

20 June 2011

Oncolytics Biotech

Year End	Revenue (C\$m)	PBT* (C\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/09	0.0	(16.0)	(26.1)	0.0	N/A	N/A
12/10	0.0	(20.0)	(29.5)	0.0	N/A	N/A
12/11e	0.0	(30.7)	(41.9)	0.0	N/A	N/A
12/12e	0.0	(29.4)	(36.2)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding goodwill amortisation and exceptional items.

Investment summary: Building for success

Oncolytics has taken a major step in its commercialisation plan for Reolysin by establishing a commercial supply agreement with SAFC. Meanwhile, the pivotal Phase III study in head and neck cancer should render interim data in Q3, with final results, expected at the end of 2012, likely to be the catalyst for a partnership. Data from an ongoing study in NSCLC shows an encouraging 30% response rate in EGFR/K-RAS mutant patients. The NCI is to initiate a study in multiple myeloma, expanding the Reolysin development programme to 13 trials, three of which are randomised, in a total of nine different cancer indications.

Commercial supply agreement

Oncolytics recently entered into a commercial supply agreement for Reolysin with SAFC, a division of Sigma-Aldrich. SAFC will continue to supply clinical requirements but will also develop, scale-up and optimise manufacturing of Reolysin so that it can supply commercial material on approval. Oncolytics is preparing to expand clinical supplies and build inventory for potential commercial sales.

Encouraging preliminary lung cancer data

Oncolytics is to present interim preliminary results from a Phase II NSCLC study; of the 20 patients, there were six PRs (30%), 12 SD (60%) and 2 PD (10%), which translate into a clinical benefit rate (CR+PR+SD) of 90% and a response rate (CR+PR) of 30%.

Financials: Funded to H212

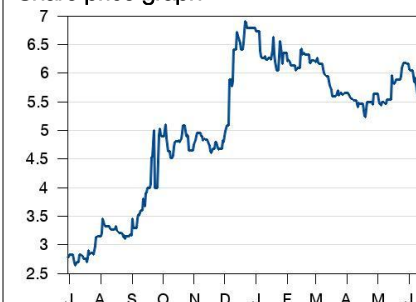
Oncolytics had cash of C\$49.9m at 31 March 2011 after receiving C\$14.5m from the exercise of warrants issued in November 2009 and 2010. The company also raised C\$28.8m in November 2010.

Valuation: Risk-adjusted NPV of C\$494m

We estimate a risk-adjusted NPV of C\$494m based on prudent assumptions of Reolysin's potential pricing and market share and applying industry-standard probabilities in each indication. This compares with the EV of C\$323m. However, our methodology is conservative and it may be justifiable to assume a higher, Phase II/III probability in all the indications given the common mechanism. The recent c \$1bn acquisition of BioVex by Amgen gives an indication of a possible trade sale value.

Price **C\$5.24**
Market Cap **C\$373m**

Share price graph



Share details

Listings and Codes **TSX: ONC**
NASDAQ: ONCY
Sector **Pharmaceuticals & Biotech**
Shares in issue **71.1m***
**Fully diluted 76.8m.*

Price

52 week **High** **Low**
C\$7.00 **C\$2.53**

Balance Sheet as at 31 December 2011*

Debt/equity (%) **N/A**
NAV per share (c) **36**
Net cash (C\$m) **41**

** Edison estimates.*

Business

Oncolytics Biotech is a Canadian company focused on developing Reolysin, a pharmaceutical formulation of the oncolytic reovirus, for the treatment of a wide variety of human cancers (Phase III trial in head and neck cancer).

Valuation

	2010	2011e	2012e
P/E relative	N/A	N/A	N/A
P/CF	N/A	N/A	N/A
EV/sales	N/A	N/A	N/A
ROE	N/A	N/A	N/A

Revenues by geography

UK	Europe	US	Other
0%	0%	0%	0%

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Oncolytics Biotech is a research client of Edison Investment Research Limited

Investment summary: Commercialisation/trials expand

Company description: Oncolytic virus specialist

Oncolytics is a Canadian biotech company focused exclusively on the development of Reolysin, a pharmaceutical formulation of the naturally-occurring, and normally non-pathogenic, reovirus (respiratory enteric orphan virus), for the treatment of cancer. This virus preferentially replicates in and destroys cells with an activated RAS signalling pathway, which is common to many cancers. Oncolytics is conducting a pivotal Phase III trial for squamous cell carcinoma of the head and neck and 12 other Phase I or II studies, many in collaboration with partners including the US NCI. Oncolytics has completed 14 Phase I and II studies with Reolysin involving some 340 patients to date. The company was formed in 1998 and floated on TSX in June 2001 and NASDAQ in October 2001. It has raised more than C\$134m of equity funding to date. The company employs 14 staff and has around 55 associates in collaborating research institutes.

Valuation: Risk-adjusted NPV of C\$494m

Our risk-adjusted NPV of C\$494m is derived exclusively for Reolysin and is based on prudent assumptions of potential pricing and market share, using industry-standard probabilities of success in each indication. This compares with an EV of C\$323m (market cap of C\$373m minus C\$50m of cash). However, this approach is conservative and a higher (eg Phase II/III) probability may be justified in all indications given the common mechanism. A novel product that demonstrates significant improvement in survival across multiple oncology indications should be a very attractive licensing candidate to a major pharmaceutical company as it would be expected to achieve 'blockbuster' sales. The recent c \$1bn acquisition of BioVex by Amgen gives an indication of possible trade sale value.

Sensitivities

Oncolytics is exposed to typical biotech company drug development risks, including the unpredictable nature of trials and the requirements of partners and potential partners. It also has a very high single product risk with all of its value residing in Reolysin. Oncolytics has attempted to reduce this risk by targeting several different indications simultaneously to find the quickest route to achieve proof of concept. The SPA agreement with the FDA suggests that the virus is, in principle, approvable. Reolysin will need to demonstrate a significant improvement in overall survival in each indication to be successful. Reolysin is unlikely to reach the market before 2013; therefore Oncolytics will need to enter a licensing deal with upfront and milestone payments if it is to avoid raising more capital in the meantime.

Financials: Funded to H212

Oncolytics has cash of C\$49.9m at 31 March 2011, after receiving C\$14.5m following the accelerated exercise of warrants this year. The company also raised C\$28.8m gross in November 2010. Oncolytics has 71.1m shares in issue and 1,868,700 warrants priced at C\$6.15 and 375,360 warrants priced at C\$4.60, both expiring on 8 November 2012, although Oncolytics can accelerate the expiry date. Our model suggests Oncolytics will need to raise capital in H212 unless it signs a licensing deal. No licensing income has been assumed in our financial model, as per our policy. Oncolytics reports quarterly in Canadian dollars in accordance with Canadian GAAP.

Investment summary: Focus on Phase III SCCHN study

Oncolytics' investment case centres on the outcome of its pivotal Phase III study in head and neck cancer, which if successful would confirm the clinical utility of Reolysin and could be the catalyst for a licensing deal. Meanwhile, Oncolytics is making progress with its preparations to commercialise Reolysin, assuming a successful outcome of this pivotal study, by entering into a commercial supply agreement with SAFC for the commercial manufacture of Reolysin. The company is also continuing to expand its clinical development programme with Reolysin with a new study in multiple myeloma.

The company's pivotal Phase III study in squamous cell carcinoma of the head and neck (SCCHN) should render interim data in mid-2011 and final results at end-2012. These data could provide the basis for a licensing deal for Reolysin, either a global or possibly regional carve-out deal. Industry interest in oncolytic viral therapy is growing, as evidenced by Amgen's purchase of BioVex, a leading oncolytic virus company, for up to US\$1bn in cash and milestone payments.

Commercial supply agreement in place

Oncolytics has started to implement a plan to commercialise Reolysin by entering into a commercial supply agreement for the commercial manufacture with SAFC, the custom manufacturing and services business unit of Sigma-Aldrich. SAFC will continue to supply clinical requirements but will also develop, scale-up, and optimise the manufacturing of Reolysin so that it can supply commercial material on the product's approval. Oncolytics is preparing to expand its clinical supplies and build inventory for potential commercial sales.

New Phase I study in multiple myeloma

The NCI is sponsoring a Phase I open-label proof of concept study of Reolysin alone in relapsed multiple myeloma patients. The study will recruit around 12 patients, in a standard cohorts-of-three dose escalation design, who will receive Reolysin up to 3×10^{10} TCID₅₀ per day administered intravenously on days one through five every 28 days. The primary endpoint will be adverse events using CTCAE criteria and the efficiency of reovirus replication in patient myeloma cells. Secondary endpoints will include clinical benefit, duration of response and time to progression. This is the sixth NCI sponsored Reolysin clinical trial.

Encouraging non-small cell lung cancer data

Oncolytics is to present an abstract of interim preliminary data from an ongoing Phase II in non-small cell lung cancer (NSCLC) study (REO16) at the 2011 World Conference on Lung Cancer. The results show that of the 20 patients, there were six PRs (30%), 12 SD (60%) and 2 PD (10%), which translate into a clinical benefit rate (CR+PR+SD) of 90% and a response rate (CR+PR) of 30%.

Data from the REO 015 study in SCCHN is also due in Q112. This will complement the REO 011 Phase I/II trial which mostly recruited these patients. Although SCCHN represents an early potential niche indication for Reolysin, NSCLC, colorectal and pancreatic cancer indications are more commercially important.

A summary of ongoing studies is shown in Exhibit 1 and data from completed Phase I and II studies are shown in Exhibit 2 (overleaf).

Exhibit 1: Reolysin clinical studies underway

Code	Indication	Notes
REO 018	SCCHN	280-pt Phase III trial of carboplatin/paclitaxel ± Reolysin in platinum-refractory (ie second line) metastatic/recurrent SCCHN. Study is structured in a two-stage adaptive design. Primary endpoint: OS. Secondary endpoints: PFS, S&T (interim results: Q311, final results: Q113).
REO 015	SCCHN	14-pt open-label Phase II trial of Reolysin with paclitaxel/carboplatin. Primary endpoint: ORR. Secondary objectives: disease control rate, duration of response, TTP, OS and S&T (results: Q112).
REO 016	NSCLC	36-pt open-label Phase II trial with paclitaxel and carboplatin in metastatic or recurrent NSCLC with Kras or EGFR-activated tumours. Primary endpoints: ORR and PFS6. Secondary endpoints: median OS, PFS and OS at one year, and safety and tolerability (results: Q411). Abstract for presentation at the World Conference on Lung Cancer shows of 20 pts, there were six PRs (30%), 12 SD (60%), 2 PD (10%), translating into a clinical benefit rate (CR+PR+SD) of 90% and a response rate (CR+PR) of 30%.
REO 020	Metastatic melanoma	43-pt open-label Phase II trial with carboplatin and paclitaxel. Primary endpoint: ORR. Secondary endpoints: PFS and OS, disease control rate and duration and S&T (results: Q212).
REO 021	Squamous NSCLC	55-pt open-label Phase II trial in combination with paclitaxel/carboplatin in metastatic or recurrent squamous NSCLC in chemotherapy-naïve patients. Primary endpoint: ORR. Secondary endpoints: PFS6 and OS (results: Q212).
REO 017	Pancreatic cancer	33-pt open-label Phase II study of Reolysin with gemcitabine in advanced or metastatic pancreatic cancer. Primary endpoint: clinical benefit rate. Secondary endpoints: PFS, S&T. Two stage design (final results: Q212). First six pts showed symptomatic improvement (4 SD, 1 PR).
NCI Study	Ovarian cancer	45-pt open-label Phase II trial in ovarian epithelial, primary peritoneal or fallopian tube cancer unresponsive to platinum chemotherapy given as IV and intraperitoneally (IP). Primary endpoint: S&T, MTD of IP Reolysin when used with IV Reolysin and ORR (results: H211).
GOG-0186H	Ovarian cancer	NCI/GOG-sponsored 150-pt Phase II study of carboplatin/paclitaxel plus Reolysin in recurrent or persistent ovarian, fallopian tube or primary peritoneal cancer (results: Q113).
NCI Study	Pancreatic cancer	70 pt open-label randomised Phase II study of carboplatin/paclitaxel ± Reolysin for first-line treatment of recurrent or metastatic pancreatic cancer. Primary endpoint: PFS. Secondary endpoints: ORR and OS (results: H114).
REO 022	Colorectal cancer	12-20 pt dose escalation Phase I trial of Reolysin with FOLFIRI (three dose levels each with 3-6 pts) in oxaliplatin-refractory or intolerant, K-Ras-mutant CRC. Primary endpoint: MTD and DLT. Secondary endpoints: ORR, CBR, PFS, OS, and safety and tolerability (results: Q112).
REO12	Solid tumours	IV administration in combination with cyclophosphamide (incl pancreatic, lung, ovarian).
COG	Solid tumours	The NCI/COG 30-pt Phase I open-label dose-escalation study of Reolysin in combination with cyclophosphamide in pts aged three to 21 years with relapsed/refractory solid tumours (results: Q411).
NCI Study	Multiple myeloma	NCI 12-pt Phase I open-label standard cohorts of 3 dose escalation study of Reolysin in relapsed multiple myeloma patients. Primary endpoint: adverse events and the efficiency of reovirus replication in myeloma cells. Secondary endpoints: clinical benefit, duration of response and TTP (not started yet).

Source: Edison Investment Research

Exhibit 2: Completed Reolysin studies

Code	Indication	Notes
REO 014	Sarcoma	53-pt Phase II study (completed in November 2009) demonstrated positive results.
REO 013	mCRC	10 pt open-label UK translational study of IV Reolysin in pts prior to surgical resection of the colorectal liver metastases. Primary objectives are to assess the presence, replication and anticancer effects of reovirus within liver metastases by examination of the resected tumour. Early results reported in 2010 concluded that the reovirus could be delivered successfully specifically to colorectal liver metastases. (Enrolment completed , results: Q311)
REO 011	Head/neck cancer	31-pt Phase I/II study in solid tumours (24 head and neck) in combination with carboplatin/paclitaxel. 19 head/neck cancer pts were evaluable for response (mostly SCCHN refractory to previous platinum-based chemotherapy for recurrent/metastatic disease). 8 PRs (42%) and 6 SDs (32%). Mean OS was > 8 months. Results presented at ASCO 2010.
REO 010	Refractory solid tumours	25-pt Phase I trial of Reolysin combined with docetaxel. 16 pts were suitable for response assessment. The combination was deemed to be safe and well tolerated and a maximum tolerated dose was not reached. 1 CR, 3 PRs and DCR (CR+PR+SD) of 88%. Publication .
REO 009	Refractory advanced cancer	16-pt Phase I/II trial of Reolysin in combination with gemcitabine in 16 heavily pre-treated pts. Of the 10 pts evaluable for response, 2 PRs (breast and nasopharyngeal) and 5 SDs for 4-8 cycles for a total disease control rate of 70%. Presentation .
REO 008	Solid tumours	16 heavily pre-treated pts were administered Reolysin intratumourally in combination with low-dose radiation. 14 evaluable pts, 13 SD, including 4 PRs for a disease control rate of 93%. Results .
REO 007	Gliomas	44-pt open-label Phase I/II trial using intralesional administration. Enrolment completed : April 2010. Results due shortly.
REO 006	Solid tumours	23-pt Phase I/II dose-escalation trial of intratumoural delivery of Reolysin in combination with radiation (at two different doses). 2 PRs and 5 SDs out of 7 evaluable pts in the low-dose (20Gy) and 5 PRs out of 7 evaluable pts in the high-dose (36Gy) radiation group. Publication .
REO 005	Solid tumours	Phase I systemic administration trial presented at ASCO 2007.
REO 004	Solid tumours	18-pt Phase I trial of systemic delivery of Reolysin. One PR (anthracycline/taxane refractory breast cancer) and 7 SDs. ORR appeared higher in pts with viral shedding (67%) than those without (33%). Poster .
REO 003	Malignant glioma	12-pt Phase I dose-escalating trial (intratumoural injection). 3 pts lived >1 year with one alive c 45 months post-treatment. Final results presented in ASCO 2006 . Published in 2008. Median survival was 21 weeks. Median TTP was 4.3 weeks (range: 2.6-39).
REO 002	Prostate	6-pt Phase I study shows evidence of viral activity in 5 pts (single intra-tumoural dose).
REO 001	Advanced solid tumours	18-pt Phase I study of sc administration. Evidence of viral activity seen in 11 pts (61%) with the tumour regression ranging from 32-100%.

Source: Edison Investment Research

Multiple myeloma (MM) is cancer of the plasma cells in the bone marrow. Plasma cells are a type of white blood cell that produces antibodies. Collections of abnormal cells accumulate in bones causing bone lesions, which can result in bone fractures, severe pain and hypercalcaemia, and in the bone marrow, where they interfere with the production of normal blood cells, which can result in anaemia, increased susceptibility to infections and bleeding. Most patients also produce a paraprotein, an abnormal antibody, which can cause acute and chronic renal failure and immunodeficiency. MM mainly affects older adults and is more common in men and is twice as common in black people as it is in white people. The aetiology is unknown but there is an increased incidence in patients exposed to radiation.

Although essentially incurable, remissions may be induced with steroids, chemotherapy, thalidomide and stem cell transplants. Newer drugs, such as lenalidomide and bortezomib, are often used in more advanced disease. Radiotherapy can be used to treat symptomatic bone lesions. With conventional treatment, the prognosis is three to four years, which may be extended to five to seven years or longer with advanced treatments; the five-year survival rate between 1999 and 2005 was approximately 37%. MM cells are frequently RAS activated, especially in relapse, and may, therefore, be a good target for Reolysin.

Head and neck cancer

REO 018 is a pivotal Phase III trial examining Reolysin in combination with paclitaxel and carboplatin using the standard regimen for patients with platinum-refractory head and neck cancers. The trial has been divided into two phases; the first phase of 80 patients is designed for a decision in futility based on PFS before continuing with the second phase of the study of around 194 patients. Reolysin is administered as the standard regimen. The interim PFS data will be used to predict OS for the second phase of the study. The trial commenced enrolment in May 2010 and could render interim data in mid-2012 and final data at the end of 2012, which should support an FDA and MHRA regulatory application in this niche indication (as the trial is subject to an SPA).

Exhibit 3: Selected competing SCCHN development programmes (Phase II or later)

Product	Company	Notes
Tykerb (lapatinib)	GSK	680-pt Phase III study in post-operative (adjuvant) and maintenance setting in high-risk subjects with resected SCCHN (results: June 2012).
Vectibix (panitumumab)	Amgen	800-pt EORTC-sponsored Phase III study of post-operative chemo-radiotherapy ± panitumumab; 110-pt Phase II study of docetaxel/cisplatin ± panitumumab (results due: July 2010). A 658-pt Phase III trial (SPECTRUM) of cisplatin/5-FU ± panitumumab in metastatic and/or recurrent SCCHN did not show a difference in OS (11.1 vs 9 months).
Arzerra (zalutumumab)	GSK/Genmab	286-pt Phase III study of zalutumumab in combination with BSC shows median OS of 6.7 months vs 5.2 months for BSC alone (p=0.0648). Patients showed a 61% increase in PFS vs BSC alone (p=0.0010). 100-pt Phase II study in non-curable SCCHN (results: Q111).
Erbix (cetuximab)	Merck KGaA	65-pt Phase III study (CHANGE) in combination with cisplatin and 5-FU (results: January 2011).
Oncovex ^{GM-CSF}	Amgen	528-pt Phase III study of OncoVEX ^{GM-CSF} with cisplatin in SCCHN (results: October 2014).
Avastin (bevacizumab)	Roche	ECOG-sponsored 400-pt Phase III study of chemotherapy ± bevacizumab in recurrent/metastatic H/N cancer (results: August 2013).
nimotuzumab	YM Biosciences/ Biocon	710-pt Phase III study of cisplatin/radiotherapy ± nimotuzumab as adjuvant treatment (results: June 2012) and 150-pt Phase III study in combination with chemo-radiotherapy. 37-pt Phase II of nimotuzumab + cisplatin/radiotherapy in locally advanced disease (results: July 2014).
Tarceva (erlotinib)	Roche/Astellas	100-pt Phase II trial in combination with docetaxel/cisplatin (results: May 2012).
Taxotere (docetaxel)	Sanofi-Aventis	240-pt Phase III trial of docetaxel in combination with 5-FU/cisplatin (results: December 2012).
EMD 1201081	Merck KGaA	104-pt Phase II trial in combination cetuximab (results: May 2011).
cilengitide	Merck KGaA	195-pt Phase I/II trial (ADVANTAGE) in combination with cisplatin/5-FU (results: Jan 2012).
Affinitor (everolimus)	Novartis	160-pt Phase II study as monotherapy (results: Dec 2015).
Nexavar (sorafenib)	Bayer/Onxy	43-pt Phase I/II study of sorafenib+ cetuximab (results due: January 2010); 43-pt Phase I/II study of sorafenib/carboplatin/paclitaxel (results: April 2011); 88-pt Phase II in combination with sorafenib (results: Jan 2016).

Source: Edison Investment Research

Oncolytic virus space

There appears to be growing interest in oncolytic viruses as a new therapeutic approach in cancer. Oncolytics is one of five companies with clinical-stage oncolytic virus products and effectively one of the two leaders in this niche area (Amgen being the other, following its purchase of BioVex), although there are also a number of studies of academic products in this area; see Exhibit 4 for details.

Exhibit 4: Oncological viral therapy competitors

Product	Company	Description	Development status/notes
OncoVEX ^{GM-CSF}	Amgen	Oncolytic HSV expressing GM-CSF	528-pt Phase III trial of OncoVEX ^{GM-CSF} vs GM-CSF in SCCHN (results: October 2014). 430-pt Phase III study in previously-treated, unresectable (Stage IIIb, IIIc and IV) melanoma (results: June 2011).
JX-594	Jennerex Biotherapeutics/ Transgene	Thymidine kinase-deleted vaccinia virus plus GM-CSF	Phase II trials planned in colon, H/N, melanoma and NSCLC. 10-pt Phase II study in combination with sorafenib in unresectable primary HCC (results: Jan 2011). Interim results from seven pts showed six Choi (necrotic) responses, five SDs and one PR (Sept 2010). Partnered with Transgene .
GL-ONC	Genelux	Engineered vaccinia	60-pt Phase I trial in lung cancer and mesothelioma (results due May 2010; still not reported).
Cavatak	Viralytics	Engineered coxsackievirus A21	9-pt Phase I trials under way in head and neck cancer and solid tumours and completed in melanoma.
HF10	Takara Bio	HSV Type 1	18-pt Phase I study in refractory SCCHN (results due: February 2012). Takara Bio acquired HF10 from M Science in October 2010.
MTH-68H	Hassadah University	Newcastle disease virus	30-pt Phase I/II study in glioblastoma multiforme, sarcoma and neuroblastoma.
NTX-010	NCI	Seneca Valley virus	34-pt Phase I study in neuroblastoma (results: June 2010); 99-pt Phase II study in SCLC (results: January 2012).
vDD-CDSR	University of Pittsburgh	Vaccinia virus	36-pt Phase I study in superficial injectable tumours (results: March 2012)
HSV1716	Children's Hosp Cincinnati	Mutant HSV type I, deleted RL1 gene	18-pt Phase I study in non-CNS solid tumours (results: October 2012).
CG0070	Biosante	Adenovirus type 5	75-pt Phase I study in bladder cancer after BCG failure (study run by Cell Genesys, subsequently acquired by Biosante).
CGTG-102	Oncos Therapeutics	Adenovirus type 5	21-pt Phase I/II study in advanced solid tumours, refractory to standard therapies, presented at ASCO 2010.

Source: Edison Investment Research

Sensitivities

Oncolytics is exposed to the usual biotech company development risks, including the unpredictable outcome of trials and a high single-product risk, with the entirety of its value residing in Reolysin. The existence of the SPA suggests that the FDA is prepared to approve Reolysin. However, it will need to demonstrate a significant improvement in overall survival, with an acceptable toxicity profile, to receive approval, given the unknown risks of injecting reoviruses into humans. It is possible that the FDA may request that Oncolytics conducts additional studies to support its pivotal Phase III trial to achieve FDA approval. In the near term, Oncolytics will need a licensing deal to commercialise Reolysin and fund pivotal Phase III trials in larger indications such as NSCLC and colorectal cancer. Ideally, such a partner would have an established oncology franchise so that it can provide the resources and experience to conduct trials in multiple indications to fully exploit the novel technology. A licensing deal should achieve a significant re-rating in valuation.

Valuation

Our risk-adjusted NPV of C\$494m is derived exclusively for Reolysin, which compares with an EV of C\$323m (market cap of C\$373m minus C\$50m of cash). This valuation is based on prudent assumptions of each product's probability of success, launch date, pricing and market penetration. This valuation assumes probabilities of trial success in eight different indications in line with industry norms. However, we note this approach may be considered conservative and a higher (eg Phase II/III) probability could be justified in all indications given the common mechanism. Our valuation model comprises assumptions tabulated in Exhibit 5.

Exhibit 5: Assumptions used in the valuation model

Cancer	Incidence 2015	Peak penetration	Year of peak	Probability of success
Head and neck	186,000	30%	2018	60%
NSCLC	421,000	50%	2019	30%
Squamous cell lung	281,000	30%	2019	30%
Metastatic melanoma	174,000	30%	2019	30%
Pancreatic	104,000	30%	2020	40%
Sarcoma metastatic to lung	16,000	30%	2018	30%
Ovarian	63,000	30%	2022	15%
Colorectal	436,000	30%	2022	15%

Source: Edison Investment Research

Success in each indication would nevertheless require demonstration of a significant improvement in survival. We have assumed that pricing averages C\$20,000 per patient per course of treatment, each patient has only one course of treatment, and that Phase III trials are completed by a licensing partner, excluding the current SCCHN trial. A novel product that demonstrates significant improvement in survival across multiple oncology indications should be a very attractive licensing candidate to a major pharmaceutical company as it would be expected to achieve 'blockbuster' sales. The recent c \$1bn acquisition of BioVex by Amgen gives an indication of possible trade sale value.

Financials

Oncolytics had cash of C\$49.9m at 31 March 2011, after receiving C\$14.5m following the accelerated exercise of warrants this year. The company also raised C\$28.8m gross in November 2010. Oncolytics has 71.1m shares in issue and 1,868,700 warrants priced at C\$6.15 and 375,360 warrants priced at C\$4.60, both expiring on 8 November 2012, although Oncolytics can accelerate the expiry date.

Our model suggests Oncolytics will need to raise capital in H212 unless it signs a licensing deal. A licensing deal with a major pharmaceutical company with an oncology franchise would provide the resources and funding to enable pivotal Phase III trials to be conducted in multiple cancer indications simultaneously, particularly the larger indications such as NSCLC and colorectal cancer, which, if successful, would enable Reolysin to achieve 'blockbuster' status.

No upfront or milestone payments from a potential licensing partner have been assumed in our model. Edison's financial model is shown in Exhibit 6 (overleaf).

Exhibit 6: Financials

	C\$'000s	2007	2008	2009	2010	2011e	2012e
Year end 31 December		Can GAAP	Can GAAP	Can GAAP	Can GAAP	Can GAAP	Can GAAP
PROFIT & LOSS							
Revenue		0	0	0	0	0	0
Cost of sales		0	0	0	0	0	0
Gross Profit		0	0	0	0	0	0
EBITDA		(16,760)	(17,659)	(16,021)	(20,006)	(30,763)	(29,200)
Operating profit (before GW and except.)		(16,801)	(17,708)	(16,058)	(20,043)	(30,804)	(29,245)
Intangible amortisation		(362)	(362)	(181)	0	(181)	(181)
Exceptionals		0	0	0	0	0	0
Other		0	0	0	0	0	0
Operating profit		(17,162)	(18,069)	(16,239)	(20,043)	(30,985)	(29,426)
Net interest		(1,212)	519	29	77	100	50
Profit before tax (norm.)		(18,012)	(17,189)	(16,029)	(19,966)	(30,704)	(29,195)
Profit before tax (FRS 3)		(18,374)	(17,550)	(16,210)	(19,966)	(30,885)	(29,376)
Tax		0	0	(22)	(8)	0	0
Profit after tax (norm.)		(18,012)	(17,189)	(16,051)	(19,974)	(30,704)	(29,195)
Profit after tax (FRS 3)		(18,374)	(17,550)	(16,232)	(19,974)	(30,885)	(29,376)
Average number of shares outstanding (m)		41.2	43.8	61.5	67.8	73.3	80.6
EPS – normalised (c)		(43.7)	(39.2)	(26.1)	(29.5)	(41.9)	(36.2)
EPS – FRS 3 (c)		(44.6)	(40.0)	(26.4)	(29.5)	(42.2)	(36.5)
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET							
Fixed assets		743	445	892	963	805	649
Intangible assets		542	181	0		(181)	(362)
Tangible assets		201	264	208	227	250	275
Investments		0	0	684	736	736	736
Current assets		25,554	13,543	34,701	43,470	40,988	13,038
Stocks		0	0	0	0	0	0
Debtors		80	86	65	285	305	326
Cash		25,214	13,277	34,129	42,906	40,683	12,712
Current liabilities		(2,821)	(4,534)	(4,227)	(2,501)	(3,501)	(4,901)
Creditors		(2,821)	(4,534)	(4,227)	(2,501)	(3,501)	(4,901)
Short-term borrowings		0	0	0	0	0	0
Long-term liabilities		0	0	0	0	0	0
Long-term borrowings		0	0	0	0	0	0
Other-long term liabilities		0	0	0	0	0	0
Net assets		23,476	9,453	31,366	41,932	38,292	8,786
CASH FLOW							
Operating cash flow		(14,422)	(15,289)	(16,064)	(21,952)	(29,783)	(27,821)
Net interest		1,393	770	(29)	(77)	(100)	(50)
Tax		0	0	0	0	0	0
Capex		(92)	(112)	(9)	(100)	(100)	(100)
Acquisitions/disposals		0	0	0	0	0	0
Financing		11,575	3,399	36,926	28,817	27,760	0
Dividends		0	0	0	0	0	0
Net cash flow		(1,546)	(11,232)	20,823	6,688	(2,223)	(27,971)
Opening net debt/(cash)		(27,614)	(25,214)	(13,277)	(34,129)	(42,906)	(40,683)
HP finance leases initiated		0	0	0	0	0	0
Other		146	(705)	30	2,089	0	0
Closing net debt/(cash)		(26,214)	(13,277)	(34,129)	(42,906)	(40,683)	(12,712)

Sources: Edison Investment Research, Oncolytics Biotech accounts

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