EDISON

Oncology Venture

Clinical update

LiPlaCis focused Phase II interim data

Pharma & biotech

In mid-September, Oncology Venture (OV) provided an update on its focused Phase II study investigating LiPlaCis in heavily pre-treated metastatic breast cancer (mBC) patients. To date, 26 patients have been enrolled in the trial via the drug response predictor (DRP) screening programme. Nine patients were segmented into the top one-third of responders and of these, 55% achieved partial remission. Notably, only the top responders as identified by the DRP achieved this, which may suggest that the DRP could prospectively identify responders.

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	(39.7)	(0.74)	0.0	N/A	N/A
12/19e	2.4	(203.8)	(3.60)	0.0	N/A	N/A

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

LiPlaCis Phase II update in 22 patients

OV recently provided an update on its ongoing single-arm, open label focused Phase II trial investigating LiPlaCis for the treatment of heavily pre-treated mBC. To date, 26 patients have been enrolled in the trial, while interim data from 22 evaluable patients showed six with partial remission, six with stable disease, six with progressive disease, and four unevaluable for response (ie one discharge and three deaths). An additional four patients have been enrolled in the trial but are not yet evaluable for response.

55% of top DRP responders achieve partial remission

Nine out of the 18 patients evaluable for response were identified by the DRP to have the highest likelihood (or top one-third) of response to LiPlaCis. Most notably, five out of these 9 patients, or 55%, achieved this clinical response. It is important to note that only the top responders as identified by the DRP are achieving this clinical response.

LiPlaCis trial expands to prostate cancer

On 4 October 2018, OV announced that the Danish Medicines Agency (DKMA) approved its application to expand the LiPlaCis Phase II trial to include metastatic prostate cancer patients. Following receipt of approval, 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 DRP.

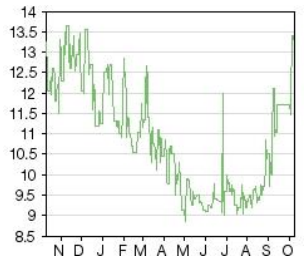
Valuation: SEK1,078m or SEK21.44 per share

We have increased our valuation to SEK1,078m or SEK21.44 per share from SEK997.9m or SEK19.85, driven by the expansion of the LiPlaCis Phase II programme to include metastatic prostate cancer patients. Also, the company believes these mBC data may support Breakthrough Therapy designation, which if secured would require fewer clinical data, move forward timelines and bring the drug to market more quickly.

9 October 2018

Price	**SEK13.30**
Market cap	**SEK669m**
	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	9.9	38.8	2.3
Rel (local)	9.8	31.5	0.8
52-week high/low	SEK15.0		SEK8.9

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

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

Analysts

Nathaniel Calloway	+1 646 653 7036
Maxim Jacobs	+1 646 653 7027
Briana Warschun	+1 646 653 7031

healthcare@edisongroup.com

Edison profile page

LiPlaCis Phase II mBC trial update on 22 patients

In mid-September, OV provided an update on its ongoing single-arm, open label focused Phase II trial investigating LiPlaCis for the treatment of heavily pre-treated mBC patients. As a reminder, patients are administered 40mg/m^2 LiPlaCis, a liposomal version of cisplatin chemotherapy, intravenously (IV) in three-week cycles on days one and eight with efficacy evaluation every six weeks. As of 17 September 2018, 22 patients have been included in the study and of those, 18 patients have been selected from the DRP screening programme. The DRP is used to classify tissue into three groups where the highly likely to respond (ie the top two groups) receive the drug and the less likely to respond (ie bottom one third) do not receive treatment. More than 1,400 mBC patients have been evaluated for efficacy. The top-one third of patients as identified by the DRP responded well to treatment (Exhibit 1). The update provided further detail on the status of the trial as it included efficacy responses from an additional three patients.

Exhibit 1: Interim data

High DRP responders (top one-third)	
Partial remission (>30% reduction in tumour size)	55%
Total evaluable patients	
Partial remission (>30% reduction in tumour size)	27%
Long-term stable disease (>24 weeks)	9%
Stable disease	18%
Progressive disease	27%
Not evaluable for response	18%

Source: Oncology Venture

Nine out of the 18 patients were determined to be the most likely to respond (top one-third), and notably five (or 55%) of these patients achieved partial remission, which is defined as a 30% or greater reduction in tumour size measured in one dimension in a CT-scan when treated with LiPlaCis. Importantly, only the top responders as identified by the DRP experienced clinical response, which elucidates to some extent that the DRP may prospectively identify responders to LiPlaCis. Additionally, eight out of nine heavily pre-treated (median of five previous treatments) patients enrolled in the trial demonstrated either partial remission, long-term stable disease or stable disease, while six out of the same nine patients experienced either a better response or a longer treatment effect duration in comparison to previous individual treatment history. Moreover, 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, one of which was deemed related to LiPlaCis toxicity. Analysis revealed the death may have been related to the patient's small size. Consequently, OV has adapted the trial protocol to adjust drug dosing to 40 mg/m^2 (from 75 mg), which has been approved by authorities. Four additional patients have been included in the trial but are not yet evaluable for response. According to the company, this 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.

Expanding the LiPlaCis trial to include prostate cancer patients

The DKMA recently approved OV's application to expand the LiPlaCis Phase II trial to include metastatic prostate cancer patients. OV now plans to increase patient enrolment to 50 (from 30) to include patients with mBC and metastatic prostate cancer. We expect this increase in patient enrolment to strengthen statistics around the DRP.

According to the National Cancer Institute, an estimated 161,360 patients in the US were diagnosed with prostate cancer in 2017, or 119.8 per 100,000 men on an age-adjusted basis,

making it the second most common cancer among men in the US and fifth most common cancer worldwide.[1] There were an estimated 26,730 deaths from the disease in the US during 2017. The stage of prostate cancer at diagnosis is a significant contributor to survival as patients with early local disease have a five-year relative survival rate of almost 100%, while patients with advanced metastasis have a relative five-year survival of 28%.[1]

Prostate cancer eventually progresses with androgen deprivation therapy (or hormone therapy), and this is termed castration-resistant prostate cancer. Newer medicines such as Xtandi (enzalutamide, Pfizer) and Zytiga (abiraterone acetate, Johnson & Johnson, J&J) have significantly improved patient outcomes. The rate of progression-free survival at 12-month follow up in one Xtandi trial was 68%.[2] Xtandi and Zytiga sales were approximately $2.5bn each in 2017.[3] The gold-standard treatment for the castration-resistant population includes docetaxel, which is a taxane chemotherapy, in combination with prednisone, a corticosteroid.[4] However, studies suggest that approximately 50% of these patients are either resistant or develop resistance to docetaxel and do not respond to treatment.[5]

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/m^2) and carboplatin every three weeks. The objective response rate to this combination therapy was relatively low at 14%.[6] 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 (PSA) decline was 20%.[7] In total, 17 publications investigating cisplatin in combination with other chemotherapies reported response rates between 23% and 29%.[7] 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 highly 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 and the company expects to enrol its first patient in Q418.

A new preclinical programme for 2X-121

In late September, OV announced it has identified positive prediction signals from 2X-121, an orally bioavailable small molecule and a dual PARP-1/2 and TNKS-1/2 inhibitor, from RNA-Seq data in paediatric cancers via a collaboration with the Paediatric Preclinical Testing Consortium funded by the National Cancer Institute. According to the company, preclinical studies are ongoing,

1 Darves-Bornoz, A., Park, J., & Katz, A. (2014). Prostate Cancer Epidemiology. Prostate Cancer,1-15

2 Beer, T. M., et al. (2014). Enzalutamide in Metastatic Prostate Cancer before Chemotherapy. New England Journal of Medicine,371(5), 424-433.

3 Evaluate Pharma

4 Hotte, S. J., &Saad, F. (2010). Current management of castrate-resistant prostate cancer. Current Oncology,17(0).

5 Magadoux, L., et al. (2014). Emerging targets to monitor and overcome docetaxel resistance in castration resistant prostate cancer (Review). International Journal of Oncology,45(3), 919-928.

6 Hauke, R., & Teply, B. (2016). Chemotherapy options in castration-resistant prostate cancer. *Indian Journal of Urology,32*(4), 262.

7 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.

investigating 2X-121 against in vivo panels of neuroblastoma, sarcoma and renal paediatric tumours using mouse models. Following results from these early preclinical data, OV may conduct additional studies to determine whether these cancer cell lines are either sensitive or resistant to 2X-121 in vitro, which may be further examined to determine the potential mechanisms of action (or resistance).

Valuation

We have increased our valuation of OV to SEK1,078m or SEK21.44 per share from SEK997.9m or SEK19.85 per share (Exhibit 2). The increase is primarily driven by the addition of prostate cancer to our valuation of the LiPlaCis programme. We assume a 25% probability of success for this new indication. Moreover, we find the LiPlaCis clinical update in mBC encouraging; nonetheless, we would like to see the complete data before making any adjustments to the valuation. The company believes these data may support Breakthrough Therapy designation. If it can secure this with the FDA, it would both require fewer clinical data and move timelines forward, which would bring the drug to market more quickly. These factors could substantially increase our valuation of the programme, although there can be no assurances that the FDA will be amenable. 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 SEK5.05, SEK2.98 and SEK4.95 per share, respectively. We expect to make further adjustments to our valuation of OV following feedback from the company's six clinical programmes.

Exhibit 2: Valuation of OV

Development Program	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 and metastatic prostate cancer	Phase II	25%	2023	$91,000	259.8	651.0	39%	253.9
Irofulven	Metastatic 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
Dovitnib	Renal and liver cancer	Phase Ib/II	35%	2024	$145,000	152.0	452.9	55%	249.1
Total									1,068.3
Net cash and equivalents (estimated after merger) (SEKm)									9.8
Total firm value (SEKm)									1,078.0
Total shares (m)									50.3
Value per basic share (SEK)									21.44

Source: Edison Investment Research

Financials

We present the financials for OV, formerly MPI, and note that the historic numbers are not fully consolidated. However, we may adjust this in the future. It is also important to note that our projections are fully consolidated. We have increased our forecasts for OV due to the inclusion of prostate cancer patients for the LiPlaCis Phase II trial. Our forecasts for OV remain unchanged and we continue to model a total of 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 3). 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)	(39,697)	(201,842)
Operating Profit (before amort. and except.)	(23,848)	(39,643)	(201,788)
Intangible Amortisation	0	0	0
Exceptionals/Other	0	0	0
Operating Profit	(23,848)	(39,643)	(201,788)
Net Interest	(7,132)	(72)	(2,015)
Other (change in fair value of warrants)	0	0	0
Profit Before Tax (norm)	(30,980)	(39,715)	(203,803)
Profit Before Tax (IFRS)	(30,980)	(39,715)	(203,803)
Tax	590	756	4,038
Deferred tax	0	0	0
Profit After Tax (norm)	(30,390)	(38,959)	(199,764)
Profit After Tax (IFRS)	(30,390)	(38,959)	(199,764)
Average Number of Shares Outstanding (m)	24.3	52.8	55.4
EPS - normalised (DKK)	(1.27)	(0.74)	(3.60)
EPS - IFRS (DKK)	(1.25)	(0.74)	(3.60)
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	26,295	53,016
Stocks	1,048	805	805
Debtors	3,048	11,231	20,862
Cash	3,326	6,749	19,801
Other	680	7,509	11,548
Current Liabilities	(10,540)	(10,521)	(33,250)
Creditors	(10,540)	(10,521)	(33,250)
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	4,911	(203,097)
CASH FLOW			
Operating Cash Flow	(10,702)	(84,913)	(198,894)
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)	(39,602)	(198,948)
Opening net debt/(cash)	(5,488)	(3,326)	36,251
HP finance leases initiated	0	0	0
Exchange rate movements	(203)	(25)	0
Other	0	50	0
Closing net debt/(cash)	(3,326)	36,251	235,199

Source: Company reports, Edison Investment Research

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 12, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia