EDISON

Oncology Venture

Clinical update

FDA OKs 505(b)(2) pathway for LiPlaCis in mBC

Pharma & biotech

Oncology Venture (OV) recently announced that the FDA agreed the 505(b)(2) pathway is an appropriate route for LiPlaCis in metastatic breast cancer (mbC) such that objective response rate (ORR) is a suitable primary endpoint for the study. OV is seeking approval for LiPlaCis via a single-arm pivotal study in ~100-200 patients with mBC. The company plans to update recruitment timelines following FDA approval of the IDE/IND application, which OV expects in H119.

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.

505(b)(2) pathway for LiPlaCis via ORR

In mid-December, OV announced that the FDA responded positively to its recently submitted pre-IDE/IND dossier detailing a potential application for LiPlaCis in mBC in the US. According to the company, the FDA agreed that the 505(b)(2) pathway is an acceptable course for LiPlaCis and that additional toxicology studies are not needed. The primary endpoint of the trial is ORR (ie partial responses plus complete responses); however, the FDA is also requesting supplementary characterisation of the patient sub-populations delineated by the drug response predictor (DRP) to be treated with LiPlaCis.

ORR is viable if granted 'breakthrough' designation

ORR is measured via single-arm studies in patients with refractory solid tumours where no alternative therapy exists. Therefore, ORR may serve as a viable endpoint for the LiPlaCis programme if the FDA grants 'breakthrough therapy' designation. In September 2017, the FDA approved Eli Lilly's Verzenio (abemaciclib), a cyclin-dependent kinase (CDK) inhibitor, as a monotherapy for HR+, HER2- advanced or mBC with an ORR of 19.7% in a 132-patient trial.

Plans for the pivotal LiPlaCis trial

OV is seeking approval for LiPlaCis via a single-arm pivotal study in ~100–200 patients with mBC whereas the ongoing Phase II trial may serve as a bridge. The company expects to update recruitment timelines for the trial following FDA approval for the IDE/IND application, which OV expects in H119.

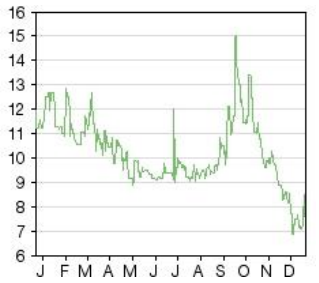
Valuation: SEK1,100.5m or SEK21.87 per share

Our valuation of OV remains unchanged at SEK1,100.5m or SEK21.87 per share (SEK20.52 per diluted share). The 505(b)(2) pathway enables drug approval with fewer patients in the clinical study and is consistent with our previous estimates for LiPlaCis of 200 patients needed for pivotal study. We expect to make further adjustments to our valuation in due course following feedback from the FDA regarding potential 'Breakthrough Therapy' designation for LiPlaCis.

21 December 2018

Price	**SEK7.6**
Market cap	**SEK382m**
	US$0.16/DKK, US$0.11/SEK
Net debt (SEKm) at 30 September 2018	0.8
Shares in issue	50.3m
Free float	70%
Code	OV.ST
Primary exchange	NASDAQ First North Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(7.8)	(43.7)	(37.7)
Rel (local)	(5.8)	(34.7)	(31.8)
52-week high/low	SEK15.0		SEK6.9

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

Initiate 2X-121 Phase II in ovarian cancer	Q119
Phase II LiPlaCis trial top-line data	H119

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Seeking LiPlaCis approval via 505(b)(2) pathway

On 18 December 2018, OV announced that the FDA provided positive feedback on 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 appropriate registration route for LiPlaCis in combination with its unique DRP. Moreover, the FDA accepted ORR as the primary endpoint for the trial 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 and the opportunity to evaluate earlier and in smaller studies in comparison to survival studies.

ORR is a relatively common endpoint for both regular and accelerated approval in refractory solid tumours where no alternative therapy exists, specifically in mBC. It is important to note, however, that ORR is not a direct measure of comprehensive drug activity and is typically supplemented with response duration, tumour-related symptom relief and drug toxicity data for approval. In September 2017, the FDA approved Eli Lilly's Verzenio (abemaciclib), a small molecule CDK 4 and 6 inhibitor, for HR+, HER2- advanced or mBC. Monotherapy approval was based on a single-arm, open-label multicentre trial in 132 women with HR+, HER2- advanced or mBC whose disease progressed on endocrine therapy, taxane therapy, and either one or two prior chemotherapy regimens. ORR was 19.7% with a median response duration of 8.6 months. Verzenio is also approved in combination with fulvestrant. Lilly reported Verzenio sales of $87.4m for the six months ending 30 June 2018.

OV is seeking approval for LiPlaCis, a liposomal version of cisplatin chemotherapy, via a single-arm pivotal study in ~100–200 patients with mBC whereas the ongoing Phase II trial may serve as a bridge. 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. As of 1 November 2018, five out of 10 patients (or 50%) in the top one-third of DRP selected patients and six out of 25 patients (or 24%) in the top two groups achieved partial remission 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. 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. OV plans to update recruitment timelines for the trial following FDA approval of the IDE/IND application, which the company expects in H119.

Valuation

The 505(b)(2) pathway enables drugs to be approved with fewer patients in the clinical study. These are consistent with our previous estimates for LiPlaCis of 200 patients needed for a pivotal study and therefore our valuation 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 include LiPlaCis, 2X-121 and dovitinib; and 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
Dovitnib	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)
Total firm value (SEKm)	1,100.5
Total shares (m)	50.3
Value per basic share (SEK)	21.87
Warrants and options (m)	3.3
Fully diluted shares in issue	53.6
Fully diluted value per share	20.52

Source: Edison Investment Research

Financials

Our financial forecasts and our financial requirements (DKK430m) for OV remain unchanged. We continue to expect these requirements to be significantly offset by the recent financing agreement with the European High Growth Opportunities Securitization Fund (EHGOSF) advised by Alpha Blue Ocean, announced on 30 November 2018. According to the agreement, OV may receive up to 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 (note, the size of tranche can be decreased to SEK7.5m) and EHGOSF may ask for five of these. These capital requirements may be further offset by DKK20m remaining available to the company attributed to the flexible loan facility established with Trention.

Exhibit 2: Financial summary

DKK'000s	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS
PROFIT & LOSS			
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
BALANCE SHEET			
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)
CASH FLOW			
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: Company reports, Edison Investment Research.

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