EDISON

Oncology Venture

Financial update

Three active trials with two more on the horizon

Pharma & biotech

Oncology Venture (OV) recently included the first patient in its irofulven Phase II trial in prostate cancer, marking its third currently active trial. OV is also planning to initiate its second 2X-121 Phase II trial in ovarian cancer at the beginning of next year. Moreover, the company recently submitted pre-IDE/IND paperwork to the US FDA as it is seeking approval for LiPLaCis via a single-arm pivotal study in ~100-200 patients. The recent debt deal of ~SEK200m should fund OV's current clinical development.

Year end	Revenue (DKKm)	PBT* (DKKm)	EPS* (DKK)	DPS (DKK)	P/E (x)	Yield (%)
12/17	5.1	(31.0)	(1.27)	0.0	N/A	N/A
12/18e	3.2	(29.2)	(0.57)	0.0	N/A	N/A
12/19e	1.9	(205.8)	(3.82)	0.0	N/A	N/A

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

First patient included in irofulven Phase II trial

In October, OV announced that the first patient was included in its Phase II irofulven trial. OV is developing irofulven, a cytotoxic DNA binding agent for the treatment of prostate cancer utilising its drug response predictor (DRP) to select patients most likely to respond to treatment. The trial is expected to enrol 13-27 patients. OV hopes to see a response rate of ~20% in these patients; according to the company this should enable a marketing approval pathway.

2X-121 in breast and ovarian cancer

OV's Phase II 2X-121 trial in breast cancer is ongoing. The company has stated that it plans to read out the first efficacy data as soon as patients have been enrolled long enough to demonstrate some response. However, an exact timeframe was not provided and will likely fall behind previous expectations (Q418). Moreover, OV is preparing to initiate a second 2X-121 Phase II trial in patients with ovarian cancer in Q119. As a reminder, 2X-121 is an orally bioavailable small molecule and a dual PARP-1/2 and TNKS-1/2 inhibitor.

Financing agreements in place to offset expenditure

We forecast significant capital requirements to bring all six anti-cancer programmes to Phase III out-licensing (DKK388m). OV recently announced an agreement with the European High Growth Opportunities Securitization Fund for up to SEK200m for convertible notes, and potentially an additional SEK100m if all warrants are exercised. The funding may be drawn down through the issuance of 20 tranches at SEK10m.

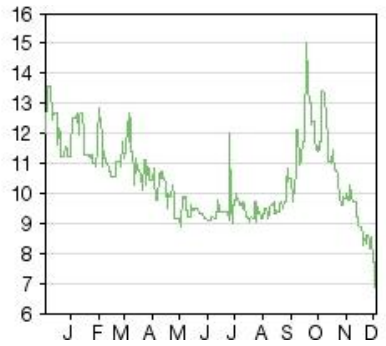
Valuation: SEK1,100.5m or SEK21.87 per share

We have slightly increased our valuation of OV to SEK1,100.5m or SEK21.87 per share (SEK20.5 per diluted share) from SEK1,078m or SEK21.44 per share, primarily driven by rolling forward our NPVs and in part offset by lower net cash at the corporate level. We expect to make further adjustments to our valuation of OV following feedback from the company's six clinical programmes.

4 December 2018

Price	**SEK6.88**
Market cap	**SEK346m**
	US$0.16/DKK, US$0.11/SEK
Net debt (SEKm) at 30 September 2018	0.8
Shares in issue	50.3m
Free float	82%
Code	OV.ST
Primary exchange	NASDAQ First North Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(29.7)	(29.2)	(42.9)
Rel (local)	(28.2)	(22.8)	(42.0)
52-week high/low	SEK15.0		SEK6.9

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-license the revamped drugs.

Next events

Initiate 2X-121 Phase II in ovarian cancer	Q119
Phase II LiPlaCis trial top-line data	H119

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Edison profile page

Multiple trials moving forward

OV recently reported its Q318 results, which included its consolidated financials post-merger and a brief update on some near-term clinical events. On 18 October 2018, OV announced that the first patient with prostate cancer was included in its Phase II irofulven clinical trial. OV's unique irofulven DRP is first being used to screen ~300 patients with metastatic castration- and docetaxel-resistant prostate cancer (mCDRPC) to identify those most likely to respond to treatment. According to the company, interim data obtained from the first eight patients enrolled in the study (ie selected by the DRP algorithm to be sensitive to irofulven) will determine whether the company continues to develop this asset. If these select patients experience a particular response, the remainder of the Phase II trial will include 13-27 patients with the highest likelihood to respond to irofulven. OV expects to see a 20% or higher response rate to irofulven in these patients. This is roughly equal to or greater than current treatment options (ie hormonal therapy, chemotherapy, typically taxanes or CYP-17 inhibitors, the combination of chemotherapy and hormonal therapy, or immunotherapy) yielding a tumour response rate of 22.6% and corresponding to median progression-free survival (PFS) and overall survival (OS) of 7.6 months and 15.1 months, respectively.[1]

OV also announced that it plans to initiate a second Phase II 2X-121 in patients with ovarian cancer in Q119 in the US and in Germany. OV previously received IDE and IND approvals for 2X-121 DRP technology and treatment protocol. As a reminder, 2X-121 is an orally bioavailable small molecule and a dual PARP-1/2 and TNKS-1/2 inhibitor. PARP enzymes repair single-strand DNA breaks and since BRCA1/2 mutated cells are incapable of double-strand break repair, PARP inhibition is particularly lethal and causes genomic instability and cell death. OV's first Phase II 2X-121 open-label trial in patients with metastatic breast cancer (mBC) was initiated in June 2018 and the primary endpoint is overall tumour response according to RECIST at more than 24 weeks post-treatment. The company has stated that it plans to read out the first efficacy data as soon as patients have been enrolled long enough to demonstrate some response. We expect the results of this trial to elucidate whether the DRP can prospectively identify 2X-121 mBC responders.

The company recently submitted a pre-IDE/IND dossier to the US FDA to discuss the filing of an application for LiPlaCis in mBC clinical trials in the US. OV's goal is to seek approval for LiPlaCis by a single-arm pivotal study in ~100-200 patients whereas the ongoing Phase II trial may serve as a bridge. Recruitment timelines will be updated following feedback from the FDA.

Valuation

We have increased our valuation of OV to SEK1,101m or SEK21.87 per share (SEK20.5 per diluted share) from SEK1,078m or SEK21.44 per share. This change is primarily driven by rolling forward our NPVs and is in part offset by lower net cash at the corporate level. According to the company, its three highest priority assets include LiPlaCis, 2X-121 and dovitinib and based on our estimates, we value these assets at SEK5.20, SEK3.09 and SEK5.10 per share, respectively. We expect to make further adjustments to our valuation of OV following feedback from the company's six clinical programmes.

[1] Akaza, H., et al. (2018). Metastatic Castration-Resistant Prostate Cancer Previously Treated With Docetaxel-Based Chemotherapy: Treatment Patterns From the PROXIMA Prospective Registry. *Journal of Global Oncology,*(4), 1-12.

Exhibit 1: Valuation of OV

Development programme	Indication	Clinical stage	Prob. of success	Launch year	Launch pricing	Peak sales ($m)	rNPV (SEKm)	% owned by OV	OV rNPV (SEKm)
LiPlaCis	Metastatic breast cancer and metastatic prostate cancer	Phase II	25%	2023	$91,000	259.8	670.7	39%	261.6
Irofulven	Metastatic prostate cancer	Phase Ib/II	20%	2023	$129,000	52.6	60.1	100%	60.1
APO010	Multiple myeloma	Phase Ib/II	20%	2023	$143,000	80.9	98.1	100%	98.1
2X-121	Metastatic breast cancer and ovarian cancer	Phase II	25%	2023	$132,000	116.4	168.9	92%	155.4
2X-111	Glioblastoma and brain metastases from breast cancer	Phase Ib/II	25%	2024	$169,000	212.6	293.0	92%	269.6
Dovitinib	Renal and liver cancer	Phase Ib/II	35%	2024	$145,000	152.0	466.4	55%	256.5
Total									1,101.3
Net debt (at 30 September 2018) (SEKm)									(0.8)
Total firm value (SEKm)									1,100.5
Total shares (m)									50.3
Value per basic share (SEK)									21.87
Warrants and options (m)									3.3
Fully diluted shares in issue									53.6
Fully diluted value per share									20.5

Source: Edison Investment Research

Financials

OV recently reported its Q318 results, presenting the financials of the merged entity for the first time. Note that the historic numbers are not fully consolidated. The company recorded revenue of DKK104,000 for the quarter ending 30 September 2018, which is down significantly from the same period the previous year (DKK1.2m in Q317) and primarily attributable to the changed group structure. We have therefore decreased our revenue forecasts for FY18 and FY19 to reflect these changes and note that the revenue generated is not material to the company's operations at this time. OV ended the quarter with DKK8.7m in cash and DKK9.3m in debt. The company reported a loss of DKK4.0m for the quarter, which we assume is primarily attributable to R&D. We have decreased our PBT loss forecasts for FY18 to DKK29.2m (from DKK39.6m), primarily driven by delaying the initiation of the LiPlaCis pivotal trial from 2018 to 2019 and the fact that the APO010 trial has not yet included any patients. We expect OV's R&D expenditure to increase next year along with the initiation of the irofulven trial, initiation of the second 2X-121 Phase II trial in patients with ovarian cancer, and potentially the single-arm pivotal LiPlaCis study following FDA feedback. Our FY19e PBT loss increases marginally to SEK206m.

Our financial requirements for OV remain unchanged; however, we expect these to be significantly offset by the recent financing agreement with the European High Growth Opportunities Securitization Fund (EHGOSF) advised by Alpha Blue Ocean announced on 30 November 2018. According to the agreement, OV may receive up to SEK200m in convertible notes and warrants over the next 24 months bearing 2% fixed interest, and potentially an additional SEK100m if all warrants are exercised. The pricing of the convertible notes and warrants will be determined once they are drawn (95% and 150% of the average of the last 15 trading days, respectively) and there is 50% warrant coverage in each tranche. The funding may be drawn down through the issuance of 20 tranches at SEK10m (note, the size of tranche can be decreased to SEK7.5m) and EHGOSF may ask for five of these. These capital requirements may be further offset by DKK20m remaining available to the company attributed to the flexible loan facility established with Trention.

Exhibit 2: Financial summary

DKK'000s	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS
PROFIT & LOSS			
Revenue	5,145	3,192	1,876
Cost of Sales	0	0	0
Gross Profit	5,145	3,192	1,876
EBITDA	(23,848)	(38,438)	(204,616)
Operating Profit (before amort. and except.)	(23,848)	(37,589)	(203,767)
Intangible Amortisation	0	0	0
Exceptionals/Other	0	0	0
Operating Profit	(23,848)	(37,589)	(203,767)
Net Interest	(7,132)	8,358	(2,015)
Other (change in fair value of warrants)	0	0	0
Profit Before Tax (norm)	(30,980)	(29,231)	(205,782)
Profit Before Tax (IFRS)	(30,980)	(29,231)	(205,782)
Tax	590	557	3,914
Deferred tax	0	0	0
Profit After Tax (norm)	(30,390)	(28,674)	(201,868)
Profit After Tax (IFRS)	(30,390)	(28,674)	(201,868)
Average Number of Shares Outstanding (m)	24.3	50.3	52.8
EPS - normalised (DKK)	(1.27)	(0.57)	(3.82)
EPS - IFRS (DKK)	(1.25)	(0.57)	(3.82)
Dividend per share (ore)	0.0	0.0	0.0
BALANCE SHEET			
Fixed Assets	4,883	205,109	205,109
Intangible Assets	135	205,149	205,149
Tangible Assets	4,424	(40)	(40)
Other	324	0	0
Current Assets	8,102	29,463	63,138
Stocks	1,048	805	805
Debtors	3,048	5,758	20,222
Cash	3,326	5,797	21,093
Other	680	17,103	21,018
Current Liabilities	(10,540)	(6,019)	(29,314)
Creditors	(10,540)	(6,019)	(29,314)
Short term borrowings	0	0	0
Long Term Liabilities	0	(81,693)	(293,693)
Long term borrowings	0	(49,302)	(261,302)
Other long term liabilities	0	(32,391)	(32,391)
Net Assets	2,445	146,860	(54,760)
CASH FLOW			
Operating Cash Flow	(10,702)	(58,158)	(195,855)
Net Interest	(170)	(252)	0
Tax	2,527	69	0
Capex	0	0	(849)
Acquisitions/disposals	(784)	14,457	0
Financing	7,478	177	0
Dividends	0	0	0
Other	(308)	(3,197)	0
Net Cash Flow	(1,959)	(46,904)	(196,704)
Opening net debt/(cash)	(5,488)	(3,326)	43,505
HP finance leases initiated	0	0	0
Exchange rate movements	(203)	(73)	0
Other	0	146	0
Closing net debt/(cash)	(3,326)	43,505	240,209

Source: Company reports, Edison Investment Research

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