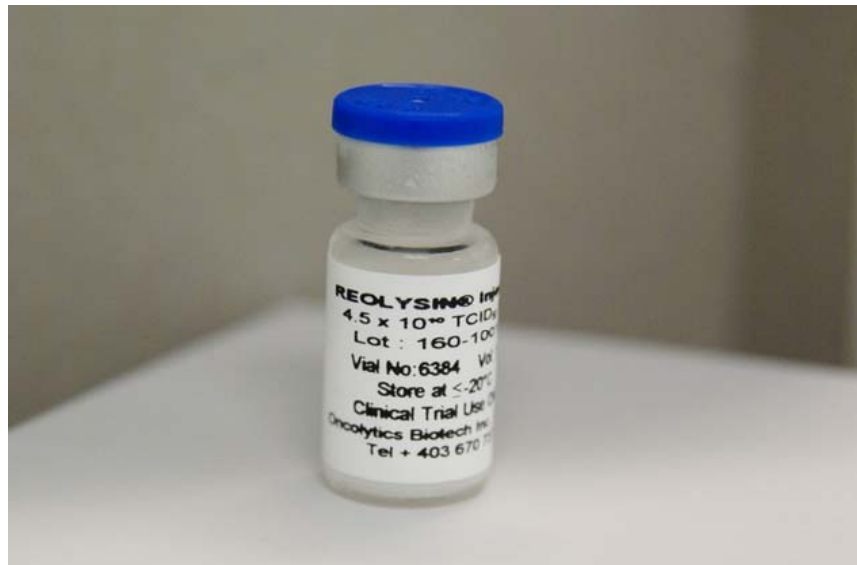
## Safety

- >420 patients treated, >330 intravenously at doses up to  $3 \times 10^{10}$  TCID<sub>50</sub> daily.
- No maximum tolerated dose (MTD) reached to date.
- Monotherapy toxicities have been generally mild (grade 1 or 2) and included chills, fever, headache, cough, myalgia, runny nose, sore throat and fatigue, and grade 1 or 2 lymphopenia and neutropenia. Transient grade 3 and 4 toxicities included lymphopenia and neutropenia. These symptoms were more frequently observed from day 2 of treatment and usually lasted less than 6 hours.

## Intellectual Property

- Approximately 290 patents issued worldwide including 45 U.S. and 11 Canadian
- Reovirus issued patent claims cover
  - Compositions of matter comprising reovirus
  - Pharmaceutical use of reoviruses to treat neoplasia and cellular proliferative diseases
  - Combination therapy with radiation, chemotherapy and/or immune suppressants
  - Methods for manufacturing reovirus and screening for susceptibility to reovirus
  - Pharmaceutical use of reoviruses in transplantation procedures
- Approximately 240 pending applications worldwide

## Manufacturing



- Now produced at 100L under cGMP with final formulation
- Commercial manufacturing agreement with SAFC in place

## Market & Capital Data

Exchanges	NASDAQ:ONCY TSX:ONC	
Shares Outstanding (Sept. 30, 2011)	71,239,918	
Warrants Expiring	Price	
Nov 8, 2012	\$6.15	1,794,750
Nov 8, 2012	\$4.60	375,360
Options	\$4.52 (average)	4,681,494
Fully Diluted (Sept. 30, 2011)	78,091,522	
Est. Cash/Cash Equivalents (Sept. 30, 2011)	\$42.1M	

## Oncolytics Summary

### REOLYSIN – A Broadly Active Novel Cancer Therapy

#### ▪ Focused Clinical Program

- Lead product is REOLYSIN®
- Phase III REOLYSIN and paclitaxel/carboplatin in platinum-refractory head and neck cancer patients (international study)
- Randomized Phase 2 REOLYSIN and paclitaxel in ovarian and reproductive organ cancer patients (US)
- Randomized Phase 2 REOLYSIN and paclitaxel/carboplatin in recurrent or metastatic pancreatic cancer (US)

#### ▪ Growing Intellectual Property Portfolio

- Broad patent coverage in US, Canada and Europe

#### ▪ Manufacturing at Commercial Scale

- 100L cGMP completed, commercial manufacturing agreement in place



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