EDISON

Oncology Venture

Earnings update

New CEO as company moves toward late stage

Pharma & biotech

Oncology Venture announced on 4 September 2019 that it has appointed a new CEO, Steve Carchedi, former senior executive of J&J and Mallinckrodt. This comes at a critical juncture for the company as it moves its programmes into the late stage and starts to look for development partners to advance these assets. The company has made substantial progress getting LiPlaCis ready to launch Phase III studies with IND and IDE applications.

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	(117.0)	(1.65)	0.0	N/A	N/A
12/20e	3.6	(130.3)	(1.71)	0.0	N/A	N/A

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

LiPlaCis makes regulatory process

Oncology Venture is currently getting LiPlaCis ready to enter Phase III for metastatic breast cancer, and as part of this it applied for an IND from the FDA. The company previously received feedback from the agency in June on the IND application suggesting that the company move to a randomised trial design, albeit with the same enrolment (200 patients). The firm has since received approval for the IDE associated with the paired LiPlaCis drug response predictor (DRP) test to be employed in the Phase III trial.

LiPlaCis Phase II best cancer data still outstanding

Despite efforts to get the product ready for Phase III, the company has not yet finsihed Phase II and released the complete data on LiPlaCis for breast cancer. The trial has been expanded to include prostate cancer patients, but this should not affect the timeline for breast cancer. An interim readout on 12 patients was released in February, but this only includes a selection of readouts and no statistics.

Awaiting updates on irofulven and APO010

The company is also engaged in Phase II clinical studies for irofulven and APO010. However, in the most recent earnings report, the company noted that no patients have been enrolled into the APO010 study since it was initiated in May 2017. The irofulven study in prostate cancer is currently going to plan, but has not provided a readout yet. There are plans to open sites in Germany to accelerate enrolment, but these are currently on hold pending funding.

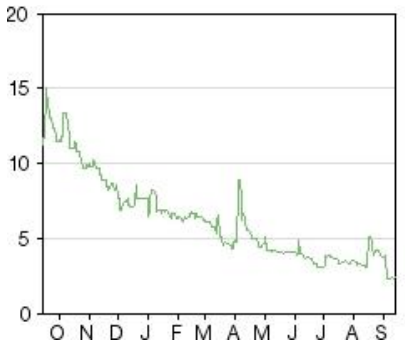
Valuation: SEK1,271m or SEK18.03

We have adjusted our valuation slightly lower to SEK1,271m or SEK18.03 per basic share from SEK1,302m or SEK18.47 per share, previously. We have delayed the commercialisation of LiPlaCis by six months and the irofulven, APO010 and 2X-111 (which has not entered the clinic) programmes by a year. We expect the company to need DKK360m (up from DKK310) to bring all its programmes to Phase III.

13 September 2019

Price	**SEK2.39**
Market cap	**SEK168m**
	SEK9.11/DKK6.41/US$
Net debt (SEKm) at Q219	20.1m
Shares in issue	70.5m
Free float	78.6%
Code	OV
Primary exchange	NASDAQ First North Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(24.6)	(33.2)	(74.5)
Rel (local)	(28.6)	(35.3)	(75.5)
52-week high/low	SEK12.71	SEK2.24	

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

Phase II LiPlaCis trial top-line data	Upcoming

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Edison profile page

A new CEO

The company announced on 4 September 2019, that its CEO, Peter Buhl Jensen, would resign and be replaced by Steve Carchedi on 15 September 2019. Steve Carchedi is the former CEO of Apexian Pharmaceuticals and serves on the board of Sunesis Pharmaceuticals and BioNumerik Pharmaceuticals. He also formerly served as the CEO of Cornerstone Pharmaceuticals, with senior sales and marketing roles at Mallinckrodt, GE Healthcare, Endo Pharmaceuticals and J&J, among others. We believe that Mr Carchedi's commercial experience is indicative of the shift the company is undergoing towards later-stage assets and their eventual commercialisation. His experience on a number of big pharma commercial teams may also prove useful when looking to out-license Oncology Venture's assets. And finally, he is based in the US, which signals the shift in focus towards the US market as the company's drugs approach late-stage trials. The company also announced that it hired a new CFO, Henrik Moltke, to replace outgoing Niels Laursen.

LiPlaCis: Regulatory progress, still waiting on Phase II

Oncology Venture intends to seek approval for LiPlaCis using a single pivotal Phase III clinical study. In June 2019, the company reported on feedback it received from the FDA on its IND application for LiPlaCis in metastatic breast cancer. The original proposal was for a single-arm, open-label study, but the FDA suggested that the company perform a randomised clinical trial. The company noted that the change does not affect the total enrolment or the timeline for the study. The company has amended and is resubmitting its IND to conform to this guidance. The company also noted that this clinical trial design would also presumably satisfy European authorities. Additionally, the company applied for an IDE for the DRP test associated with LiPlaCis, which was approved by the agency in August and was granted a European patent on the technology in June.

The company has also repeatedly stated that it believes LiPlaCis has the potential to seek a breakthrough designation, although this would depend on the data from the ongoing Phase II breast cancer study, which has not been released yet. The company noted in its Q219 financial report that the breast cancer study was still ongoing and has communicated that an update on the study will be provided following feed-back from the FDA. Feedback from management indicates that the company intends to run the breast cancer portion of the study until potentially after the pivotal study is initiated. We do not know if the company intends to release a complete data package prior to initiating the pivotal study.

The most recent data we have from the study are from February 2019, and do not provide a complete account of patient responses or other factors such as safety. The response rate was 33% (or four out of 12 patients) in the top one-third of DRP-selected patients (40mg/m^2 LiPlaCis intravenously (IV) in three-week cycles on days one and eight). These patients achieved partial response (PR) or better. 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). Additionally, the company reported that 40% of patients in the upper 20% of DRP-selected patients who have not previously received cisplatin also achieved PR or better. For comparison, the microtubule inhibitor Halaven (eribulin mesylate, Eisai) approved in 2010 has a response rate of 11% in this pre-treated population.

OV increases stake in dovitinib

Dovitinib is another one of the company's core development programmes. The company has engaged in a unique regulatory strategy in which it will use existing clinical data (from the drug's previous life under Novartis) to seek approval on the basis of non-inferiority to sorafenib. We do not necessarily believe that approval on the basis of non-inferiority will translate into a market for the drug (and give no value to this alone), but it will likely streamline future approvals of the drug in combination with the DRP. The company is additionally developing a novel DRP that examines the response of patients to a combination of dovitinib and a PD-1 or PD-L1 inhibitor.

The company recently increased its stake in the compound to 63% (from 55%) at a purchase price of US$0.8m. Moreover, it renegotiated its option contract to allow for the company to buy up to 100% of the programme (85% previously) at US$0.1m per percentage point. The remaining portion of the drug is owned by Sass & Larsen, a company representing a private investor.

Irofulven and APO010 trials slow going

Oncology Venture also recently provided an update on its other development programmes in its financial report, including the assets irofulven and APO010. Neither of these drugs is what we would consider a 'lead asset' for the company, but both are currently being studied in Phase II clinical studies. In the report the company noted that the study of irofulven in prostate cancer patients is ongoing in Denmark and proceeding as planned, but it recently set up a collaboration to expand its clinical sites into Germany 'in order to speed-up patient inclusion.' However, the company also noted that opening the German sites is contingent on financing. The company also noted that it has had difficulty enrolling patients in the ongoing Phase II study of APO010. It noted that no patients have been enrolled in the study to date. We consider this programme stalled until further notice.

Valuation

We have adjusted our valuation slightly lower to SEK1,271m or SEK18.03 per basic share, from SEK1,302m or SEK18.47 per share, previously. We have adjusted a number of timelines to reflect the progress made to date on the individual programmes. Given the lateness of the report of clinical data on LiPlaCis, we have delayed the commercialisation of the product by six months. Similarly, given the lack of material progress on Irofulven, APO010 and 2X-111, we have delayed the commercialisation of these programmes by a year. Irofulven and APO010 appear to be in stalled clinical trials, as described above, and 2X-111 has not yet entered the clinic. Despite these adjustments, our enterprise value increased for the company (SEK1,291m vs SEK1,267m) due to rolling forward our NPVs. Our valuation is also lowered by the increase in net debt: SEK20.1m net debt, compared to SEK34.9m net cash previously.

Exhibit 1: Valuation of Oncology Venture

Development programme	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	259.0	728.0	39%	283.9
Irofulven	Metastatic prostate cancer	Phase Ib/II	20%	2024	$129,000	52.4	69.4	100%	69.4
APO010	Multiple myeloma	Phase Ib/II	20%	2025	$146,000	75.9	89.6	100%	89.6
2X-121	Metastatic breast cancer and ovarian cancer	Phase II	25%	2023	$132,000	116.4	197.4	92%	181.6
2X-111	Glioblastoma and brain metastases from breast cancer	Phase Ib/II	25%	2025	$169,000	202.4	300.0	92%	276.0
Dovitinib	Renal cancer	Phase Ib/II	35–50%	2024–25	$145,000	176.9	619.3	63%	390.2
Total									1,290.7
Net cash/(debt) (Q219) (SEKm)									(20.1)
Total firm value (SEKm)									**1,270.6**
Total shares (m)									70.5
Value per basic share (SEK)									**18.03**
Warrants and options (m)									23.5
Fully diluted shares in issue (m)									94.0
Fully diluted value per share (SEKm)									15.16

Source: Oncology Venture reports, Edison Investment Research

Financials

The delays that we have incorporated in our model have substantially changed our near-term spending expectations. Because we no longer expect clinical progress in 2019 for Irofulven, APO010 and 2X-111, and we expect delayed progress on LiPlaCis, this has reduced our expected loss for 2019 to DKK104m from DKK190m. However, these costs are largely retained, just in later years. This has increased our expected financing requirement to DKK360m (from DKK310m), which we include as illustrative debt (DKK100m in H219, DKK260m in 2020). This financing requirement is solely to bring the company's products to a Phase III ready state, where they can be out licensed, and we would expect substantially higher financing requirements if the company seeks to fully develop any programmes internally.

The company ended Q219 with SEK20.1m in net debt. This is also after the company completed a rights offering during the period, which raised DKK56m gross (DKK48.7m in cash and DKK7.7m in debt conversion). The company's new CEO has suggested that the company immediately initiate another rights offering targeting SEK100m.

Exhibit 2: Financial summary

DKK000s	2017	2018	2019e	2020e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	5,145	2,147	3,646	3,646
Cost of Sales	0	0	0	0
Gross Profit	5,145	2,147	3,646	3,646
EBITDA	(23,794)	(32,258)	(116,407)	(131,190)
Operating Profit (before amort. and except.)	(23,848)	(32,471)	(114,942)	(130,132)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(23,848)	(32,471)	(114,942)	(130,132)
Net Interest	(7,132)	(192)	(2,015)	(212)
Other	0	10,146	0	0
Profit Before Tax (norm)	(30,980)	(22,517)	(116,957)	(130,344)
Profit Before Tax (IFRS)	(30,980)	(22,517)	(116,957)	(130,344)
Tax	590	6,973	12,595	2,823
Deferred tax	0	0	0	0
Profit After Tax (norm)	(30,390)	(15,544)	(104,362)	(127,522)
Profit After Tax (IFRS)	(30,390)	(15,544)	(104,362)	(127,522)
Average Number of Shares Outstanding (m)	24.3	33.8	63.1	74.7
EPS - normalised (DKK)	(1.27)	(0.44)	(1.65)	(1.71)
EPS - IFRS (DKK)	(1.27)	(0.44)	(1.65)	(1.71)
Dividend per share (ore)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	4,883	237,096	239,508	238,490
Intangible Assets	135	236,733	236,692	236,692
Tangible Assets	4,424	363	2,816	1,798
Other	324	0	0	0
Current Assets	8,102	14,401	66,977	154,886
Stocks	1,048	0	0	0
Debtors	3,048	5,262	7,390	14,582
Cash	3,326	1,547	40,831	118,725
Other	680	7,592	18,756	21,579
Current Liabilities	(10,540)	(35,407)	(46,498)	(18,774)
Creditors	(10,540)	(16,515)	(46,498)	(18,774)
Short term borrowings	0	(18,892)	0	0
Long Term Liabilities	0	(34,234)	(158,709)	(418,709)
Long term borrowings	0	0	(121,908)	(381,908)
Other long term liabilities	0	(34,234)	(36,801)	(36,801)
Net Assets	2,445	181,856	101,278	(44,108)
CASH FLOW				
Operating Cash Flow	(10,702)	(31,392)	(96,251)	(182,065)
Net Interest	(170)	(2,391)	(8,848)	0
Tax	2,527	6,159	(22)	0
Capex	0	0	(368)	(40)
Acquisitions/disposals	(784)	9,855	(3,758)	0
Financing	7,478	198	41,060	0
Dividends	0	0	0	0
Other	(308)	(3,299)	(75)	(102)
Net Cash Flow	(1,959)	(20,870)	(68,262)	(182,207)
Opening net debt/(cash)	(5,488)	(3,326)	17,345	81,078
HP finance leases initiated	0	0	0	0
Exchange rate movements	(203)	(199)	(47)	0
Other	0	398	4,576	102
Closing net debt/(cash)	(3,326)	17,345	81,078	263,183

Source: Oncology Venture reports, Edison Investment Research

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