

# **Oncology Venture**

Rounding out a productive year of R&D

Oncology Venture (OV) has ramped-up R&D with multiple trials moving forward. Its Phase II study of LiPlaCis in metastatic breast cancer (mBC) remains ongoing as it awaits FDA approval of the IDE/IND application, which it expects in H119. In March, OV included the first patient in its expanded LiPlaCis Phase II study investigating prostate cancer. Additionally, its 2X-121 Phase II study in mBC is ongoing and OV plans to initiate its second 2X-121 Phase II trial in ovarian cancer in the near future.

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
12/18	2.1	(22.5)	(0.44)	0.0	N/A	N/A
12/19e	3.6	(192.6)	(3.58)	0.0	N/A	N/A
12/20e	3.6	(89.3)	(1.58)	0.0	N/A	N/A

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

# LiPlaCis for mBC awaiting feedback from FDA

According to OV, data from the LiPlaCis Phase II trial in mBC may support obtaining 'breakthrough therapy' designation, 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.

# LiPlaCis trial expands to metastatic prostate cancer

In March 2019, OV announced the first patient has been included in a Phase II study investigating LiPlaCis in prostate cancer. OV previously received approval from the Danish Medicines Agency (DKMA) to expand the LiPlaCis Phase II trial to include metastatic prostate cancer patients. OV plans to increase patient enrolment to 50 (from 30) to include patients with mBC and metastatic prostate cancer, which we expect to strengthen statistics around the drug response predictor (DRP).

# Irofulven and two 2X-121 trials underway

In October, OV announced the first patient was included in its Phase II irofulven trial, which 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. Moreover, OV's 2X-121 Phase II trial in mBC remains ongoing and OV expects to initiate a second trial in ovarian cancer in the near future.

# Valuation: SEK1,117.7m or SEK22.22 per share

We have increased our valuation of OV to SEK1,117.7m or SEK22.22 per share (SEK20.84 per diluted share) from SEK1,100.5m or SEK21.87 (SEK20.52) primarily attributed to rolling forward our NPVs and partially offset by lower net cash. We expect to make further adjustments to our valuation of OV following feedback from the company's six clinical programmes.

Financial update

Pharma & biotech

## 28 March 2019

Price SEK4.55

Market cap SEK229m

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

Net debt (SEKm) at 31 December 2018 24.6

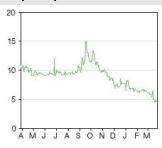
Shares in issue 50.3m

Free float 70%
Code MPI

Primary exchange NASDAQ First North Stockholm

Secondary exchange N/A

### Share price performance



%	1m	3m	12m
Abs	(28.4)	(36.6)	(55.9)
Rel (local)	(27.9)	(43.6)	(58.9)
52-week high/low	SE	EK15.0	SEK4.5

## **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 inlicensed 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	H119
LiPlaCis IND/IDE application approval	H119
Phase II LiPlaCis trial top-line data	H119

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# Multiple programmes progressing nicely

In mid-December, OV announced the FDA responded positively to its pre-IDE/IND dossier detailing a potential application for LiPlaCis in mBC in the US. According to the company, the FDA agreed the 505(b)(2) pathway is an acceptable course for LiPlaCis and additional toxicology studies are not needed. The primary endpoint of the upcoming trial is overall response rate (ORR; ie partial responses plus complete responses). Although the FDA accepted ORR as the primary endpoint, it is contingent on OV's ability to provide additional characterisation of the patient sub-populations selected by the DRP to be treated with the drug. Several advantages to using ORR as a primary endpoint include assessment in single-arm studies<sup>1</sup> and the opportunity to evaluate potential efficacy and safety earlier and in smaller studies in comparison to overall survival studies.

In 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/m² LiPlaCis 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 partial response (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 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 up or down to optimise patient response to LiPlaCis.

OV is seeking approval for LiPlaCis, a liposomal version of cisplatin chemotherapy, via an upcoming single-arm pivotal study in ~100–200 patients with mBC using the ongoing Phase II trial as a bridge. This strategy likely depends on 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. According to the company, these data may in fact support 'breakthrough therapy' designation. OV plans to update recruitment timelines for the trial following FDA approval of the IDE/IND application, which the company expects in H119.

## First prostate cancer patient included in LiPlaCis Phase II trial

In October 2018, OV received clearance from the DKMA to expand the ongoing Phase II study of LiPlaCis to include metastatic prostate cancer patients and the first patient with prostate cancer was included on 11 March 2019. The company expanded enrolment to 50 (from 30) to include patients with mBC and prostate cancer. We expect this increase in patient enrolment to strengthen statistics around the DRP.

<sup>&</sup>lt;sup>1</sup> FDA Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics Guidance for Industry; Source: https://www.fda.gov/downloads/Drugs/Guidances/ucm071590.pdf



Platinum-based chemotherapy has previously been investigated for this patient population; however, its application has not endured clinical practice. In one study, 34 men with castrate-resistant prostate cancer with progression after monotherapy docetaxel were treated with a combination of docetaxel (60mg/m²) and carboplatin every three weeks. The ORR to this combination therapy was relatively low at 14%.² Moreover, a comprehensive review article detailed response rates to a number of cisplatin regimens in metastatic prostate cancer. In three publications, the response rate of cisplatin monotherapy, defined as a greater than a 50% prostate-specific antigen decline, was 20%.³ In total, 17 publications investigating cisplatin in combination with other chemotherapies reported response rates between 23% and 29%.³ These studies also reported substantial cytotoxicity including neutropenia and thrombocytopenia, which is expected with platinum-based chemotherapy.

Although response rates to platinum-based chemotherapy have previously been suboptimal, the use of OV's LiPlaCis DRP may reveal improved outcomes in patients assessed by the DRP as being more likely to respond to the drug. According to the company, more than 80 patients with metastatic castration-resistant prostate cancer have consented to have their tumour tissue analysed by the LiPlaCis DRP.

## Irofulven for prostate cancer

In October, the first prostate cancer patient was included in its Phase II irofulven trial. OV is developing irofulven, a cytotoxic DNA binding agent for the treatment of prostate cancer, using its DRP to select patients most likely to respond to treatment. OV's unique irofulven DRP is first being used to screen ~300 patients with metastatic castration- and docetaxel-resistant prostate cancer 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 entirety 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, which is approximately on par with the standard of care. For example, current treatment options (ie hormonal therapy, chemotherapy, typically taxanes or CYP-17 inhibitors, the combination of chemotherapy and hormonal therapy, or immunotherapy) yield a tumour response rate of 22.6% and corresponds to median progression-free survival and overall survival of 7.6 months and 15.1 months, respectively.

## Two 2X-121 trials underway

OV's Phase II 2X-121 trial in breast cancer is ongoing. 2X-121 is an orally bioavailable small molecule and a dual PARP-1/2 and TNKS-1/2 inhibitor. The open-label trial 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 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 has fallen behind previous expectations (Q418). In October 2018, OV announced its plans to initiate a second Phase II 2X-121, this time in patients with ovarian cancer in the US and in Germany in H119. OV previously received IDE and IND approvals for 2X-121 DRP technology and treatment protocol.

<sup>&</sup>lt;sup>2</sup> Hauke, R., & Teply, B. (2016). Chemotherapy options in castration-resistant prostate cancer. Indian Journal of Urology,32(4), 262.

<sup>&</sup>lt;sup>3</sup> Hager, S., et al. (2016). Anti-tumour activity of platinum compounds in advanced prostate cancer—a systematic literature review. Annals of Oncology,27(6), 975-984.

<sup>&</sup>lt;sup>4</sup> Akaza, H., et al. (2018). Metastatic Castration-Resistant Prostate Cancer Previously Treated With DocetaxelBased Chemotherapy: Treatment Patterns From the PROXIMA Prospective Registry. Journal of Global Oncology, (4), 1-12.



## Refinement of the dovitinib DRP biomarker

In February this year, 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. We note that this is the first time OV has commented on the possibility of treating patients with endometrial cancer with dovitinib and its DRP companion diagnostic. The company has not yet announced trials in these indications for dovitinib, however OV previously discussed going into renal and liver cancer, which we model trials initiating within the next year. Furthermore, we expect the company to select the best indications based on its data mining process to move forward with.

## **Valuation**

We have increased our valuation of OV to SEK1,117.7m or SEK22.22 per share (SEK20.84 per diluted share) from SEK1,100.5m or SEK21.87 (SEK20.52). This increase is primarily attributed to rolling forward our NPVs and is partly offset by lower net cash. Future adjustments to our valuation of the LiPlaCis programme are contingent on feedback from the FDA 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 SEK5.39, SEK3.29 and SEK5.26 per share, respectively. We expect to make further adjustments to our valuation of OV following feedback from the company's six clinical programmes.

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	695.3	39%	271.2
Irofulven	Metastatic prostate cancer	Phase lb/II	20%	2023	\$129,000	52.6	61.9	100%	61.9
APO010	Multiple myeloma	Phase lb/II	20%	2023	\$143,000	80.9	101.1	100%	101.1
2X-121	Metastatic breast cancer and ovarian cancer	Phase II	25%	2023	\$132,000	116.4	180.0	92%	165.6
2X-111	Glioblastoma and brain metastases from breast cancer	Phase lb/II	25%	2024	\$169,000	212.6	302.3	92%	278.2
Dovitinib	Renal and liver cancer	Phase lb/II	35%	2024	\$145,000	152.0	480.9	55%	264.5
Total									1,142.3
Net debt (at 31	December 2018) (SEKm)								(24.6)
Total firm value	(SEKm)								1,117.7
Total shares (m)	)								50.3
Value per basic	share (SEK)								22.22
Warrants and or	otions (m)								3.3
Fully diluted sha	ares in issue								53.6
Fully diluted val	ue per share								20.84



## **Financials**

OV recently announced its FY18 results. For FY18, OV reported revenue of DKK2.1m, primarily attributable to rendered services, and a post-tax loss of DKK15.5m. As of 31 December 2018, OV had DKK1.5m in cash and equivalents and DKK18.9m in debt. Operating losses came in slightly under expectations at DKK32.5m compared to our previous estimates (DKK37.6m). This is due in part to lower than expected SG&A expenditure, which we have adjusted for and carried forward. We do expect OV's operational expenditure to increase significantly over the next few years as several trials continue to ramp-up.

Due to lower spend and the drawdown of part of the flexible loan facility established with Trention, we have lowered our expectations to DKK388m (from DKK430m) in capital requirements, which we record as illustrative debt, to bring all six of its anticancer programmes to Phase III out-licensing (Exhibit 2). The company has established several avenues to significantly address these financing requirements. Firstly, the company recently announced it is preparing for a rights issue of SEK60m–SEK100m. As per the terms of the rights issue, shareholders may subscribe for one new share and one warrant for SEK4.00 for every two existing shares held, with a warrant strike price of at least SEK7.50. According to the company, guarantees and undertakings of approximately SEK60m have already been received. For accounting purposes, we record this as long-term debt and will move it to proceeds from equity in 2019 once the offering is complete. Secondly, OV intends to use SEK20m remaining from the flexible loan facility established with Trention to strengthen its financials in the near term.

Additional funding sources include the outstanding financing agreement with the European High Growth Opportunities Securitization Fund (EHGOSF, advised by Alpha Blue Ocean) for 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 (the size of tranche can be decreased to SEK7.5m). This agreement was revised in March 2019, allowing OV to solely determine the drawdown of the tranches and taking full control over the potential implementation of this financing (previously EHGOSF was in control of five of these drawdowns). 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.



DKK'000s	2017	2018	2019e	2020
Year end 31 December	IFRS	IFRS	IFRS	IFR
PROFIT & LOSS				
Revenue	5,145	2,147	3,646	3,64
Cost of Sales	0	0	0	
Gross Profit	5,145	2,147	3,646	3,64
EBITDA	(23,794)	(32,258)	(190,777)	(89,29
Operating Profit (before amort. and except.)	(23,848)	(32,471)	(190,564)	(89,08
Intangible Amortisation	0	0	0	
Exceptionals/Other	0	0	0	
Operating Profit	(23,848)	(32,471)	(190,564)	(89,08
Net Interest	(7,132)	(192)	(2,015)	(21
Other	0	10,146	0	
Profit Before Tax (norm)	(30,980)	(22,517)	(192,579)	(89,29
Profit Before Tax (IFRS)	(30,980)	(22,517)	(192,579)	(89,29
Tax	590	6,973	3,694	1,76
Deferred tax	0	0	0	
Profit After Tax (norm)	(30,390)	(15,544)	(188,885)	(87,53
Profit After Tax (IFRS)	(30,390)	(15,544)	(188,885)	(87,53
Average Number of Shares Outstanding (m)	24.3	33.8	52.8	55
EPS - normalised (DKK)	(1.27)	(0.44)	(3.58)	(1.5
EPS - IFRS (DKK)	(1.27)	(0.44)	(3.58)	(1.5
Dividend per share (ore)	0.0	0.0	0.0	(1.0
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BALANCE SHEET	4 000	007.000	007.000	007.0
Fixed Assets	4,883	237,096	237,096	237,09
Intangible Assets	135	236,733	236,733	236,73
Tangible Assets	4,424	363	363	36
Other Other	324	0	0	447.00
Current Assets	8,102	14,401	46,634	117,68
Stocks	1,048	0	0	0.00
Debtors	3,048	5,262	19,083	9,09
Cash	3,326	1,547	16,265	95,54
Other Comment Link little	680	7,592	11,286	13,04
Current Liabilities	(10,540)	(35,407)	(27,017)	(12,79
Creditors	(10,540)	(16,515)	(27,017)	(12,79
Short term borrowings	0	(18,892)	(005,400)	(444.40
Long Term Liabilities	0	(34,234)	(265,126)	(441,12
Long term borrowings	0	(24.024)	(230,892)	(406,89
Other long term liabilities	0	(34,234)	(34,234)	(34,23
Net Assets	2,445	181,856	(8,413)	(99,13
CASH FLOW				
Operating Cash Flow	(10,702)	(31,392)	(197,069)	(96,50
Net Interest	(170)	(2,391)	0	
Tax	2,527	6,159	0	
Capex	0	0	(213)	(21
Acquisitions/disposals	(784)	9,855	0	
Financing	7,478	198	0	
Dividends	0	0	0	
Other	(308)	(3,299)	0	(10
Net Cash Flow	(1,959)	(20,870)	(197,282)	(96,82
Opening net debt/(cash)	(5,488)	(3,326)	17,345	214,6
HP finance leases initiated	0	0	0	
Exchange rate movements	(203)	(199)	0	
Other	Ó	398	0	(
Closing net debt/(cash)	(3,326)	17,345	214,627	311,4



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