EDISON

Oncology Venture

Earnings update

COVID-19 programme to enter the clinic soon

Pharma & biotech

On 26 August 2020 Oncology Venture reported that its PARP inhibitor stenoparib (aka 2X-121) demonstrated activity against COVID-19 in vitro. Following up on this on its 28 August earnings conference call, the company announced that it intends to advance the programme to the clinic as soon as possible and it is currently seeking financing through grants and other sources to support the programme.

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	(101.4)	(0.59)	0.0	N/A	N/A
12/21e	0.9	(240.7)	(1.16)	0.0	N/A	N/A

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

Company reports preclinical anti-COVID-19 activity

The company stated that stenoparib showed inhibition of COVID-19 as a monotherapy and in combination with remdesivir. On the company's conference call, it was stated that the drug achieved complete inhibition or near complete inhibition of the virus; we will need more detailed information to draw conclusions. The timeline to get the drug tested in the clinic is still up in the air. The company is currently applying for grants from a range of funding sources, including BARDA, which is supporting a large number of COVID-19 programmes in the US.

Potential for anti-viral and anti-inflammatory activity

The mechanistic rationale for using PARP inhibitors against COVID-19 is not well understood, but the drugs in this class are known to have anti-inflammatory activity and the PARP enzyme is known to modify the capsid of the SARS virus. The initial report of PARP inhibitor activity against COVID-19 was from a Chinese study of a different drug (mefuparib), which found high levels of viral inhibition (over 99%) but at high concentrations (30μM). This may not be representative of stenoparib (which may have higher or lower activity), but the sign of activity in this indication suggests that more research is warranted.

Stenoparib breast cancer trial terminated

The company is terminating its Phase II clinical study of stenoparib for breast cancer after it found that it could not optimise its drug response predictor using old diagnostic biopsies in the heavily pre-treated population being studied, and that new biopsies would be required. The trial had been ongoing since 2018. The drug remains in an ongoing Phase II for ovarian cancer (OC).

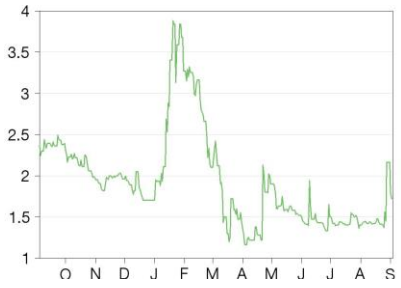
Valuation: Decreased to SEK1,156m or SEK5.98/share

Our valuation has decreased to SEK1,156m or SEK5.98 per share from SEK1,212m or SEK6.59 per share. This is driven by the removal of breast cancer from our models for stenoparib and offset by rolling forward our NPVs. We are not adding the COVID-19 opportunity to our valuation at this time.

4 September 2020

Price	**SEK1.71**
Market cap	**SEK331m**
	SEK10.03/DKK6.81/US$
Net debt (DKKm) at 30 June 2020	DKK1.89
Shares in issue	193.4m
Free float	92.1%
Code	OV
Primary exchange	Nasdaq First North Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	19.6	18.9	(52.1)
Rel (local)	18.3	13.3	(58.4)
52-week high/low	SEK3.88		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 stenoparib (2X-121), the TKI dovitinib and microtubule inhibitor Ixempra.

Next events

Ixempra study initiation	Q320
Dovitinib NDA submission	Late H220
Stenoparib OC Phase II results	Late 2021

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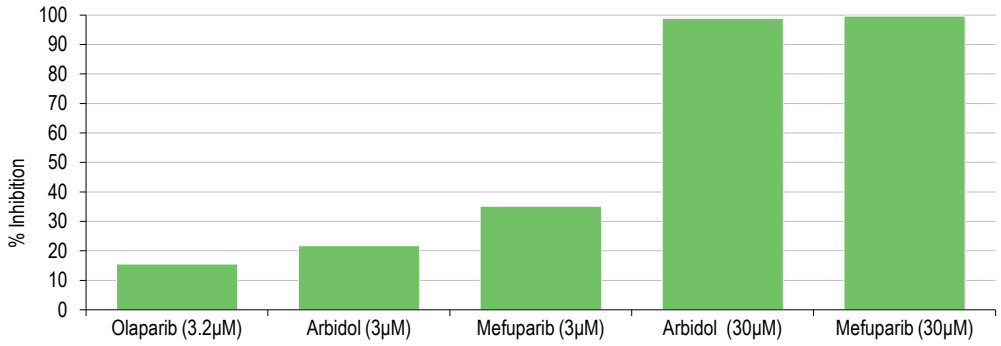
Background on PARPs for COVID-19

The idea of testing stenoparib against COVID-19 comes from a study from Tsinghua University in Beijing that is available as a preprint (and thus has not been peer reviewed). The study used a drug knowledge base as well as transcriptome data gathered on MERS and SARS to predict which molecules could have an effect on the virus. The study identified PARP inhibitor PJ-34 as a potential candidate and subsequently demonstrated anti-COVID-19 activity in vitro. In addition, the algorithm predicted a number of other drugs with potential activity against COVID-19 such as chloroquine (which famously has not panned out as a treatment), gemcitabine (a chemotherapy) and cyclosporine (an immunosuppressant) among others.

The drug PJ-34 was still in preclinical testing, so the research team opted to investigate two other PARP inhibitors in its place: olaparib and mefuparib (CVL218). These were compared to a selection of antivirals including arbidol, an anti-influenza agent common in Russia and China that is currently being used in those countries for COVID-19 (Exhibit 1). Cells were inoculated in the presence of drug for two hours, and the viral load was subsequently measured after two days and compared to control. Because of this setup, the researchers were effectively measuring if the drugs could prevent initial infection (as opposed to prevent replication in previously infected cells). The results showed that mefuparib demonstrated 35% inhibition at 3μM and 99.7% at 30μM. The 99% rate of inhibition seen with the drug in this assay may appear encouraging, but the concentration (30μM) is exceptionally high. The researchers demonstrated that these sorts of concentrations were achievable in rats, but not for all tissues and the results were short lived (no longer than six hours in any tissue), and that the oral dose needed was very large (20mg/kg, equivalent to over 1.5g for an American adult). This being said, mefuparib showed higher activity than olaparib as well as arbidol, which has demonstrated a clinical effect in some early studies.

Exhibit 1: Inhibition of COVID-19 in vitro with PARP inhibitors



Source: Ge et al. (2020).

Despite the limitations of this study it did show the potential for antiviral activity in PARP inhibitors, and we believe that this avenue is worthy of further investigation. We see from the study that there is significant variation in the anti-viral activity of different drugs of this class: olaparib had only half of the activity of mefuparib. Although Oncology Venture has done some early preclinical testing and made some very positive statements, we will need more information regarding how stenoparib was tested and at what concentrations in order to understand where it stands on this spectrum.

The mechanism of action for PARP inhibitors provides little insight into the nature of this anti-viral activity. The PARP (poly-ADP-ribose polymerase) enzyme's main function is to respond to DNA damage, which has little overlap with the pathology of COVID-19, which is caused by an RNA virus. However, the nucleocapsid of SARS-CoV (the original SARS virus) is ADP ribosylated, which

suggests that perhaps PARP is important for the maturation of the SARS-CoV-2 capsid.[1] Unrelated to viral replication, PARP inhibitors are known to limit the expression of pro-inflammatory cytokines like IL-6, IL-1 and TNF-α, and this activity could potentially be useful in COVID-19. A major cause of mortality in the disease is the uncontrolled release of such molecules, a so-called cytokine storm. However, there are other more effective inhibitors of these cytokines that are already being used in the clinic (tocilizumab and anakinra). In our view, the key to the success of stenoparib in this indication will be if it can inhibit viral infection or replication, and any anti-inflammatory effect will sweeten the drug's profile.

The company stated that it intends to immediately seek financing to start clinical studies of stenoparib for COVID-19, and that it has applied for a grant from the Biomedical Advanced Research and Development Authority (BARDA). Although the company has not provided a timeline for the initiation of clinical studies, we expect things to move swiftly. Moreover, the company has highlighted that once it has the greenlight to run a trial, it should move quickly as patients are only expected to be dosed for a matter of weeks. We are looking forward to hearing more regarding the progress of this programme.

Stenoparib breast cancer programme terminated

Along with the positive COVID-19 results, the company reported that it would be discontinuing a long running Phase II clinical study in Denmark to examine stenoparib for metastatic breast cancer. The study had been running since 2018, and its intended goal was to optimise the company's drug response predictor (DRP) against this population. The company stated that the reason why the trial was discontinued was because it had been using diagnostic biopsies for transcriptomic analysis in the DRP, and that this proved to be ineffective. These diagnostic biopsies could be many years old and not reflective of the current state of the disease in this heavily treated population, and that new biopsies would be needed. We expect future clinical trial designs to ensure that the patients included have a recent biopsy that is representative of the disease. The company's Phase II in ovarian cancer is still ongoing (albeit delayed by COVID-19) and has enrolled 10 of the 30 planned patients. It is expected to start enrolling more patients again in late Q420.

Valuation

Our valuation has decreased to SEK1,156m or SEK5.98 per share from SEK1,212m or SEK6.59 per share. This decrease is driven by the removal of breast cancer from our initial approval indications for stenoparib. If the drug is approved for ovarian cancer, the company may reinitiate studies into breast cancer, similar to other approved PARP inhibitors. This lowered the valuation for the programme to SEK144.6m from SEK215.4m. The decrease is also driven by lower estimated net cash (SEK10.9m from SEK20.9m) and offset by rolling forward our NPVs. We are not adding the COVID-19 programme to our valuation at this time due to the high number of uncertainties regarding the product, the market and the pathway forward for this programme. This is our practice for all early stage COVID-19 programmes under our coverage. We may change this however in the future if stenoparib can gain traction in the clinic.

[1] Curtin N, et al. (2020) Repositioning PARP inhibitors for SARS-CoV-2 infection(COVID-19); a new multi-pronged therapy for acute respiratory distress syndrome? *Brit J Pharmacol* 177, 3635-3645.

Exhibit 2: Valuation of Oncology Venture

Development programme	Indication	Clinical stage	Prob. of success	Launch year	Launch pricing	Peak sales ($m)	rNPV (SEKm)
Stenoparib	Metastatic ovarian cancer	Phase II	25%	2025	$138,000	51.3	144.6
Dovitinib	Renal cancer	NDA	35–50%	2024–25	$145,000	176.4	806.6
Ixempra	Metastatic breast cancer	Phase II	50%	2025	$41,000	56.4	194.1
Total							1,145.3
Pro-forma net cash (Q220 + subsequent transactions, SEKm)							10.9
Total firm value (SEKm)							1,156.1
Total shares (m)							193.4
Value per basic share (SEK)							5.98
Dilutive warrants and options (m)							7.5
Fully diluted shares in issue (m)							200.9
Fully diluted value per share (SEKm)							5.84

Source: Oncology Venture reports, Edison Investment Research.

Financials

The company was able to reduce its net loss for H120 (DKK20.2m) by over half compared to the previous year (DKK40.7m). This is due primary to the company's ongoing efforts to clean up the balance sheet, which has reduced the company's financial expenses (primarily interest) to DKK1.4m for H120 from DKK15.1m for H119. The company continues to regularly take advantage of its financing facilities with Negma Group/Park Partners and Global Corporate Finance, which since the end of Q220 have improved the company's net cash position by SEK13.5m (resulting in our current estimate of pro-forma H120 net cash of SEK10.9m), resulting in the combined issuances of 10.1m shares and conversion of all outstanding convertible loan notes.

Operational spending has come in lower than our expectations for 2020 so far. The company reported an operating loss of DKK23.1m for H120 (vs DKK28.6m loss in H119). This is in part due to DKK7m in licensing revenue to the company (recorded as an exceptional item), presumably from its deal with Smerud. Additional, spending has been lower than expected, perhaps due to the impact of COVID-19 or the company's cost control measures. We have reduced our expected operating loss for 2020 to DKK104.2m from DKK124.7, previously. We expect spending to increase substantially in H220 as the company enters the clinic with Ixempra and files its NDA for dovitinib. We forecast that the company will need an additional DKK915m to reach profitability (down from DKK1,015), which we record as debt for illustrative purposes (DKK135m in 2020, DKK400m in 2021 and DKK380m in 2022). We expect the company to address its near-term cash needs through a combination of its existing facilities as well as potentially additional licensing agreements.

Exhibit 3: 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)	(103,168)	(238,283)
Operating Profit (before amort. and except.)	(32,471)	(148,102)	(104,238)	(239,353)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	7,099	0
Operating Profit	(32,471)	(148,102)	(97,139)	(239,353)
Net Interest	(192)	(26,822)	2,837	(1,387)
Other	10,146	0	0	0
Profit Before Tax (norm)	(22,517)	(174,924)	(101,401)	(240,740)
Profit Before Tax (IFRS)	(22,517)	(174,924)	(94,302)	(240,740)
Tax	6,973	36,792	6,242	4,585
Deferred tax	0	0	0	0
Profit After Tax (norm)	(15,544)	(138,132)	(95,158)	(236,156)
Profit After Tax (IFRS)	(15,544)	(138,132)	(88,059)	(236,156)
Average Number of Shares Outstanding (m)	33.8	63.4	161.7	203.0
EPS - normalised (DKK)	(0.44)	(2.08)	(0.59)	(1.16)
EPS - IFRS (DKK)	(0.44)	(2.08)	(0.54)	(1.16)
Dividend per share (ore)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	237,096	158,895	161,583	160,569
Intangible Assets	236,733	155,978	155,849	155,849
Tangible Assets	363	2,917	2,032	1,018
Other	0	0	3,702	3,702
Current Assets	14,401	22,306	114,886	259,760
Stocks	0	0	0	0
Debtors	5,262	5,937	8,640	23,685
Cash	1,547	10,176	96,522	221,766
Other	7,592	6,193	9,724	14,309
Current Liabilities	(35,407)	(31,497)	(58,641)	(38,656)
Creditors	(16,515)	(27,919)	(54,151)	(34,166)
Short term borrowings	(18,892)	(3,578)	(4,490)	(4,490)
Long Term Liabilities	(34,234)	(8,370)	(143,049)	(543,049)
Long term borrowings	0	0	(135,000)	(535,000)
Other long term liabilities	(34,234)	(8,370)	(8,049)	(8,049)
Net Assets	181,856	141,334	74,780	(161,376)
CASH FLOW				
Operating Cash Flow	(31,392)	(54,511)	(67,938)	(274,701)
Net Interest	(2,391)	(26,846)	395	0
Tax	6,159	8,942	5,352	0
Capex	0	(56)	(56)	(56)
Acquisitions/disposals	9,855	0	(13,365)	0
Financing	198	62,715	23,329	0
Dividends	0	0	0	0
Other	(3,299)	(4,253)	(278)	0
Net Cash Flow	(20,870)	(14,009)	(52,561)	(274,757)
Opening net debt/(cash)	(3,326)	17,345	(6,598)	42,968
HP finance leases initiated	0	0	0	0
Exchange rate movements	(199)	(98)	(36)	0
Other	398	38,050	3,031	0
Closing net debt/(cash)	17,345	(6,598)	42,968	317,724

Source: Oncology Venture accounts, Edison Investment Research

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