EDISON

Oncology Venture

Financial update

Presence at ASCO 2018

Pharma & biotech

Oncology Venture (OV) attended the annual American Society of Clinical Oncology (ASCO) in June with three abstracts. Results from a Phase I study of 2X-121, a dual PARP-1/2 and TNKS-1/2 inhibitor, as a single agent in patients with solid tumours were presented along with data on the development of the 2X-121 drug response predictor (DRP) algorithm. OV also provided supplementary data supporting the LiPlaCis and APO010 programmes at the conference. In late May, OV announced the merger between OV and the Medical Prognosis Institute (MPI) was approved by the board of directors.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/16	1.3	(40.5)	(3.33)	0.0	N/A	N/A
12/17	2.1	(64.9)	(5.28)	0.0	N/A	N/A
12/18e	1.7	(121.8)	(7.47)	0.0	N/A	N/A
12/19e	1.0	(238.5)	(13.92)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

2X-121 data detailed in ASCO presentation

OV presented data from the 41-patient Phase I study of 2X-121as a single agent in patients with advanced solid tumours, along with data on the development and preliminary testing of the 414-gene 2X-121 DRP algorithm in 13 patients. The responders and non-responders were identified with median overall survival of more than 800 days and 208 days, respectively. The company expects to initiate the focused Phase II trial this year.

Merger between OV and MPI approved

On 30 May 2018, OV announced that its board of directors approved the merger plan between itself and the MPI, which was first proposed in March this year. Post-merger, the combined entity will comprise 50.3m shares and current OV shareholders will own 51% of the new company. Information about the closing date of this transaction has not yet been released.

Potential increase in stake of dovitinib to 75%

On 31 May 2018, OV announced it has the option to acquire 35% of the shares in OV-SPV2 (~40% owned by OV, 10% owned by MPI, 50% owned by Sass & Larsen Aps) for $3.5m before 31 August 2018 from Sass & Larsen. This transaction may increase OV's stake in the dovitinib programme (from 40% to 75%), a tyrosine kinase inhibitor (TKI) that was in-licensed from Novartis in January this year.

Valuation: SEK830.2m or SEK60.02 per share

We have slightly increased our valuation of OV to SEK830.2m or SEK60.02 per share from SEK823.8m or SEK59.56 per share. This increase is primarily driven by rolling forward our NPVs and is partially offset by offset by lower net cash. Our valuation may change to reflect the potential increase of OV's stake in dovitinib via a 35% share buy-back option of OV-SPV2 for $3.5m.

11 June 2018

Price	**SEK17.40**
Market cap	**SEK240m**
	US$0.12/SEK
Net cash (SEKm) as of 31 March 2018	40.1
Shares in issue	13.8m
Free float	67%
Code	OV.SS
Primary exchange	AktieTorget
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	5.5	2.7	(50.6)
Rel (local)	10.0	1.6	(44.5)
52-week high/low	SEK33.6	SEK15.5	

Business description

Oncology Venture is a Denmark-based biopharmaceutical company focused on oncology. Its patent-protected mRNA-based drug response predictor platform enables the identification of patients with gene expression highly likely to respond to treatment. To date the company has in-licensed six drug candidates with the intent to conduct focused Phase II clinical trials and then out-licence the revamped drugs.

Next events

Phase II 2X-121 trial initiation	2018
Randomised Phase II LiPlaCis trial initiation	2018
Phase II LiPlaCis top-line data	H119

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2X-121 presentation at ASCO 2018

On 1 June 2018, OV presented results from a 41-patient open-label Phase I study of 2X-121 as a single agent in patients with advanced solid tumours (including pancreatic, ovarian, breast, colorectal, lung and other cancers). As a reminder, 2X-121 is an orally bioavailable small molecule and a dual PARP-1/2 and TNKS-1/2 inhibitor (previously named E7449, in-licensed from Eisai in July 2017). PARP enzymes repair single-strand DNA breaks; as a result, PARP inhibition causes double strand breaks, which require BRCA1/2 for repair.[1] Thus, PARP inhibition is particularly lethal in cancers containing BCRA1/2 mutations. It is important to note this trial included cancers without regard to BRCA mutation status where PARP inhibitors are more active. BRCA status was only known in six patients in this study (three with ovarian cancer; two breast cancer; one pancreatic cancer).

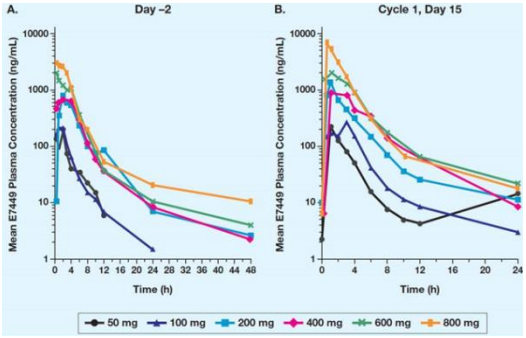
In total, 28 patients were administered 2X-121 orally, once daily at six dose levels in 28-day treatment cycles (Exhibit 1). Out of the 25 evaluable patients, the maximum tolerated dose was found to be 600mg, which was limited by fatigue, and this cohort was expanded to include 21 patients in total. PK were dose proportional and 2X-121 was absorbed rapidly at 1.5 hours with a half-life of eight hours (Exhibit 2). All dose levels demonstrated PARP inhibition, while the 600mg daily dose demonstrated maintained inhibition at approximately 90% (Exhibit 3).

Exhibit 1: Dose escalation in 25 evaluable patients

Dose cohort (no. patients treated)	No. evaluable patients	Median no. cycles received (range)	No. patients with DLT
50 mg (3)	3	6 (1-8)	0
100 mg (3)	3	2 (2-14)	0
200 mg (4)	4	3 (1-4)	0
400 mg (4)	3	5 (0-10)	0
600 mg (8) *	6	2 (0-13)	1
800 mg (6)	6	2 (0-11)	4

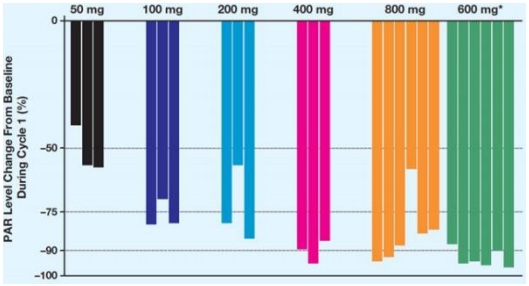
Source: 2X Oncology and Oncology Venture at ASCO 2018. Notes: *Maximum tolerated dose; DLT= dose limiting toxicities.

Exhibit 2: 2X-121 rapidly absorbed



Source: 2X Oncology and Oncology Venture at ASCO 2018. Notes: Serum samples collected for PK analysis.

Exhibit 3: PARP inhibition at all dose levels



Source: 2X Oncology and Oncology Venture at ASCO 2018. Notes: Peripheral blood mononuclear cell (PBMC) isolation used for PARP activity.

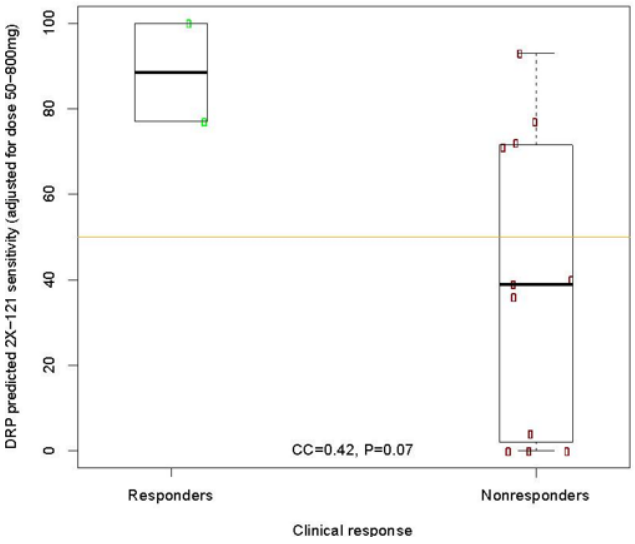
Two patients achieved partial response, both with ovarian cancer, while 13 patients demonstrated stable disease. Eight of the 13 patients maintained stable disease for over 24 weeks, and seven out of eight of these patients had pancreatic cancer. It is important to note there are no PARP inhibitors approved for the treatment of pancreatic cancer. The Abramson Cancer Centre of the University of Pennsylvania is recruiting 42-patients with BRCA1/2 or PALB2 mutated advanced pancreatic

1 Dziadkowiec, K.N. (2016). PARP inhibitors: review of mechanisms of action and BRCA1/2 mutation targeting. PrzMenopauzalny 15(4), 215-219.

cancer to participate in an open-label Phase II trial investigating the use of Rubraca (rucaparib, Clovis Oncology). Top-line data from this trial are expected in 2021.

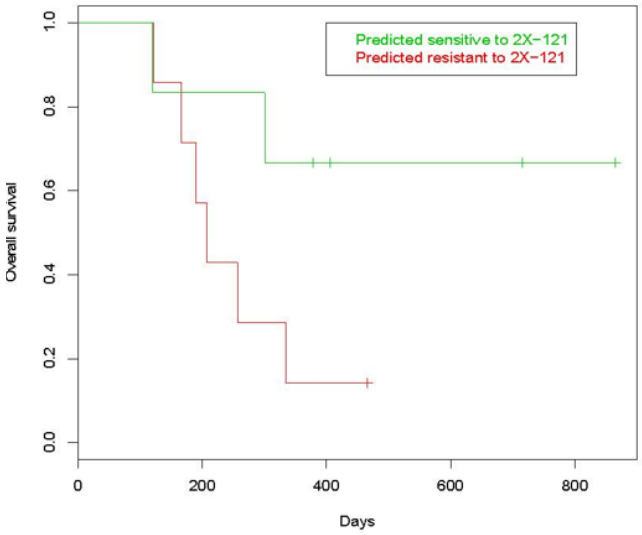
This presentation also described OV's 2X-121 DRP that was developed to identify drug responders and non-responders. The 2X-121 DRP, which is a biomarker based on mRNA expression of 414 genes from 61 cell lines, was tested in a small 13 patient blinded retrospective trial using biopsy materials (formalin fixed paraffin-embedded samples) from this dataset provided by Eisai. From the 13 available patient samples, the DRP correctly distinguished two patients who achieved partial responses from non-responders (ie stable disease and disease progression) (Exhibit 4). Moreover, the DRP separated the patients into two groups: those sensitive to treatment (six responders) and those resistant (seven non-responders). The difference between median time to progression among the responders and non-responders was minimal (p=0.14). However, median overall survival was greater than 800 days for the predicted sensitive/responder group and 208 days for the non-responder group, respectively (HR=0.26, p=0.07) (Exhibit 5).

Exhibit 4: 2X-121 DRP identifies two partial responders



Source: 2X Oncology and Oncology Venture at ASCO 2018

Exhibit 5: Overall survival of the two groups



Source: 2X Oncology and Oncology Venture at ASCO 2018

Although the results are supportive of clinical activity, the real value is in the ability of the DRP to identify responders, which will need to be tested prospectively. It is also important to note the possibility of overtraining the 2X-121 DRP model, which can negatively affect performance on new data. Because the DRP makes use of 414 genes, which may include irrelevant data and noise, and was tested only a small dataset (13 patient samples), we expect the DRP to require further testing and validation.

As a reminder, OV plans to use its 2X-121 DRP to select the top 10% patients with metastatic breast cancer (mBC) and relapsed ovarian cancer highly likely to respond to the drug. OV is in possession of 13,000 capsules for initial studies. The laboratory in Europe is established with approximately 1,400 DRP screened patients with breast cancer whereas the US lab is undergoing Clinical Laboratory Improvement Amendments validation. The study is expected to begin this year and should be complete after approximately 12 months.

LiPlaCis Phase II mBC trial update on 12 patients

OV provided an update on its ongoing single-arm, open-label focused Phase II study investigating LiPlaCis in heavily pre-treated mBC patients via an electronically published abstract at ASCO in June. As a reminder, patients are administered 75mg LiPlaCis, which is liposomal version of

cisplatin, intravenously (IV) in three-week cycles on day one and on day eight with efficacy evaluation every six weeks.

In total, 12 out of 20 evaluable patients selected from the DRP screening programme, which is used to classify tissue as highly likely to respond (high, top two-thirds) or less likely to respond (low, bottom one-third) from more than 1,400 mBC patients have been enrolled to date. Objective response rate (ORR) in the intention to treat group (from the top two-thirds) was 17%. However, two patients died before completing the treatment cycle and, according to the company and a safety committee, the deaths were unrelated to LiPlaCis. LiPlaCis was the median eighth line of treatment for this cohort.

Moreover, six out of the remaining 10 patients evaluable for response had a DRP score in the top third and four had a DRP score in the middle third. Out of the 10 patients, two patients achieved partial remission, while five and three experienced stable disease and progressive disease, respectively. Also, five out of the six patients with a DRP score in the top third were platinum-naïve and experienced a median progression free survival (PFS) of 25 weeks, which was significantly greater than a median PFS of eight weeks demonstrated by the two platinum-naïve patients with a DRP score in the middle third (p=0.008). This focused Phase II trial remains ongoing and, according to the company, depending on the required length of treatment, top-line results are expected by year-end 2018.

Resistance to APO010 in human myeloma cell lines

OV also published an electronic abstract at ASCO 2018 detailing the characterisation of resistance to APO010, a synthetic hexameric formulation of natural Fas ligands that targets first apoptosis signal receptors (Fas, also known as apoptosis antigen 1 or cluster differentiation 95 [CD95]) on cancer cells to potentially induce caspase-dependent apoptosis and antineoplastic activity,[2] in human myeloma cell lines.

OV developed APO010-resistent variants of four human myeloma cell lines (LP1, Raji, MOLP-8, and KMS-12-BM) by exposing cells to increasing concentrations of APO010 over six months to one year. The developed APO010-resistant cell lines showed increased resistance to APO010 and Fas-receptor downregulation in comparison to the non-manipulated cell lines. According to the company, post-transcriptional or post-translational modification of the Fas-receptor is likely responsible for APO010 resistance. Describing the molecular mechanism of resistance to the drug may identify predictive biomarkers of APO010 in multiple myeloma (MM) treatment.

As a reminder, OV is investigating APO010 in a focused Phase Ib/II trial for the treatment of relapsed or refractory MM. OV is targeting enrolment of 15 patients most likely to respond to APO010 out of approximately 150 patient DRP screenings (using the 160-gene APO010 DRP). The company first aims to demonstrate effective APO010 monotherapy and follow-up with combination trials with other agents such as PD-1 inhibitors. The Phase I dose escalation portion of this trial is ongoing. The company may increase patient enrolment to include 30 patients in dose escalation, and if that is the case, the company expects to complete enrolment by H119.

Valuation

We have slightly increased our valuation of OV to SEK830.2m or SEK60.02 per share from SEK823.8m or SEK59.56 per share derived from a risk-adjusted NPV analysis on the future earnings of six active clinical programmes, and as standard practice, this includes costs associated with each asset (Exhibit 6). This increase is primarily driven by rolling forward our NPVs, offset by

2 Villunger, A., et al. (1997). Constitutive Expression of Fas (Apo-1/CD95) Ligand on Multiple Myeloma Cells: A Potential Mechanism of Tumor-Induced Suppression of Immune Surveillance. Blood, 90(1), 12-20.

lower net cash. Our valuation may change in accordance with OV's decision to buy back shares in its incorporated subsidiary OV-SPV2 (~40% owned by OV, 10% owned by MPI, 50% owned by Sass & Larsen Aps). Announced in late May, OV has the option to acquire 35% of the shares in OV-SPV2 for $3.5m before 31 August 2018, which may increase OV's stake in the programme (from 40% to 75%) and should provide significant upside to the valuation.

Exhibit 6: Valuation of OV

Development Program	Indication	Clinical stage	Prob. of success	Launch year	Launch pricing	Peak sales ($m)	rNPV (mSEK)	% owned by OV	OV rNPV (mSEK)
LiPlaCis	Metastatic breast cancer	Phase II	25%	2023	$91,000	190.6	388.8	29%	112.7
Irofulven	Prostate cancer	Phase Ib/II	20%	2023	$129,000	52.6	52.4	100%	52.4
APO010	Multiple myeloma	Phase Ib/II	20%	2023	$143,000	80.9	81.7	100%	81.7
2X-121	mBC and ovarian cancer	Phase Ib/II	25%	2023	$132,000	116.4	144.7	92%	133.1
2X-111	Glioblastoma and brain metastases from breast cancer	Phase Ib/II	25%	2024	$169,000	212.6	272.3	92%	250.5
Dovitinib	Renal and liver cancer	Phase Ib/II	35%	2024	$145,000	152.0	399.0	40%	159.6
Total									790.1
Net cash and equivalents (as of 31 March 2018) (mSEK)									40.1
Total firm value (mSEK)									830.2
Total shares (m)									13.8
Value per basic share (SEK)									60.02

Source: Edison Investment Research

Financials

OV's Q118 post-tax loss was SEK14.4m (Q117: loss of SEK11.6m), which was primarily attributable to costs associated with production (SEK1m), preparing and running clinical trials (SEK5m), and sales and marketing activities (SEK1m).

OV ended the period with SEK40.1m in cash and equivalents. As a standalone company, our forecasts model a total of SEK610m (SEK60m in 2018, SEK300m in 2019, and SEK250m in 2020) in R&D expenditure, which we record as illustrative debt, to bring all six of its anticancer programmes to Phase III out-licensing (Exhibit 7). However, following the merger, we expect MPI's cash (DKK3.3m at end FY17) to partially offset this funding requirement. Such financial requirements may be offset further via the selling or outlicensing of Phase III-ready drugs. These estimates are based on expected cost per patient (ie $100,000 per patient) and Phase II clinical trial size.

Our combined R&D forecasts remain unchanged with SEK74m in 2018 and SEK194m in 2019 primarily associated with the advancement of the LiPlaCis programme into Phase IIb, ongoing irofulven and APO010 Phase IIa clinical trials, as well as 2X Oncology's 2X-121 and 2X-111 development programmes, which are expected to initiate this year.

Due to the forthcoming merger between OV and MPI, which was approved by the board of directors in late May, we expect these financials to change to reflect the new entity.

Exhibit 7: Financial summary

SEK'000s	2016	2017	2018e	2019e
Year end 31 December	Swedish GAAP	Swedish GAAP	Swedish GAAP	Swedish GAAP
PROFIT & LOSS				
Revenue	1,305	2,091	1,727	978
Cost of Sales	0	0	0	0
Gross Profit	1,305	2,091	1,727	978
EBITDA	(43,408)	(81,001)	(127,386)	(250,200)
Operating Profit (before amort. and except.)	(40,874)	(67,462)	(124,367)	(247,181)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(40,874)	(67,462)	(124,367)	(247,181)
Net Interest	346	2,588	2,562	8,674
Other (change in fair value of warrants)	0	0	0	0
Profit Before Tax (norm)	(40,528)	(64,874)	(121,804)	(238,507)
Profit Before Tax (IFRS)	(40,528)	(64,874)	(121,804)	(238,507)
Tax	6,985	7,114	13,357	26,154
Deferred tax	0	0	0	0
Profit After Tax (norm)	(33,543)	(57,760)	(108,448)	(212,353)
Profit After Tax (IFRS)	(33,543)	(57,760)	(108,448)	(212,353)
Average Number of Shares Outstanding (m)	10.1	10.9	14.5	15.3
EPS - normalised (ore)	(332.94)	(527.74)	(746.66)	(1,392.43)
EPS - IFRS (SEK)	(3.33)	(5.28)	(7.47)	(13.92)
Dividend per share (ore)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	19,767	45,384	44,517	42,784
Intangible Assets	18,885	44,633	43,766	40,747
Tangible Assets	624	485	467	1,753
Other	258	266	284	284
Current Assets	38,450	33,830	34,777	142,882
Stocks	316	9,149	10,540	10,540
Debtors	6,841	2,593	4,868	9,533
Cash	18,872	11,978	10,417	113,857
Other	12,421	10,110	8,952	8,952
Current Liabilities	(11,820)	(32,461)	(38,901)	(56,600)
Creditors	(11,820)	(32,461)	(38,901)	(56,600)
Short term borrowings	0	0	0	0
Long Term Liabilities	0	0	(60,256)	(361,282)
Long term borrowings	0	0	(60,256)	(361,282)
Other long term liabilities	0	0	0	0
Net Assets	46,397	46,753	(19,864)	(232,217)
CASH FLOW				
Operating Cash Flow	(36,066)	(48,216)	(98,463)	(195,273)
Net Interest	346	0	0	0
Tax	0	0	(1,682)	0
Capex	882	(8)	(2,557)	(1,286)
Acquisitions/disposals	(2,296)	(19,943)	0	0
Financing	39,523	60,702	39,457	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	2,389	(7,465)	(63,245)	(196,560)
Opening net debt/(cash)	(16,786)	(18,872)	(11,978)	51,664
HP finance leases initiated	0	0	0	0
Exchange rate movements	(303)	571	(397)	0
Other	0	0	0	799
Closing net debt/(cash)	(18,872)	(11,978)	51,664	247,425

Source: Company reports, Edison Investment Research. Note: financial summary reflects Oncology Venture as a single entity, ahead of proposed merger with MPI.

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