EDISON

Oncology Venture

Earnings update

Company consolidates ownership of dovitinib

Pharma & biotech

Oncology Venture (OV) announced on 8 June 2020 that it acquired the remaining 37% minority stake in its dovitinib asset for SEK36m in stock (25.9m shares issued at SEK1.388 per share). The deal also includes a 10% royalty payment over the next 24 months following the signing (although we do not expect significant revenue from the asset during this period). The product's new drug application is currently planned to be submitted to the FDA in H220.

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	0.9	(124.4)	(0.75)	0.0	N/A	N/A
12/21e	0.9	(260.1)	(1.59)	0.0	N/A	N/A

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

Executing on the new corporate strategy

We have already outlined the plan from the new management to prioritise its development programmes, which is part of a larger strategy to run the company and deliver value more efficiently. The company is winding down the clinical activity for the legacy programmes (such as LiPlaCis), but it guided toward these activities being completed in Q120 and for there to be reduced costs in Q220. Additionally, Oncology Venture has made efforts to recapitalise. In the year to date, Oncology Venture eliminated the previous outstanding debt and entered a new SEK100m convertible note agreement (of which SEK10m has been drawn) and a $5m (SEK50m) equity facility.

Company to investigate 2X-121 for COVID-19

Recent preclinical research has indicated that poly-ADP-ribose polymerase (PARP) inhibitors can potentially be used as a treatment for COVID-19. Such drugs may inhibit viral genome replication as well as limit the inflammatory response. Oncology Venture has initiated early-stage studies to investigate if its PARP inhibitor 2X-121 can replicate this activity seen with other drugs. We are not including this programme in our valuation given its very early stage and the unpredictable nature of the COVID-19 market, but see it as worthy of investigation and we are glad to see the company participate in the effort to combat the disease.

Valuation: SEK1,178.9m or SEK7.36 per basic share

We have increased our valuation to SEK1,178.9m or SEK7.36 per basic share, from SEK892.8m or SEK6.83. This is driven by adjusting dovitinib ownership to 100%. Additionally, we have rolled forward our NPVs and these changes are offset by lower net cash (SEK5.4m from SEK19.3m). We have delayed the clinical programme for 2X-121 on account of slow enrolment to date and the future impact of COVID-19. We forecast that Oncology Venture will fully utilise its remaining financing facilities in 2020 (SEK137m) to progress its clinical and regulatory programmes.

9 June 2020

Price	**SEK1.51**
Market cap	**SEK242m**
	SEK10.03/DKK6.81/US$
Net debt (DKKm) at 31 March 2020	0.015
Shares in issue	160.2m
Free float	89%
Code	OV
Primary exchange	Nasdaq First North Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(15.1)	(34.5)	(64.0)
Rel (local)	(23.2)	(38.1)	(67.9)
52-week high/low	SEK4.98	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	Late 2021

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Edison profile page

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Dovitinib now 100% owned by OV

The company detailed in a press release on 8 June 2020 the details of its transaction to acquire the remaining portion of dovitinib rights (37%) from the other stakeholder in the drug, investor Sass & Larsen. The parties agreed to a transaction price of SEK36m, which was given to Sass & Larsen in the form of 25,936,599 OV shares at SEK1.388 each. This pricing was based on the closing market price on the day of the transaction. The deal also includes a 10% royalty payable on sales of the drug for the next two years following completion of the transaction. We currently do not expect significant sales of the drug during this period until after the approval of an sNDA to support its use in combination with the DRP (expected in 2024).

We assume that this transaction was made under the terms of a previous agreement entered into by OV and Sass & Larsen. Almost exactly one year ago in June 2019, OV acquired 8% of dovitinib for DKK5.4m and entered into an option agreement to acquire the remaining portion of the drug at a later date. We assume that the royalty provision was included in the deal terms in the event the dovitinib ownership consolidation transaction would occur closer to the drug's commercial stage.

We view this transaction as very favourable for Oncology Venture. The implied valuation for the product based on the deal is SEK97m, which is substantially less than our risk-adjusted total NPV for the product (SEK786.8m). The company intends to submit an NDA for marketing approval for the drug to the FDA in late H220.

Financial update: Tightening the ship

On 29 May 2020, Oncology Venture outlined the progress it has made so far in its efforts to re-gear for future growth since the new management team joined in autumn 2019. Oncology Venture's strategy has been focused on both identifying programmes with the best return on investment as well as eliminating operational and financial overhangs. We previously reported on the company's efforts to reprioritise its pipeline towards three lead assets: dovitinib, 2X-121 and Ixempra. However, clinical studies for the deprioritised assets continue to be wound down and have contributed to costs. The operational loss for Q120 was DKK17.6m, which is comparable to averaged quarterly results from last year (Q119 DKK13.0m, Q219 DKK15.6m, Q319 DKK18.2m, Q419 not representative). Management stated that it expects reduced costs in Q220 as the winding down of these programmes is completed (although we expect operating costs to increase in subsequent periods with increased clinical and regulatory costs for the prioritised programmes). Additionally, the company stated that it has eliminated operational inefficiencies and reduced its headcount to improve costs. Finally, we expect some operational slowdowns on account of COVID-19 (more detail outlined below) to lead to a further reduction in costs. We have adjusted our estimates for the 2020 operating loss to DKK124.7m from a previous estimate of DKK151.1m.

Coupled with reducing costs is the strategy to refinance Oncology Venture under more attractive terms, which it has made significant progress toward in the year to date. Oncology Venture had DKK26.8m in interest and other financial expenses for 2019. However, recently it has eliminated its previous debt and entered into new financing facilities worth up to SEK150m. The first with Negma Group provides SEK100m of zero coupon convertible debt available to the company (drawable in 10 tranches of SEK10m each and convertible at 95% of the seven-day volume weighted average price (VWAP)), of which it has already drawn SEK10m (SEK2m has been subsequently converted). Because of the timing of this financing agreement around the close of the quarter, the company ended Q120 with only SEK7,000 in cash, a matter of days before drawing down the first tranche.

Additionally, the company entered an equity facility with Global Corporate Finance in May for $5m (SEK50m). The company will be able to draw five tranches up to $1m with shares issued at 95% of the five-day VWAP. Oncology Venture has already used this facility to eliminate an additional SEK3.4m in debt.

The above developments have reduced our expected financing requirement for Oncology Venture to DKK1.02bn from DKK1.10m. We record and model this financing need as illustrative debt (DKK140m additional debt in 2020, DKK500m in 2021 and DKK380m in 2022), although we expect the company to finance near-term costs with its current facilities (Negma, Global Corporate Finance) and seek partnering agreements to defray much of its remaining costs. The company has SEK137m remaining in the facilities, which corresponds to 95.5m new shares at 95% of the current share price (SEK1.50).

A PARP for COVID-19?

Oncology Venture announced on 22 April 2020 that it would test the activity of 2X-121 as an antiviral against COVID-19 in a study being conducted at the Pathogen and Microbiome Institute at Northern Arizona University. 2X-121 is of a class of drug (PARP inhibitors) that has found activity in the oncology setting (and are approved for ovarian, breast cancer and prostate cancer) but has not historically been investigated for antiviral activity. The company cited a recent preprint from a group in China that investigated the PARP mefuparib and found that it was more effective in vitro than remdesivir. Additionally, it was found that the drug supressed IL-6 production from immune cells, potentially reducing inflammation. Other scientists have published a review article in support of the idea (but without supporting data). These results are highly preliminary and the report has not been published in a peer reviewed journal yet, but they are encouraging and we believe the company is correct to follow up on this lead if there is any chance that PARP inhibitors may be effective against the disease.

Clinical and regulatory update

As the situation develops with the worldwide COVID-19 pandemic, there remains a high degree of uncertainty regarding the potential impacts on operating businesses, including Oncology Venture. The company remains in a relatively good position with regards to its development programmes. Given that progress with dovitinib is regulatory in nature, we see limited impacts on the company's target to have an NDA submitted by the end of 2020. The company is still targeting starting the Ixempra Phase II study in Q320, although it has published cautionary statements that these plans may be affected by the disease. We remain cautiously optimistic that this programme can initiate on time, given that we forecast some lifting of quarantine restrictions by Q320. However, we are adjusting our clinical timeline for the ongoing Phase II studies of 2X-121. The company reported that eight patients (of a planned 30) have been enrolled to date, which is the same as was reported in November 2019. The company planned on starting a new clinical site at Guy's Hospital in the UK (in addition to the current site at the Dana-Farber Cancer Institute), but this has not yet passed the hospital's internal review. This compounded with the impact of COVID-19 on trial enrolment has prompted us to push back the expected date for top-line results from the study to late 2021 (from mid-2021 previously).

Valuation

We have increased our valuation to SEK1,178.9m or SEK7.36 per basic share, from SEK892.8m or SEK6.83. This increase is driven by the recognition of 100% of the value for dovitinib in our estimates and is offset by the inclusion of 25.9m new shares as part of the agreement.

Additionally, it is offset by lower net cash estimates (SEK4.4m – SEK0.02m net debt at Q120 end + SEK4.4m net cash from the subsequent Negma and Global Corporate Finance agreements, from SEK19.3m at YE19). There is risk to this valuation being diluted from these agreements. If the company were to fully utilise these facilities at the current stock price (95.5 new shares for SEK137m as described above) and fully convert its debt, this would increase our total valuation to SEK1,316m, but lower it to SEK5.14 on a per share basis. Our valuations for Ixempra and dovitinib have increased from rolling forward our NPVs, but the valuation of 2X-121 is lower as a result of incorporating the expected delays in the clinical programme. The expected initial launch of the product has been delayed to 2025 (from 2024/25 previously) and this decreased its valuation to SEK198.2m from SEK209.2m. We have not associated any valuation with the 2X-121 COVID-19 programme as it is at too early a stage and the potential market is highly competitive and unpredictable at this time.

Exhibit 1: Valuation of Oncology Venture

Development program	Indication	Clinical stage	Probability 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%	2025	$138,000	122.1	215.4	92%	198.2
Dovitinib	Renal cancer	Phase Ib/II	35–50%	2024–25	$145,000	176.9	786.8	100%	786.8
Ixempra	Metastatic breast cancer	Phase II	50%	2025	$41,000	56.4	188.5	100%	188.5
Total									1,173.5
Net cash (Q120 + debt conversion, SEKm)									5.4
Total firm value (SEKm)									1,178.9
Total shares (m)									160.2
Value per basic share (SEK)									7.36
Dilutive warrants and options (m)									57.9
Fully diluted shares in issue (m)									218.1
Fully diluted value per share (SEK)									6.87

Source: Oncology Venture reports, Edison Investment Research

Exhibit 2: Financial summary

DKK'000s	2018	2019	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	2,147	801	901	901
Cost of Sales	0	0	0	0
Gross Profit	2,147	801	901	901
EBITDA	(32,258)	(66,502)	(123,598)	(258,713)
Operating Profit (before amort. and except.)	(32,471)	(148,102)	(124,650)	(259,765)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(32,471)	(148,102)	(124,650)	(259,765)
Net Interest	(192)	(26,822)	218	(345)
Other	10,146	0	0	0
Profit Before Tax (norm)	(22,517)	(174,924)	(124,432)	(260,110)
Profit Before Tax (IFRS)	(22,517)	(174,924)	(124,432)	(260,110)
Tax	6,973	36,792	9,065	4,954
Deferred tax	0	0	0	0
Profit After Tax (norm)	(15,544)	(138,132)	(115,367)	(255,157)
Profit After Tax (IFRS)	(15,544)	(138,132)	(115,367)	(255,157)
Average Number of Shares Outstanding (m)	33.8	63.4	153.6	161.3
EPS - normalised (DKK)	(0.44)	(2.08)	(0.75)	(1.58)
EPS - IFRS (DKK)	(0.44)	(2.08)	(0.75)	(1.58)
Dividend per share (ore)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	237,096	158,895	183,457	182,461
Intangible Assets	236,733	155,978	181,473	181,473
Tangible Assets	363	2,917	1,984	988
Other	0	0	0	0
Current Assets	14,401	22,306	98,745	314,053
Stocks	0	0	0	0
Debtors	5,262	5,937	10,803	25,591
Cash	1,547	10,176	73,306	268,872
Other	7,592	6,193	14,636	19,589
Current Liabilities	(35,407)	(31,497)	(67,560)	(37,029)
Creditors	(16,515)	(27,919)	(67,538)	(37,007)
Short term borrowings	(18,892)	(3,578)	(22)	(22)
Long Term Liabilities	(34,234)	(8,370)	(151,176)	(651,176)
Long term borrowings	0	0	(144,740)	(644,740)
Other long term liabilities	(34,234)	(8,370)	(6,436)	(6,436)
Net Assets	181,856	141,334	63,466	(191,691)
CASH FLOW				
Operating Cash Flow	(31,392)	(54,511)	(87,058)	(304,377)
Net Interest	(2,391)	(26,846)	363	0
Tax	6,159	8,942	13	0
Capex	0	(56)	(56)	(56)
Acquisitions/disposals	9,855	0	(25,560)	0
Financing	198	62,715	36,235	0
Dividends	0	0	0	0
Other	(3,299)	(4,253)	(1,914)	0
Net Cash Flow	(20,870)	(14,009)	(77,977)	(304,433)
Opening net debt/(cash)	(3,326)	17,345	(6,598)	71,456
HP finance leases initiated	0	0	0	0
Exchange rate movements	(199)	(98)	77	0
Other	398	38,050	(154)	0
Closing net debt/(cash)	17,345	(6,598)	71,456	375,890

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