

# **Oncolytics Biotech**

## Promising lung cancer data

Promising tumour response data from two Phase II studies of Reolysin in squamous cell carcinoma of the lung (SCC lung) and in non-small cell lung cancer (NSCLC) support further randomised trials in these indications. Oncolytics has an ongoing Phase II trial in SCC and adenocarcinoma of the lung. Data from the lead Phase II squamous cell head and neck cancer trial are expected soon.

Year end	Revenue (C\$m)	PBT* (C\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/11	0.0	(28.3)	(39.9)	0.0	N/A	N/A
12/12	0.0	(36.3)	(47.3)	0.0	N/A	N/A
12/13e	0.0	(37.2)	(43.9)	0.0	N/A	N/A
12/14e	0.0	(36.3)	(42.2)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

## Positive Phase II lung cancer data

Results from a single-arm Phase II trial (REO 021) in metastatic stage IIIB or stage IV, or recurrent chemotherapy-naïve SCC lung patients treated with Reolysin in combination with carboplatin and paclitaxel demonstrated that of the 25 evaluable patients, 23 (92%) exhibited overall tumour shrinkage (mean shrinkage was 32.7%); 10 (40%) had partial responses (PRs), 13 (52%) showed stable disease (SD) and two (8%) had progressive disease (PD), for a disease control rate [DCR] (complete response [CR] + PR + SD) of 92%. Final results from a single-arm Phase II trial (REO 016) in metastatic NSCLC patients with a Ras-activated pathway treated with Reolysin in combination with carboplatin and paclitaxel showed that of the 37 evaluable patients, 11 (30%) had PRs, 21 (57%) SD and four (11%) PD for a DCR of 89%. To date, six-month PFS was 36% and one-year survival was 53%.

## More active in metastatic head and neck cancer

Preliminary data from the REO 018 Phase III trial in squamous cell carcinoma of the head and neck (SCCHN) suggested that Reolysin in combination with carboplatin and paclitaxel was more active in metastatic than in loco-regional disease. The trial has been restructured to provide data for the basis for a future pivotal study in metastatic SCCHN; these data are expected soon.

### Financials: Funded to H214

Following a capital raising of around US\$32m (gross) in February, Oncolytics ended Q2 with cash of C\$38.2m, which should provide a cash runway into H214.

### Valuation: Risk-adjusted NPV of C\$457m

Our rNPV has increased to C\$457m following the recent positive SCC lung and NSCLC data. This is based on prudent assumptions of Reolysin's probability of success in each indication, launch date, pricing and market penetration. By comparison, Oncolytics's EV is currently C\$174m, based on a market cap of C\$212m and end-Q2 cash of C\$38.2m.

Update: SCC lung data

Pharma & biotech

#### 3 October 2013

Price	C\$2.50
Market cap	C\$212m

 Net cash (C\$m) at end June 2013
 38.2

 Shares in issue
 84.8m

 Free float
 98%

 Code
 ONC

 Primary exchange
 TSX

 Secondary exchange
 NASDAQ

### Share price performance



### **Business description**

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).

# Next events SCCHN data Q413 Pancreatic Phase II data Q413

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## **Oncolytics datasheet**

Code	Indication	Trial design	Notes	
REO 018	Squamous cell carcinoma of the hea and neck (SCCHN)	160-pt Phase III trial of carboplatin/paclitaxel ±	<b>Primary:</b> OS. Secondary: PFS, S&T. Reolysin + carbo-tax shown to be significantly better than control in stabilising or shrinking metastatic tumours (p=0.03) (results: H213).	
		local ± mets and distal mets.		
IND211 (NCIC-CTG)	Non-small cell lung cancer (NSCLC)	150-pt Phase II study of pemetrexed ± Reolysin (squamous) or docetaxel ± Reolysin (adeno).	<b>Primary</b> : PFS. <b>Secondary</b> : AE, RR (PR, ORR, OS), molecular factors (results: Q414).	
IND213 (NCIC-CTG)	Metastatic breast cancer	100-pt Phase II trial of Reolysin ± paclitaxel.	<b>Primary</b> : PFS. <b>Secondary</b> : ORR, OS, molecular factors (results: Q414).	
IND210 (NCIC-CTG)	Metastatic colorectal cancer	100-pt Phase II trial of FOLFOX6 and bevacizumab ± Reolysin.	<b>Primary</b> : PFS. <b>Secondary</b> : CEA, ORR, OS, molecular factors and QoL (results: Q214).	
REO 022	Cancer	12-20-pt Phase I trial of Reolysin with FOLFIRI (three doses, each with 3-6 pts) in oxaliplatin-refractory or intolerant KRAS mutants.	Primary: MTD and DLT. Secondary: ORR, CBR, PFS, OS, and safety and tolerability (results: TBA).	
NCIC-CTG Study	Metastatic CRPC	80-pt Phase II trial of docetaxel/prednisone ± Reolysin.	<b>Primary</b> : disease progression. <b>Secondary</b> : circulating tumour cells. PSA and OS (results: Q414).	
OSU-10045 (NCI)	Metastatic pancreatic cancer	70-pt open-label Phase II study of carboplatin/paclitaxel ± Reolysin (first-line rec/met).	Primary: PFS. Secondary: ORR and OS (results: H114).	
GOG-0186H (NCI)	Ovarian cancer	45-pt open-label Phase II trial of Reolysin given IV and intraperitoneally (IP).	<b>Primary</b> : S&T, MTD of IP Reolysin when used with IV Reolysin and ORR (results: N/A).	
GOG- 0186H		150-pt open-label Phase II study of carboplatin/paclitaxel ± Reolysin.	<b>Primary:</b> PFS and AEs. <b>Secondary:</b> PFS and OS, tumour respons by RECIST (results: H213).	
REO12	Solid tumours	36-pt open-label study of Reolysin + cyclophosphamide (incl pancreatic, lung, ovarian).	Primary: MED. Secondary: safety, anti-tumour activity.	
COG- ADVL1014 (NCI/COG)		45-pt Phase I study of Reolysin + cyclophosphamide in paediatric pts.	<b>Primary</b> : MTD, Phase II dose, AEs. <b>Secondary</b> : PK, anti-tumour activity, neutralising antibodies (results: Q414).	
OSU-11148 (NCI)	Multiple myeloma	12-pt Phase I open-label dose escalation study of Reolysin in relapsed MM.	<b>Primary:</b> AEs, MTD, ORR. <b>Secondary:</b> PFS, duration of response and TTP (results: Q114).	
Source: Edis	son Investment Res	search		
Exhibit 2:	Selected compl	eted Reolysin study results (Phase I/II	or II only)	
Code		Notes	<b>3</b> ,	
REO 021	SCC lung	36-pt open-label <u>Phase II trial</u> of Reolysin + paclitaxel/ca ORR. Secondary: PFS and OS. First stage: 5 (of 15) PR 36) pts; 9 PR, 9SD, ORR: 42.8%, DCR: 85.7%. Of 25 ev shrinkage: 32.7%); 10 (40%) PR, 13 (52%) SD and 2 (8		
REO 016		87-pt open-label Phase II trial with paclitaxel and carboplatin in metastatic or recurrent NSCLC with KRAS or EGFR-activated umours. Primary: ORR and PFS6. Secondary: median OS, PFS and OS at one year, and safety and tolerability. Interim data on 20 pts show 6 PRs (30%), 12 SD (60%), 2 PD (10%) for CBR of 90% and ORR of 30%. Final data in 37 pts: 11 PR (30%), 21 SD (57%), 4PD (11%) = 89% DCR. To date, 6-month PFS 36% and 1-year survival 53%.		
KLO 010		on 20 pts show 6 PRs (30%), 12 SD (60%), 2 PD (10%)		
REO 020	Metastatic melanoma	on 20 pts show 6 PRs (30%), 12 SD (60%), 2 PD (10%) 21 SD (57%), 4PD (11%) = 89% DCR. To date, 6-month 43-pt open-label <u>Phase II trial</u> of Reolysin + carboplatin/ <sub>l</sub> and S&T. First stage: 14 (of 18): 3 PR, 7 SD, ORR: 21.4	PFS 36% and 1-year survival 53%. paclitaxel. Primary: ORR. Secondary: PFS, OS, DCR and duration %, DCR: 71.5%. Met primary end point, but not proceeding to second	
REO 020	Metastatic melanoma  Pancreatic cancer	on 20 pts show 6 PRs (30%), 12 SD (60%), 2 PD (10%) 21 SD (57%), 4PD (11%) = 89% DCR. To date, 6-month 43-pt open-label Phase II trial of Reolysin + carboplatin/l and S&T. First stage: 14 (of 18): 3 PR, 7 SD, ORR: 21.4 stage because of changing treatment landscape. Reolys 33-pt open-label Phase II study of Reolysin + gemcitabin	PFS 36% and 1-year survival 53%. paclitaxel. Primary: ORR. Secondary: PFS, OS, DCR and duration %, DCR: 71.5%. Met primary end point, but not proceeding to second	
REO 020 REO 017	Metastatic melanoma  Pancreatic cancer  SCCHN	on 20 pts show 6 PRs (30%), 12 SD (60%), 2 PD (10%) 21 SD (57%), 4PD (11%) = 89% DCR. To date, 6-month 43-pt open-label Phase II trial of Reolysin + carboplatin/land S&T. First stage: 14 (of 18): 3 PR, 7 SD, ORR: 21.4 stage because of changing treatment landscape. Reolys 33-pt open-label Phase II study of Reolysin + gemcitabir SD≥12 wks; ORR: 62%, CBR of 62%.  14-pt open-label Phase II trial of Reolysin with paclitaxel	PFS 36% and 1-year survival 53%. paclitaxel. Primary: ORR. Secondary: PFS, OS, DCR and duration %, DCR: 71.5%. Met primary end point, but not proceeding to second in to be re-evaluated with new immunotherapies. The Primary end point met in Dec 2011 with 8/13 evaluable pts in comparation. All 14 pts had received previous chemotherapy and/or t. Of the 13 pts evaluable for response, 4 PRs; ORR of 31%. 6 SD>1	
	Metastatic melanoma  Pancreatic cancer  SCCHN  Sarcoma	on 20 pts show 6 PRs (30%), 12 SD (60%), 2 PD (10%) 21 SD (57%), 4PD (11%) = 89% DCR. To date, 6-month 43-pt open-label Phase II trial of Reolysin + carboplatin/land S&T. First stage: 14 (of 18): 3 PR, 7 SD, ORR: 21.4 stage because of changing treatment landscape. Reolysis 33-pt open-label Phase II study of Reolysin + gemcitabir SD≥12 wks; ORR: 62%, CBR of 62%.  14-pt open-label Phase II trial of Reolysin with paclitaxel radiotherapy; 10 had received previous taxane treatmen wks, DCR of 46%. 2 of the 4 PRs and both SD patients 153-pt Phase II study (completed in November 2009) den	PFS 36% and 1-year survival 53%. paclitaxel. Primary: ORR. Secondary: PFS, OS, DCR and duration %, DCR: 71.5%. Met primary end point, but not proceeding to second in to be re-evaluated with new immunotherapies. The Primary end point met in Dec 2011 with 8/13 evaluable pts in correction. All 14 pts had received previous chemotherapy and/or t. Of the 13 pts evaluable for response, 4 PRs; ORR of 31%. 6 SD>1 and received previous treatment with taxanes.	



## **Update: Positive Phase II lung cancer data**

Promising tumour response data from the (REO 021) Phase II trial in squamous cell carcinoma of the lung (SCC lung) and the (REO 016) Phase II trial in NSCLC support further randomised trials in these indications. Meanwhile, an ongoing NCIC Phase II trial in SCC and adenocarcinoma of the lung is enrolling patients. Preliminary data from the REO 018 Phase III squamous cell carcinoma of the head and neck (SCCHN) trial suggested that Reolysin in combination with carboplatin and paclitaxel is more active in metastatic than in loco-regional disease. The trial has been restructured to provide data for the basis for a future pivotal study in metastatic SCCHN; these data are expected soon.

### Positive Phase II SCC lung and NSCLC data

Final results from a single-arm Phase II trial (REO 021) in metastatic stage IIIB or stage IV, or recurrent chemotherapy-naïve SCC lung patients treated with Reolysin in combination with carboplatin and paclitaxel demonstrated that of the 25 evaluable patients, 23 (92%) exhibited overall tumour shrinkage (mean shrinkage was 32.7%); 10 (40%) had PRs, 13 (52%) showed SD and two (8%) had PD for a disease control rate [DCR] (CR + PR + SD) of 92%. Oncolytics had previously announced that the trial had reached its primary endpoint in March. A waterfall plot is shown in Exhibit 3 below. Final progression-free survival (PFS) and safety data will be reported later in 2013. Oncolytics is now planning to conduct randomised clinical trials for SCC lung.

Patients by Increasing Overall Percentage Tumour Shrinkage

Exhibit 3: REO-021: Best overall percentage response in target lesions (final data)

Source: Oncolytics Biotech

Final results from a single-arm Phase II trial (REO 016) in metastatic or recurrent NSCLC patients with a Ras-activated pathway treated with Reolysin in combination with carboplatin and paclitaxel demonstrated that of the 37 evaluable patients (20 Kras, three EGFR, four BRAF mutations and 10 EGFR amplifications), 11 (30%) had PR (five EGFR amplified, two BRAF, three Kras and one EGFR mutated), 21 (57%) showed SD and four (11%) had PD, for a DCR of 89%. To date, PFS at six months was 36% and one-year survival was 53%. These results compare favourably with reported one-year survival rates of various chemotherapy combination treatments averaging 33% in advanced and 16% in Stage IV NSCLC patients.

Non-small cell lung cancer (NSCLC) accounts for 85% of all lung cancer and can be divided into adenocarcinoma (35-40%), squamous cell (25-30%) and large cell anaplastic (10-15%). Incidence of NSCLC is around 0.06% of the population, approximately 215,000 Americans with an estimated 161,000 deaths, see Exhibit 4 for details. NSCLC is only moderately chemosensitive, but chemotherapy is used in addition to surgery and radiotherapy to treat cancer that has spread to the lymph nodes. The standard chemotherapy regimen includes cisplatin/carboplatin, which can also be used pre-operatively.



-XIIIDIC T	: Non-small cell lung cancer background
What is non-small cell lung cancer?	Lung cancer is the commonest cause of cancer related mortality worldwide. Non-small cell lung cancer (NSCLC) accounts for 85% of all lung cancers and can be divided into: adenocarcinoma (35-40%), squamous cell carcinoma [SCC lung] (25-30%) and large cell carcinoma (10-15%). The commonest cause is smoking (80-90%). Other causes include: genetic factors ( <i>ras, c-myc, c-raf</i> oncogenes, <i>p</i> 53 tumour suppressor gene), radon gas, asbestos, arsenic, chromium, nickel and air pollution.
Incidence	US (2009): 64.3 per 100,000 or 215,000 cases and 161,000 deaths UK (2009): 49.7 per 100,000 or 41,428 cases
Staging	Based on TNM classification: Tumour (0-4), Node (0-3), Metastasis (0-1). Nearly 70% of patients have locally advanced or metastatic disease at diagnosis.
Symptoms	NSCLC is often insidious; there may be no symptoms until the disease is well-advanced. At initial diagnosis, 20% of patients have localised disease, 25% have regional metastasis and 55% have distant spread of disease. Common symptoms include: cough, chest pain, shortness of breath, coughing up blood, wheezing, hoarseness, recurrent chest infections, weight loss, anorexia and fatigue. Metastatic symptoms include: bone pain, spinal cord compression and neurological symptoms.
Diagnosis	<ul> <li>Chest X-ray, CT scan, PET scan</li> <li>Bronchoscopy and biopsy, sputum cytology, thoracoscopy, transthoracic needle biopsy.</li> </ul>
Treatment	<ul> <li>Treatments include:</li> <li>Surgery: treatment of choice for Stage I and II. Types include: lobectomy, pneumonectomy and wedge resection.</li> <li>Chemotherapy: 80% receive chemotherapy. First-line treatment should include a platinum (cis/carboplatin). Combinations include: cisplatin-gemcitabine, cisplatin-paclitaxel, cisplatin-docetaxel, and carboplatin-paclitaxel, suggested similar overall response rates (approximately 19%), and median survival (7.9 months). One- and two-year overall survival was also similar at 33% and 11%, respectively.</li> <li>Biologicals: bevacizumab, cetuximab and tyrosine kinase inhibitors: afatinib, gefitinib, erlotinib, crizotinib.</li> <li>Radiotherapy</li> </ul>
Prognosis	Five-year survival rate: US: 15.7%, EU: 8%. Depends on how advanced at diagnosis: local: 49%, regional: 16%, metastases: 2%. By stage: IA: 75%, IB: 55%, IIA: 50%, IIB: 40%, IIIA: 10-35%, IIIB: <5%, IV: <5%.

Source: Edison Investment Research

Chemotherapy combinations including cisplatin/carboplatin with vinorelbine, gemcitabine, paclitaxel/docetaxel and pemetrexed can double the response rate but toxicity is also higher. Erbitux (cetuximab) is thought to act synergistically with cis/carboplatin, paclitaxel and vinorelbine in EGFR mutant patients but toxicity can be high. Bevacizumab (Avastin) can be used in non-squamous patients. Other EGFR inhibitors are gefitinib (Iressa) and erlotinib (Tarceva). There are numerous products in Phase III trials for NSCLC including mAbs, targeted therapies such as Giotrif<sup>1</sup> (afatinib, Boehringer Ingelheim), immunotherapies and vaccines such as tecemotide (Merck KGaA/Oncothyreon). However, there are relatively few products in Phase III trials for SCC lung; see Exhibit 5 for details. The unmet medical need remains high. Patients with squamous cell carcinoma represent about 30% of all patients affected by NSCLC and has a poorer prognosis compared to non-squamous.

Exhibit 5: Products in Phase III trials for SCC lung				
Product	Company	Notes		
Gilotrif (afatinib)	Boehringer Ingelheim	800-pt Phase III randomised, open-label trial of afatinib versus erlotinib in advanced SCC lung as second-line therapy following first-line platinum-based chemotherapy. Results: Q413.		
Ipilimumab	BMS	920-pt Phase III randomised, multicentre, double-blind, trial comparing efficacy of ipilimumab/paclitaxel/carboplatin versus placebo/paclitaxel/carboplatin in stage IV/recurrent NSCLC. Results: Q215.		
TG4010	Transgene	1,000-pt randomised, double-blind Phase IIB/III study comparing first-line therapy with or without TG4010 immunotherapy stage IV NSCLC (squamous and non-squamous). Results: Q116.		
Source: Edison Investment Desearch				

Lilly recently obtained a positive Phase III result in its SQUIRE study of necitumumab as a first-line treatment of stage IV metastatic squamous NSCLC in combination with gemcitabine plus cisplatin. The study showed an increase in OS when given IMC-11F8 in combination with chemotherapy, as compared to chemotherapy alone. If approved, necitumumab would be the first biologic therapy indicated to treat patients with squamous lung cancer.

Several randomised controlled trials have failed to show a clear superiority of one platinum-containing combination over another. A landmark ECOG trial comparing cisplatin-gemcitabine, cisplatin-paclitaxel, cisplatin-docetaxel and carboplatin-paclitaxel suggested similar ORRs (around 19%) and median survival (7.9 months); one and two-year overall survival (OS) were also similar at 33% and 11% respectively. A meta-analysis comparing cisplatin-gemcitabine with other platinum-containing regimens suggested an improved median survival (9.0 versus 8.2 months) and an

Recently approved in US/EU for NSCLC with activating EGFR mutations in patients who are EGFR tyrosine kinase inhibitor-naïve.



absolute improvement in one year OS of 3.9% as compared to non-gemcitabine combinations. However, this effect was not sustained when compared against other third-generation cisplatin combinations.2

Abraxane (nab-paclitaxel, Celgene) is approved for locally advanced or metastatic NSCLC, as firstline treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. Approval was based on a single-phase, multicentre, randomised openlabel study. ORR was significantly higher (33% versus 25%; p=0.005). In SCC lung, the ORR was also statistically superior (41% vs 24%; p < 0.001). However, there was no statistically significant difference in OS.

Compound	Study	Median PFS (test vs control)	Median OS (test vs control)
Nintedanib/ Boehringer Ingelheim	1,315-pt Phase III study (LUME- LUNG-1) of docetaxel ± nintedanib	ITT: 3.4 vs 2.7 mths, HR=0.79 (95%CI: 0.68-0.92, p=0.0019).  Adenocarcinoma: 4.0 vs 2.8 mths, HR=0.77, (95%CI: 0.62-0.96, p=0.0193).  Squamous: 2.9 vs 2.2 mths, HR= 0.77 (0.62 to 0.96), p=0.0200.	ITT: 10.1 mths vs 9.1 mths, HR=0.94 (95% CI: 0.83-1.05, p= 0.2720).  Adenocarcinoma: 12.6mths vs 10.3mths, HR=0.83 (95% CI: 0.70-0.99, p=0.0359).  Squamous: 8.6 vs 8.7 mths (HR-1.01, 95% CI 0.95, 1.01, p=0.8907).
	713-pt Phase III study (LUME- Lung 2) of pemetrexed ± nintedanib	ITT: 4.4mths vs 3.6mths (HR=0.83 [95% CI: 0.7–0.99], p=0.04). DCR was significant (61% vs 53%, odds ratio 1.37, p=0.039). No difference in response rate.	No difference in OS (HR=1.03), although study was stopped early after failing interim analysis with 713 of planned 1,300 pts.
Lucanix (belagenpumat ucel-L)/ NovaRx	532-pt Phase III study in post- frontline maintenance therapy		ITT: N/S due to the inclusion of pts > 2 wks from completion of first line chemotherapy.  <12 wks from completion first line therapy (n=305): 20.7 vs 13.4 mths (HR 0.75).  Squamous: 20.7 vs 12.3 mths (HR 0.58).  Prior radiation Tx: 40.1 vs 10.3 mths (HR 0.45).
Dacomitinib/ Pfizer	188-pt Phase II trial of dacomitinib vs erlotinib	ITT: 2.86mths vs 1.91 mths (HR=0.66; 95%CI 0.47-0.91; p=0.012).  K-ras wt: 3.71 mths vs 1.91 mths (HR=0.55; 95%CI 0.35-0.85; p=0.006).  K-ras wt/EGFR wt: 2.21 mths vs 1.84 mths (HR=0.61; 95%CI 0.37-0.99; p=0.043).	ITT: 9.53 vs 7.44 mths (HR=0.80; 95%CI 0.56-1.13; p=0.205).
Onartuzumab/ Roche	128-pt Phase II study of erlotinib ± onartuzumab (second/third-line)	ITT: 2.2 mths vs. 2.6 mths, NS (HR=1.09, p=0.687). Met high: 2.9 mths vs 1.5 mths (HR=0.53; p=0.04). Met low 1.4 mths vs. 2.7 mths (HR=1.82, p=0.050)	ITT: N/A (presumably NS).  Met high: 12.6 mths vs 3.8 mths (HR=0.37; p=0.002).  Met low: 8.1 mths vs. 15.3 mths (HR=1.78, p=0.158)
Bavituximab/ Peregrine	121-pt Phase II study of docetaxel ± bavituximab	Active (n=41, 3mg/kg) vs control* (n=80, pooled pbo + 1mg/kg B). 4.5 vs 3.3 mths.	11.7 vs 7.3 mths for control.* (HR=0.73; p=0.217).
Selumetinib/ AZ/Array	87-pt Phase II study of docetaxel ± selumetinib in K-ras mt	5.3 vs 2.1 mths (HR=0.58; 80%CI 0.42-0.79; p=0.0138).	9.4 vs 5.2 mths (HR=0.80; 80%CI 0.56-1.14; p=0.2069).

which were pooled as a result of labelling errors.

### **Sensitivities**

Oncolytics is exposed to typical biotech company development risks, including the unpredictable outcome of trials, as highlighted in last year's outcome of the SCCHN study. It has a very high single-product risk, with the entirety of its value residing in Reolysin. The investment case hinges on Oncolytics's ability to secure a licensing deal to commercialise Reolysin and fund the pivotal Phase III trials required in larger indications such as NSCLC and CRC. 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.

<sup>&</sup>lt;sup>2</sup> Le Chevalier T, Scagliotti G, Natale R, Danson S, Rosell R, Stahel R, et al. Efficacy of gemcitabine plus platinum chemotherapy compared with other platinum containing regimens in advanced non-small-cell lung cancer: a meta-analysis of survival outcomes. Lung Cancer. Jan 2005; 47(1): 69-80.



### **Valuation**

Our risk-adjusted valuation has increased to C\$457m following the impact of the recent positive SCC lung and NSCLC data on our risk-adjustment; the probability of success has been increased from 30% to 40%. This valuation compares to a current EV of C\$176m, based on a market cap of C\$214m and an end-Q2 cash of C\$38.2m. This valuation model is based on what Edison believes to be prudent assumptions of probability of success, launch date, pricing and market penetration in each indication. The probabilities of success in the different indications are in line with industry norms. No upfront or milestone payments from a licensing partner have been assumed in our model. For simplicity, our valuation model assumes a Reolysin price of C\$20,000 per course of treatment across all the indications considered; however, higher pricing may be possible.

### **Financials**

Following a capital raising of around US\$32m (gross) in February, Oncolytics ended Q2 with cash of C\$38.2m, which should provide a cash runway into H214. For the capital raising, 8.0m ordinary shares were issued at US\$4.00 per share. Our forecast FY13 R&D spend has been revised to reflect fewer ongoing Oncolytics sponsored trials. However, R&D spend will be reviewed when the future of the SCCHN programme has been clarified later this year.



	C\$'000s	2011	2012	2013e	2014e	2015
Year end 31 December		Can GAAP	Can GAAP	Can GAAP	Can GAAP	Can GAA
PROFIT & LOSS						
Revenue		0	0	0	0	
Cost of sales		0	0	0	0	
Gross Profit		0	0	0	0	
EBITDA		(28,684)	(36,617)	(37,448)	(36,614)	(33,474
Operating profit (before GW and except.)		(28,725)	(36,688)	(37,521)	(36,688)	(33,548
Intangible amortisation		(736)	0	0	0	
Exceptionals		0	0	0	0	
Other		39	0	0	0	
Operating profit		(29,422)	(36,688)	(37,521)	(36,688)	(33,548
Net interest		416	345	345	345	34
Profit before tax (norm)		(28,309)	(36,343)	(37,176)	(36,343)	(33,203
Profit before tax (FRS 3)		(29,006)	(36,343)	(37,176)	(36,343)	(33,203
Tax		(40)	(30)	Ó	Ó	,
Profit after tax (norm)		(28,310)	(36,313)	(37,176)	(36,343)	(33,203
Profit after tax (FRS 3)		(29,046)	(36,374)	(37,176)	(36,343)	(33,203
Average number of shares outstanding (m)		70.9	76.7	84.8	86.1	88.
EPS – normalised (c)		(39.9)	(47.3)	(43.9)	(42.2)	(37.7
EPS – FRS 3 (c)		(41.0)	(47.4)	(43.9)	(42.2)	(37.7
Dividend per share (c)		0.0	0.0	0.0	0.0	0.
Dividend per share (c)		0.0	0.0	0.0	0.0	0.1
BALANCE SHEET						
Fixed assets		392	409	409	409	409
Intangible assets		0	0	0	0	
Tangible assets		392	409	409	409	40:
Investments		0	0	0	0	(
Current assets		35,633	21,669	16,662	3,686	3,48
Stocks		0	0	0	0	
Debtors		55	45	48	51	5
Cash		34,856	21,293	16,314	3,334	3,12
Current liabilities		(6,504)	(7,291)	(10,208)	(14,291)	(20,007
Creditors		(6,504)	(7,291)	(10,208)	(14,291)	(20,007
Short-term borrowings		0	0	0	0	
Long-term liabilities		0	0	0	(20,000)	(48,000
Long-term borrowings		0	0	0	(20,000)	(48,000
Other-long term liabilities		0	0	0	0	
Net assets		29,520	14,787	6,863	(30,196)	(64,115
CASH FLOW						
Operating cash flow		(24,451)	(36,374)	(34,534)	(32,535)	(27,761
Net interest		(416)	(345)	(345)	(345)	(345
Tax		0	0	0	0	(0-10
Capex		(100)	(126)	(100)	(100)	(100
Acquisitions/disposals		(100)	(120)	(100)	0	(100
Financing		16,917	21.747	30,000	0	
Dividends		0	21,747	30,000	0	
Net cash flow		(8,050)	(15,097)	(4,979)	(32,980)	(28,206
Opening net debt/(cash)		(42,906)	(34,856)	(21,293)	(16,314)	16,66
HP finance leases initiated		(42,900)	(34,630)	(21,293)	(10,314)	10,00
Other		0	1,535	0	0	
Closing net debt/(cash)		(34,856)	(21,293)	(16,314)	16,666	44,87
Ciosing net debu(casii)		(34,030)	(21,293)	(10,314)	10,000	44,07

Source: Company accounts, Edison Investment Research. Note: Long-term liabilities assume capital raisings for illustrative purposes.



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