

# Oncology Venture

## Multiple programme updates

Clinical update

Pharma & biotech

13 February 2019

**Price** **SEK6.46**

**Market cap** **SEK326m**

US\$0.16/DKK; US\$0.11/SEK

Net debt (SEKm) at 30 September 2018 0.8

Shares in issue 50.4m

Free float 70%

Code OV

Primary exchange NASDAQ First North  
Stockholm

Secondary exchange N/A

Oncology Venture (OV) continues to provide regular response data from its ongoing LiPlaCis Phase II trial in patients with metastatic breast cancer (mBC). To date, 33% of the top one-third sub-population delineated by the drug response predictor (DRP) achieved partial remission (PR) or better. The data also suggested that tightening the LiPlaCis DRP threshold may increase response rates.

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.

## More data from the LiPlaCis Phase II trial

OV provided an update from its current Phase II trial investigating LiPlaCis for the treatment of mBC. The company reported that four of 12 patients in the top one-third of DRP-selected patients achieved PR or better. Moreover, patients in the top one-third achieved a median time to progression of 18 weeks versus seven weeks in the middle third of patients. We note that the data reported here are lower than earlier reported data (November 2018), where five out of 10 patients in the top third achieved PR or better.

## Shifting the DRP threshold increases response rate

OV also presented LiPlaCis data with the DRP threshold segmented by 20% for the first time. The response rate for the top 20% of DRP-selected patients was 40%, specifically in those who were cisplatin-naïve. OV may adjust this thresholding window in the future to optimise the response rate, which is a detail of active research.

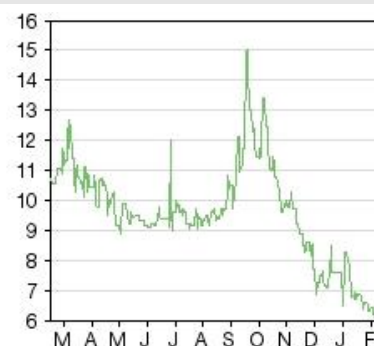
## Data mining for dovitinib DRP complete

OV recently completed its data mining process for the refinement of its dovitinib DRP biomarker to identify patients with renal cancer and endometrial cancer highly likely to respond to the drug. OV has stated that the dovitinib DRP companion diagnostic is guiding towards two- to four-fold higher response rates. This is an essential step in OV's business model and, once the DRP model is adequate, OV will likely move forward with running a clinical trial in those patients most likely to respond.

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

Our valuation of OV remains unchanged at SEK1,100.5m or SEK21.87 per share (SEK20.52 per diluted share) based on a risk-adjusted NPV analysis of each in-licensed anticancer drug. We expect to make further adjustments to our valuation following feedback from the FDA regarding potential breakthrough therapy designation for LiPlaCis.

## Share price performance



% 1m 3m 12m

Abs (5.3) (29.9) (40.2)

Rel (local) (10.0) (31.9) (42.4)

52-week high/low SEK15.0 SEK6.1

## 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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## Shifting the DRP threshold shows LiPlaCis responders

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On 7 February 2019, OV provided an update on its ongoing single-arm, open-label Phase II trial investigating LiPlaCis for the treatment of heavily pre-treated mBC patients. Patients are administered 40mg/m<sup>2</sup> LiPlaCis, a liposomal version of cisplatin chemotherapy, intravenously (IV) in three-week cycles on days one and eight with efficacy evaluation every six weeks. The response rate was 33% (or four out of 12 patients) in the top one-third of DRP-selected patients. These patients achieved PR or better, which is defined as a 30% or greater reduction in tumour size measured in one dimension in a CT scan when treated with LiPlaCis. Moreover, the top one-third of patients also reached a median time to progression of 18 weeks versus seven weeks in the remaining enrolled patients (who had DRP scores between 33% and 67%, as those below 33% were excluded from the study). Interestingly, these response data are slightly lower than what was previously reported in the November 2018 clinical update, where five out of 10 patients (50%) in the top one-third of DRP-selected patients and six out of 25 patients (24%) in the upper two-thirds of DRP selected patients achieved PR or better. However, the data are still evolving.

Additionally, 40% of patients in the upper 20% of DRP-selected patients who have not previously received cisplatin also achieved PR or better,. This marks the first time that OV has presented data using a 20% DRP threshold, highlighting that thresholding is under active investigation. The company may shift the DRP threshold either up or down to optimise patient response to LiPlaCis. According to OV, these data may support obtaining breakthrough therapy designation from the US FDA, which could expedite the development and review of the LiPlaCis programme if it demonstrates considerable improvement over existing therapies on clinically significant endpoints. OV plans to update recruitment timelines for the trial following FDA approval of the IDE/IND application, which the company expects in H119. However, it is important to note the company did not comment on the overall number of patients included in the trial to date.

## Dovitinib data mining in renal and endometrial cancer complete

Also in February, OV provided an update on the process of developing the DRP assay for dovitinib. With its data mining process for the refinement of its dovitinib DRP biomarker, the company had to identify patients highly likely to respond to the drug. As a reminder, OV in-licensed dovitinib, an oral TKI that inhibits fibroblast growth factor, vascular endothelial growth factor and platelet-derived growth factor receptors, from Novartis. As part of the agreement, OV also received an ample amount of biopsy and gene expression data from previous studies from Novartis. OV recently announced that its data mining process for dovitinib and its unique DRP is complete for two distinct indications, renal cancer and endometrial cancer, which is an essential step in OV's business model. Optimising the DRP is also important for identifying the patients most likely to respond. According to the company, the unique dovitinib DRP is guiding towards two- to four-fold higher response rates.

This is the first time OV has commented on the possibility of treating patients with endometrial cancer with dovitinib and its DRP companion diagnostic. Non-resectable endometrial cancer is typically treated either radiation therapy or chemotherapy.<sup>1</sup> Hormone therapies such as progestins and tamoxifen are used to treat late-stage or recurrent endometrial cancer in combination with surgery and radiation therapy.<sup>1</sup> TKIs are not typically used to treat this indication; however, it is possible that a specific subset of this population may respond to the drug. Moreover, in August 2018 the US FDA granted breakthrough therapy designation for Lenvima (lenvatinib, Eisai), an oral TKI, in combination with Keytruda (pembrolizumab, Merck), an anti-PD-1, for patients with

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<sup>1</sup> American Cancer Society.

advanced and/or metastatic endometrial carcinoma. In the [Phase Ib/II](#) trial in 54 patients, the objective response rate at 24 weeks was 50%.

## Valuation

Our valuation of OV remains unchanged at SEK1,100.5m or SEK21.87 per share (SEK20.52 per diluted share). Adjustments to our valuation of the LiPlaCis programme are contingent on FDA feedback regarding breakthrough therapy designation. According to the company, its three highest-priority assets are LiPlaCis, 2X-121 and dovitinib; 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.

### Exhibit 1: Valuation of OV

Development Program	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)
<b>Total firm value (SEKm)</b>									<b>1,100.5</b>
Total shares (m)									50.3
<b>Value per basic share (SEK)</b>									<b>21.87</b>
Warrants and options (m)									3.3
Fully diluted shares in issue (m)									53.6
<b>Fully diluted value per share (SEK)</b>									<b>20.52</b>

Source: Edison Investment Research

## Financials

Our financial forecasts of OV remain unchanged. We continue to expect OV to require DKK430m in R&D expenditure, which we record as illustrative debt, to bring all six of its anticancer programmes to Phase III out-licensing (Exhibit 2). We assume that all six of OV's assets will move forward; however, costs may be brought down if the development programmes do not progress as we expect.

**Exhibit 2: Financial summary**

	DKK000s	2017	2018e	2019e
Year end 31 December		IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>				
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 (ore)		(127.00)	(56.99)	(382.13)
EPS - IFRS (DKK)		(1.25)	(0.57)	(3.82)
Dividend per share (ore)		0.0	0.0	0.0
<b>BALANCE SHEET</b>				
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)
<b>CASH FLOW</b>				
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: Oncology Venture reports, Edison Investment Research

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