EDISON

Oncology Venture

Financial update

Merger with Medical Prognosis Institute finalised

Pharma & biotech

In early September, Oncology Venture AB and Medical Prognosis Institute (MPI) completed their strategic merger and the new entity, Oncology Venture A/S (OV), now trades on the NASDAQ First North Stockholm. Recently, OV's three highest priority programmes all demonstrated progress. OV reported interim data from the LiPlaCis trial and is increasing enrolment, whereas 2X-121 received an IND from the US FDA in ovarian cancer. Furthermore, OV has a 55% stake in dovitinib, a tyrosine kinase inhibitor that was in-licensed from Novartis.

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	5.1	(36.5)	(0.68)	0.0	N/A	N/A
12/19e	2.4	(200.6)	(3.55)	0.0	N/A	N/A

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

OV completes merger with MPI

On 31 August 2018, Oncology Venture AB de-listed from the Spotlight Stock Market (previously AktieTorget). Since 3 September 2018, the new combined entity has traded on the NASDAQ First North Stockholm. Shareholders of Oncology Venture AB own 51% of the new company. OV exclusively owns MPI's mRNA-based drug response predictor (DRP) technology, which is the key to its focused Phase II trials.

Increase in enrolment in Phase II LiPlaCis trial

Based on feedback from the Danish Medicines Agency (DKMA), OV increased enrolment of the Phase II LiPlaCis trial to include 30 patients (from 20 patients) with metastatic breast cancer (mBC) to strengthen statistics around the DRP threshold. In total, 21 patients have been enrolled in the trial to date, while interim data from 19 evaluable patients showed three with partial remission, seven with stable disease and five with progressive disease, while four patients were unevaluable for response. Following the death of one patient which may be due to drug toxicity related to the patient's small size, OV adapted the trial protocol to adjust drug dosing according to patient size.

Receives IND and IDE for 2X-121 in ovarian cancer

OV has announced the US FDA approved the IND and IDE application for 2X-121, a dual PARP-1/2 and TNKS-1/2 inhibitor in advanced ovarian cancer. OV plans to enrol 30 patients in the US and Germany. This marks OV's second focused Phase II trial for this asset. Its first trial was initiated in June 2018 in mBC.

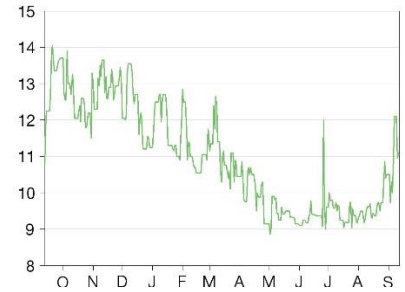
Valuation: SEK997.9m or SEK19.85 per share

We have increased our valuation of OV to SEK997.9m or SEK19.85 per share from SEK830.2m or SEK60.02 per share, which was largely driven by rolling forward our NPVs and OV's increase in stake of dovitinib from 40% to 55% following the merger with MPI (10%) and its recent purchase of additional shares (5%) from Sass & Larsen for $0.5m, as well as OV's increase in stake of LiPlaCis from 29% to 39%.

13 September 2018

Price	**SEK11.05**
Market cap	**SEK556m**
	US$0.16/DKK, US$0.11/SEK
Net cash (SEKm) estimated after merger	9.8
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	14.9	17.8	2.3
Rel (local)	14.7	14.1	(3.3)
52-week high/low	SEK14.05		SEK8.86

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

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

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LiPlaCis Phase II mBC trial update on 19 patients

OV provided an update on its ongoing single-arm, open-label focused Phase II study investigating LiPlaCis in heavily pre-treated mBC patients. As a reminder, patients are administered 75mg LiPlaCis, a liposomal version of cisplatin, intravenously (IV) in three-week cycles on days one and eight with efficacy evaluation every six weeks. Based on feedback from the DKMA, OV increased enrolment to include 30 patients (from 20) to strengthen statistics around the DRP threshold. As of 2 July 2018, 21 patients have been included in the study. Of the 19 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 evaluated for efficacy (Exhibit 1).

Exhibit 1: Interim data from 19 patients

Disease status	No. of patients
Partial remission	3
Long-term stable disease (>24 weeks)	3
Stable disease	4
Progressive disease	5
Not evaluable for response	4

Source: Oncology Venture

Time to progression (TTP) in the top third of patients with the highest DRP scores in comparison to the middle third of patients was 25 weeks and eight weeks, respectively. Of the top third of patients with the highest DRP scores, all seven heavily pre-treated patients with a median of seven previous treatments (excluding platin drugs) demonstrated clinical benefit as defined by stable disease (SD), long-term SD, or partial response (PR). For this cohort (10 patients, three not evaluable for response), median TTP following LiPlaCis compared to their last prior treatment 25 weeks versus 14.5 weeks, respectively. Five of seven of these patients experienced better response than all prior medical treatments for mBC whereas three experienced PR, one demonstrated SD for more than 24 weeks and one demonstrated SD at 21 weeks. Of the four patients not evaluable for response, one was dismissed from the trial due to early renal toxicity and three due to early death, whereas one death was deemed related to LiPlaCis toxicity. Analysis revealed the patient's death may have been related to their small size. Consequently, OV has adapted the trial protocol to adjust drug dosing according to patient size, which has been approved by authorities. We find this data encouraging, specifically the notable difference among the top third of DRP scorers versus the middle third DRP scorers in relation to TTP. We expect the increase in enrolment to improve statistics.

Moreover, OV and the DKMA recently discussed the potential design of a LiPlaCis randomised pivotal trial for mBC. The primary endpoint of the pivotal trial will be overall survival, with progression-free survival as a corresponding endpoint. According to the company, the DKMA suggested the comparator arm for the randomised trial be narrowed to include just three specific alternative products. Furthermore, if the LiPlaCis trial qualifies for the EMA PRIME (priority medicines) programme, the planned clinical trial will be considered a pivotal Phase II study. EMA PRIME supports drug development programmes that target an unmet clinical need and works with the developer to optimise development plans such that these medicines can reach patients faster.

FDA approves IND for 2X-121 for ovarian cancer trial

In late August, OV announced that the US FDA approved its Investigational New Drug (IND) application and corresponding Investigational Device Exemption (IDE) application to initiate the 2X-121 Phase II clinical trial in for the treatment of advanced ovarian cancer using its unique 2X-121 DRP. 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 and because BRCA1/2 mutated cells are incapable of double-strand break repair, PARP inhibition is particularly lethal and causes genomic instability and cell death.[1]

OV expects to enrol 30 patients in the US and Germany with advanced ovarian cancer and will use its 2X-121 DRP to select the top 10% of patients who are highly likely to respond to the drug. Once selected to participate in the trial, patients will receive 600mg of 2X-121 orally, daily until disease progression. The primary endpoint of the trial is antitumor efficacy (ie complete remission and partial remission). The secondary endpoints include safety data as well as additional efficacy parameters such as include progression free survival, duration of response and overall survival (OS).

This marks OV's second trial investigating 2X-121. The first 2X-121 trial in mBC was initiated in Q218. Both trials are supported by previous encouraging data from a 41-patient study of 2X-121 as a single agent in patients with advanced solid tumours (including pancreatic, ovarian, breast, colorectal, lung and other cancers), along with development and preliminary testing of the 414-gene 2X-121 DRP algorithm in 13 patients. The results were recently presented at the American Society of Clinical Oncology (ASCO) annual meeting in June 2018. The maximum tolerated dose was identified as 600mg, which maintained PARP inhibition at approximately 90%. The 2X-121 DRP identified responders and non-responders with median overall survival of more than 800 days and 208 days, respectively. It is important to note this trial included cancers without regard to BRCA mutation status, where PARP inhibitors are more active.

DRP retrospective study on anthracyclines in advanced BC

Also in August, OV published a paper detailing a retrospective study evaluating the potential of its unique epirubicin mRNA-based DRP to predict treatment response in 140 patients with advanced BC. Epirubicin is an anthracycline chemotherapy, and drugs of this class (ie doxorubicin and pegylated doxorubicin) are commonly used for local and mBC treatment. The study found that estimated median TTP for a patient with a DRP value of ≥75%, or a predicted good responder, was 13 months whereas median TTP for a patient with a DRP value ≤ 25%, a predicted poor responder, was 7 months (p=0.03).[2] Although the results are supportive of clinical activity, the real value is in the ability of the anthracycline DRP to identify responders, which will need to be tested prospectively. This trial supports OV's upcoming 2X-111 focused Phase II trial in the treatment of brain metastases from breast cancer and glioblastoma using the DRP. As a reminder, 2X-111 is a glutathione PEGylated liposomal formulation of doxorubicin, which is also an anthracycline chemotherapy that was in-licensed from 2-BBB Medicines. OV obtained a US IND in June 2017 and plans to initiate the Phase II trials this year.

Valuation

We have increased our valuation of OV to SEK997.9m or SEK19.85 per share from SEK830.2m or SEK60.02 per share. The decrease in the per-share value is attributed to the higher number of shares as a result of the merger with MPI. The increase in absolute valuation was primarily driven by rolling forward our NPVs, compounded by the strength of the US dollar (SEK9.11/US$1), and change in ownership stake in the assets following the merger with MPI including OV's increase in

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

[2] Buhl, A. S., Christensen, T. D., et al. (2018). Predicting efficacy of epirubicin by a multigene assay in advanced breast cancer within a Danish Breast Cancer Cooperative Group (DBCG) cohort: A retrospective-prospective blinded study. *Breast Cancer Research and Treatment*.

stake of dovitinib from 40% to 55% (MPI previously owned 10% of OV-SPV2) and the $0.5m purchase of an additional 5% of Sass & Larsen's shares in OV-SPV2. Moreover, Sass & Larsen and OV extended the buy-in option agreement for the purchase an additional 30% of shares in OV-SPV2 for $3.0m through 30 April 2019, which may provide significant upside given our current valuation of OV-SPV2's only asset, dovitinib. Likewise, OV's stake in LiPlaCis increased to 39% from 29% (MPI previously owned 10% of LiPlaCis). According to the company, its three highest priority assets include LiPlaCis, 2X-121 and dovitinib. Furthermore, MPI was previously developing the DRP platform as a standalone diagnostic test to determine patient responses to specific anti-cancer drugs. OV has indicated it plans to pursue this opportunity in 2019, at which point we may update our valuation to reflect this programme in the future.

Exhibit 2: Valuation of OV

Development Programme	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	445.6	39%	173.8
Irofulven	Prostate cancer	Phase Ib/II	20%	2023	$129,000	52.6	58.3	100%	58.3
APO010	Multiple myeloma	Phase Ib/II	20%	2023	$143,000	80.9	95.3	100%	95.3
2X-121	Metastatic breast cancer and ovarian cancer	Phase II	25%	2023	$132,000	116.4	163.1	92%	150.1
2X-111	Glioblastoma and brain metastases from breast cancer	Phase Ib/II	25%	2024	$169,000	212.6	284.4	92%	261.6
Dovitinib	Renal and liver cancer	Phase Ib/II	35%	2024	$145,000	152.0	452.9	55%	249.1
Total									988.2
Net cash and equivalents (estimated after merger) (SEKm)									9.8
Total firm value (SEKm)									997.9
Total shares (m)									50.3
Value per basic share (SEK)									19.85

Source: Edison Investment Research

Financials

We are now presenting the financials for OV, formerly MPI, and note that the historicals are not fully consolidated. However, we may adjust this in the future. It is also important to note that our projections are fully consolidated. For H118, OV reported revenue of DKK1.6m (H117 revenue: DKK3.1m), primarily attributable to rendered services, and a post-tax gain of DKK2.4m, which is up from the previous year (H117 post-tax loss: DKK20.5m) and attributable to the DKK10.8m profit on the divestment of ownership stake in Oncology Venture Sweden AB (ie the standalone company prior to the merger).

OV ended the period with DKK2.4m in cash and equivalents and on 31 August 2018 announced the DKK28.2m (SEK40m) cash flexible loan agreement with Trention. As per the agreement, the loan may be activated at the discretion of OV and will be due by August 2019. Our forecasts for the newly formed OV continue to model a total of DKK430m (DKK42m in 2018, DKK212m in 2019 and DKK176m 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 3). These estimates are based on the expected trial cost per patient ($100,000) and Phase II clinical trial size. These costs are primarily associated with the advancement of the LiPlaCis programme into Phase IIb, and ongoing irofulven and APO010 Phase IIa clinical trials. They also include 2X Oncology's recent initiation of its Phase II 2X-121 trial and its 2X-111 development programme, which is expected to initiate this year. We assume that all six of OV's assets will move forward; however, if the development programmes do not progress as we expect, this may bring costs down. Furthermore, OV may draw down part of this financing from the SEK40m flexibility loan from Trention, which was announced on 31 August 2018.

Exhibit 3: Financial summary

DKK'000s	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS
PROFIT & LOSS			
Revenue	5,145	5,094	2,419
Cost of Sales	0	0	0
Gross Profit	5,145	5,094	2,419
EBITDA	(23,848)	(36,492)	(198,637)
Operating Profit (before amort. and except.)	(23,848)	(36,438)	(198,583)
Intangible Amortisation	0	0	0
Exceptionals/Other	0	0	0
Operating Profit	(23,848)	(36,438)	(198,583)
Net Interest	(7,132)	(72)	(2,015)
Other (change in fair value of warrants)	0	0	0
Profit Before Tax (norm)	(30,980)	(36,510)	(200,598)
Profit Before Tax (IFRS)	(30,980)	(36,510)	(200,598)
Tax	590	695	3,977
Deferred tax	0	0	0
Profit After Tax (norm)	(30,390)	(35,815)	(196,620)
Profit After Tax (IFRS)	(30,390)	(35,815)	(196,620)
Average Number of Shares Outstanding (m)	24.3	52.8	55.4
EPS - normalised (DKK)	(1.27)	(0.68)	(3.55)
EPS - IFRS (DKK)	(1.25)	(0.68)	(3.55)
Dividend per share (ore)	0.0	0.0	0.0
BALANCE SHEET			
Fixed Assets	4,883	32,137	32,137
Intangible Assets	135	31,481	31,481
Tangible Assets	4,424	332	332
Other	324	324	324
Current Assets	8,102	28,989	58,855
Stocks	1,048	805	805
Debtors	3,048	11,231	20,547
Cash	3,326	9,505	26,077
Other	680	7,448	11,426
Current Liabilities	(10,540)	(10,072)	(32,801)
Creditors	(10,540)	(10,072)	(32,801)
Short term borrowings	0	0	0
Long Term Liabilities	0	(43,000)	(255,000)
Long term borrowings	0	(43,000)	(255,000)
Other long term liabilities	0	0	0
Net Assets	2,445	8,055	(196,809)
CASH FLOW			
Operating Cash Flow	(10,702)	(82,157)	(195,374)
Net Interest	(170)	(58)	0
Tax	2,527	69	0
Capex	0	(27)	(54)
Acquisitions/disposals	(784)	45,150	0
Financing	7,478	177	0
Dividends	0	0	0
Other	(308)	0	0
Net Cash Flow	(1,959)	(36,846)	(195,428)
Opening net debt/(cash)	(5,488)	(3,326)	33,495
HP finance leases initiated	0	0	0
Exchange rate movements	(203)	(25)	0
Other	0	50	0
Closing net debt/(cash)	(3,326)	33,495	228,923

Source: Company reports, Edison Investment Research

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