

# Oncology Venture

## New management unveils new strategy

Earnings update

Pharma & biotech

15 April 2020

**Price** **SEK1.38**

**Market cap** **SEK180m**

SEK10.03/DKK6.81/US\$

Net cash (DKKm) at YE19 6.6

Shares in issue 130.7m

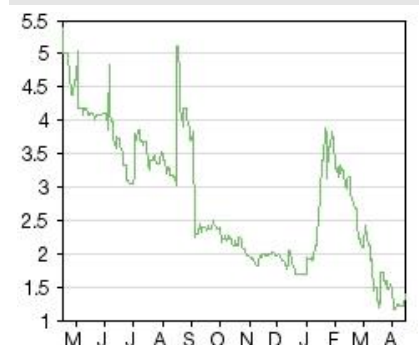
Free float 80.4%

Code OV

Primary exchange Nasdaq First North Stockholm

Secondary exchange N/A

### Share price performance



% 1m 3m 12m

Abs (8.0) (45.5) (74.5)

Rel (local) (18.2) (35.8) (73.4)

52-week high/low SEK5.23 SEK1.16

### 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. The company is advancing the PARP inhibitor 2X-121, the TKI dovitinib, and microtubule inhibitor Ixempra.

### Next events

Ixempra study initiation Q320

Dovitinib NDA submission Late H220

2X-121 Phase II results 2021

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Oncology Venture recently hired new upper management to streamline and focus its operations. This involves a prioritisation of its programmes towards its most attractive assets, which were determined to be the PARP 2X-121, the TKI dovitinib, and the microtubule disruptor Ixempra (ixabepilone). The company has provided updated timelines for its assets, all of which have major upcoming catalysts. We view this shift in focus as highly strategic and are encouraged by the company's new direction.

Year end	Revenue (DKKm)	PBT* (DKKm)	EPS* (DKK)	DPS (DKK)	P/E (x)	Yield (%)
12/18	2.1	(22.5)	(0.44)	0.0	N/A	N/A
12/19	0.8	(174.9)	(2.08)	0.0	N/A	N/A
12/20e	2.7	(151.7)	(1.17)	0.0	N/A	N/A
12/21e	1.8	(332.7)	(2.45)	0.0	N/A	N/A

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

## Focus is based on lower risk and faster returns

Oncology Venture selected three priority assets, based on which programmes can deliver value to investors and the market. The company's other assets, such as LiPlaCis, remain in ongoing clinical studies, but the progress of these studies will continue to the planned conclusion of the current clinical study. We are confident that the three chosen assets will be able to advance significantly more quickly through the clinical and regulatory process.

## Ixempra advancing to the clinic

The company previously obtained an option for the European rights to Ixempra from R-Pharm in April 2019 and recently announced it would be advancing the programme to clinical trials in Q320. The company proposed a 40-person clinical study in European centres for treatment of breast cancer; we expect it can complete the study in early 2021. In accordance with this, we have added the product to our model with an initial valuation of SEK183m.

## FDA: Dovitinib can be submitted on non-inferiority

Oncology Venture announced the outcome of its pre-NDA meeting with the FDA regarding its plan to submit an NDA for dovitinib on the basis of non-inferiority to sorafenib (Bayer). Management indicates the agency said that it would accept such an application and that progression free survival could be used as the endpoint for non-inferiority. This is good news because the company will not need to do any additional studies to submit the application, which it is planning for late in H220.

## Valuation: SEK893m or SEK6.83 per basic share

After the strategy change, we arrive at a new valuation of Oncology Venture of SEK893m or SEK6.83 per basic share. The company in Q419 completed a SEK100.6m rights offering and has entered into a separate SEK100m convertible loan facility. We expect current clinical programmes to require DKK1.1bn in additional financing, although we expect significant partnering efforts to offset this.

## A new company direction

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Oncology Venture announced in September 2019 that the board had appointed a new CEO and CFO to 'facilitate a focused commercial strategy'. The new management has delivered on its promises to overhaul the company's strategy and focus on three of its most high-value assets. The company will now focus its future development activity on 2X-121, dovitinib and Ixempra. These three assets were chosen because the company believes that they will provide the fastest and lowest-risk generation of value to investors. We concur with this assessment, as these three assets stand out from the field of other programmes in a number of ways.

### The selection of assets

We have previously commented on some of the difficulties the company has faced in enrolling and advancing its clinical studies. For instance, the APO010 clinical study has not enrolled any patients since its inception in 2017 and the irifolven study has not reported any results. Although management has reported some results from its ongoing Phase II LiPlaCis study (the latest in February 2019), progress has been behind schedule. However, we do not expect these limitations from the three now-prioritised lead programmes for a range of reasons.

For instance, the company may be able to secure an approval for dovitinib without the need for additional clinical data on the basis of non-inferiority to sorafenib, which would substantially elevate the value of this asset. To this end, the company recently had a meeting with the FDA to discuss this pathway forward (a pre-NDA meeting), in which the agency agreed with the company that it could submit an NDA on the basis of non-inferiority. Moreover, management indicated that the agency will accept an application with the endpoint for non-inferiority being progression free survival (PFS). This is important because non-inferiority on PFS is well supported by the previous studies.<sup>1</sup> Although we do not expect the drug to be marketed following this initial approval, it would substantially lower the hurdle for future dovitinib approvals in combination with the company's Drug Response predictor (DRP) technology. The company plans to submit the NDA in late H220.

The situation with Ixempra is similar in that a large body of clinical data has already been gathered on the product, as it is approved in the US to treat metastatic and locally advanced breast cancer. The product is a microtubule disrupting agent, similar in function to taxane, and is approved for use in patients who are refractory to taxane or anthracycline. We know the product has activity in this population and the DRP has the potential to identify the strongest responders. The company secured an option for the European rights to the product in April 2019, which it plans to utilise and advance the product to the clinic in Q320.

The 2X-121 product is a poly-ADP ribose polymerase (PARP) inhibitor, a class of drugs that has recently seen multiple approvals. The lead compound in the class is Lynparza (olaparib, AstraZeneca), which had \$647m in sales in 2018. This is an attractive asset to pair with the DRP, because the activity of the drug is already known to be contingent on genetic mutations that affect a cell's ability to respond to DNA damage, with current labels limited to patients' expression of mutations in the genes BRCA1 and -2. There is some speculation, however, that drugs of this class can be used in a broader range of patients with other mutations or in combination with other drugs that may enhance their effects. 2X-121 is in a Phase II clinical trial for ovarian cancer at the Dana-Farber Cancer Institute, which recently expanded to a new clinical site at Guy's Hospital in London. The target enrolment for the study is 30, with eight enrolled as of 12 November 2019. The drug is also being studied for breast cancer in a Phase II clinical study at sites across Denmark. We expect

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<sup>1</sup> Motzer RJ, et al. (2014) Dovitinib versus sorafenib for third-line targeted treatment of patients with metastatic renal cell carcinoma: an open-label, randomised phase 3 trial. *Lancet Oncol* 15, 286-296.

the company to report results from these studies in 2021. The company expects to initially develop the product for ovarian cancer, but as with other PARP inhibitors, we expect this to expand to breast cancer if it is successful in this initial indication. This compound is one of the few PARP inhibitors under development that has not been partnered with a big pharma company.

## Path forward and the future

The prior management had expressed the intention to in-license assets, develop them through early proof of concept and early clinical stages and then out-license these products for further development and approval. This strategy, however, has the risk of limiting the viable options it could take forward, because it lacked the capacity to run large registrational clinical studies. Moreover, any potential partners would have much greater leverage over Oncology Venture given that the company had few options besides seeking partners, which may have negatively affected deal terms. We believe this was in part the reason why the company was exploring a departure from this strategy and was in discussions with the FDA regarding advancing LiPlaCis to Phase III internally. The new management has changed this strategy expressly and intends to advance its key assets either internally or through partners opportunistically. The new management has significant experience in clinical development and we believe it can deliver on these promises, if it can secure financing.

The company has also provided a roadmap to the expansion of the DRP commercial strategy. The goal is to use these initial clinical programmes to demonstrate the value of the diagnostic, which can then be paired with the assets of other companies. The track record of the DRP identifying patients who are responders is well established in the literature and it continues to expand this proof of utility, as with the recent [presentation](#) at the European Society for Medical Oncology on using the product to predict responses to fluorouracil. What the company needs to demonstrate is that this can be used to support the approval of drugs paired with the test and, if it can, this could be very valuable to other companies interested in expanding the value of their products.

One factor that could potentially affect the ability of the company to deliver on these plans is the ongoing COVID-19 pandemic, which has had wide reaching impacts on the economy more generally and specifically on the healthcare industry. The company has stated that it does not expect long-lasting impacts from the disease on its development plan, but admits that ultimately these factors are hard to predict and that it is watching the situation closely. The most immediate impact that we could envision is a delay in the clinical development of 2X-121 and Ixempra, as it may be difficult to open trial sites or enrol patients. We will be keeping tabs on the progress of these programs to see if any changes need to be made to our models on account of COVID-19, but as of now we do not expect major delays.

## Valuation

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We have overhauled our model for the company to align it with the new clinical development strategy, which involves reducing the pipeline, and we have arrived at a new valuation of SEK893m or SEK6.83 per basic share. This is lower than our previous valuation (SEK1,271m) but carries lower risk. We have added Ixempra to our model with an initial valuation of SEK183m. This valuation assumes the product will be used in the top 20% of DRP responders with metastatic or locally advanced breast cancers and that it will be able to achieve 25% penetration into this potential market. Based on data provided by EvaluatePharma on Medicare patients, US revenue per patient has been between \$13,000 and \$16,000 in the period where data was available (until 2016). This corresponds to approximately three three-week courses per patient. We expect a European launch in 2025 and assign a probability of success of 50% on the basis that the drug is already approved in the US. We have also adjusted our timeline for 2X-121 and expect an initial

approval in 2024 and a potential breast cancer follow-on indication in 2025. The effect of the reduced pipeline of our valuation is offset by rolling forward our NPVs and exchange rate effects (SEK10.03/DKK6.81/US\$ from SEK9.11/DKK6.41/US\$).

**Exhibit 1: Valuation of Oncology Venture**

Development program	Indication	Clinical stage	Prob. of success	Launch year	Launch pricing	Peak sales (\$m)	rNPV (SEKm)	% rights held by OV	OV rNPV (SEKm)
2X-121	Metastatic breast cancer and ovarian cancer	Phase II	25%	2024-25	\$135,000	122.2	227.4	92%	209.2
Dovitinib	Renal cancer	Phase Ib/II	35-50%	2024-25	\$145,000	176.9	763.9	63%	481.3
Ixemptra	Metastatic breast cancer	Phase II	50%	2025	\$41,000	56.4	183.0	100%	183.0
Total									873.5
Net cash (YE19 + cash from EHGO, SEKm)									19.3
Total firm value (SEKm)									892.8
Total shares (m)									130.7
Value per basic share (SEK)									6.83
Dilutive warrants and options (m)									57.9
Fully diluted shares in issue (m)									188.6
Fully diluted value per share (SEKm)									6.43

Source: Oncology Venture reports, Edison Investment Research

## Financials

Oncology Venture reported an operating loss of DKK148m for 2019, of which DKK81.6m was a write down on the value of the company's newly deprioritized assets. The company ended the year with only DKK10.2m in cash (and DKK3.6m in debt), but management announced on 31 March that it has entered into a convertible debt agreement worth up to SEK100m with Negma Group Ltd and Park Partners GP (rolling conversion price of 95% of the lowest closing volume weighted average of the last seven trading days). The program will be in place for 24 months and is separated into 10 SEK10m tranches (callable by Oncology Venture). This is following the rights offering of the company in Q4 19 of SEK100.6m (net proceeds were about SEK84m). The fully subscribed offering included 50.3m units at SEK2.00 per unit of one share and one warrant exercisable at SEK6.00. The company also completed a debt conversion of SEK0.89m (DKK0.63m) in which 287,500 shares were issued at SEK2.20. The company was also able to reduce its short-term debt from DKK37.7m in Q3 19 to DKK3.6m at year end.

Post-year end (February 2020) the company issued 9.3m shares and 4.0m warrants (at SEK3.30) for SEK10.5m gross in a final payment in the financing agreement with European High Growth Opportunities Securitization Fund (EHGO).

**Exhibit 2: Financial summary**

	DKK'000s	2018	2019	2020e	2021e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>					
Revenue		2,147	801	2,698	1,810
Cost of Sales		0	0	0	0
Gross Profit		2,147	801	2,698	1,810
EBITDA		(32,258)	(66,502)	(151,084)	(332,033)
Operating Profit (before amort. and except.)		(32,471)	(148,102)	(151,084)	(332,033)
Intangible Amortisation		0	0	0	0
Exceptionals/Other		0	0	0	0
Operating Profit		(32,471)	(148,102)	(151,084)	(332,033)
Net Interest		(192)	(26,822)	(644)	(644)
Other		10,146	0	0	0
Profit Before Tax (norm)		(22,517)	(174,924)	(151,728)	(332,677)
Profit Before Tax (IFRS)		(22,517)	(174,924)	(151,728)	(332,677)
Tax		6,973	36,792	2,890	6,336
Deferred tax		0	0	0	0
Profit After Tax (norm)		(15,544)	(138,132)	(148,839)	(326,341)
Profit After Tax (IFRS)		(15,544)	(138,132)	(148,839)	(326,341)
Average number of shares outstanding (m)		33.8	63.4	127.1	133.5
EPS - normalised (DKK)		(0.44)	(2.08)	(1.17)	(2.45)
EPS - IFRS (DKK)		(0.44)	(2.08)	(1.17)	(2.45)
Dividend per share (ore)		0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>					
Fixed Assets		237,096	158,895	158,951	159,007
Intangible Assets		236,733	155,978	155,978	155,978
Tangible Assets		363	2,917	2,973	3,029
Other		0	0	0	0
Current Assets		14,401	22,306	134,387	333,355
Stocks		0	0	0	0
Debtors		5,262	5,937	14,928	32,731
Cash		1,547	10,176	110,377	285,206
Other		7,592	6,193	9,083	15,418
Current Liabilities		(35,407)	(31,497)	(25,330)	(50,695)
Creditors		(16,515)	(27,919)	(21,752)	(47,117)
Short term borrowings		(18,892)	(3,578)	(3,578)	(3,578)
Long Term Liabilities		(34,234)	(8,370)	(268,370)	(768,370)
Long term borrowings		0	0	(260,000)	(760,000)
Other long term liabilities		(34,234)	(8,370)	(8,370)	(8,370)
Net Assets		181,856	141,334	(362)	(326,703)
<b>CASH FLOW</b>					
Operating Cash Flow		(31,392)	(54,511)	(166,886)	(325,115)
Net Interest		(2,391)	(26,846)	0	0
Tax		6,159	8,942	0	0
Capex		0	(56)	(56)	(56)
Acquisitions/disposals		9,855	0	0	0
Financing		198	62,715	7,143	0
Dividends		0	0	0	0
Other		(3,299)	(4,253)	0	0
Net Cash Flow		(20,870)	(14,009)	(159,799)	(325,171)
Opening net debt/(cash)		(3,326)	17,345	(6,598)	153,201
HP finance leases initiated		0	0	0	0
Exchange rate movements		(199)	(98)	0	0
Other		398	38,050	0	0
Closing net debt/(cash)		17,345	(6,598)	153,201	478,372

Source: Oncology Venture reports, Edison Investment Research

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