

Fluoguide

An earlier version of this comment erroneously referred to pricing of Cytalux, but it should have referred to Rakuten's Akalux-BioBlade.

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Company Comment	Healthcare	Denmark	13 January 2022
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Nordic Seminar: FluoGuide looks to maximise potential pricing power

At SEB's Nordic Seminar, FluoGuide CEO Morten Albrechtsen clearly laid out the equity story and discussed the path to approval and reimbursement. We were particularly interested in his thoughts about the need for flexibility in the clinical programme to be able to demonstrate clinical efficacy, superiority, and methods of use, in order to maximise reimbursement. We were also encouraged that FluoGuide's clinical program continues to be on track.

Cytalux is a case study that illuminates the bar for success

We had an interesting discussion about what the bar for success is for FG001, and here the recent approval of Cytalux (OTL38) for ovarian cancer is instructive, as the FDA required that it cross a threshold of 10% improvement in positive predictive value. This is a very low bar for approval, in our view. Cytalux delivered a 27% improvement. We note that OTL38 targets the folate receptor, which has broader distribution than uPAR, and that 20% of patients had normal tissue removed as well. Importantly, however, the bar for success also relates to reimbursement, and there we agree with management that demonstrating improvement in patient outcomes would greatly increase pricing power.

FluoGuide prepared to be flexible in clinical program to maximise pricing power

FluoGuide has planned to take FG001 to the market for surgical guidance, and subsequently seek label expansion to include photothermal therapy (PTT), in which FG001 would be used to directly kill residual tumour tissue post-surgery. An important challenge, however, is that although proving a benefit from PTT with FG001 would increase its value to society, and hence, in principle, enable FluoGuide to set a higher price, in reality it is extremely difficult to increase a drug's price more than a few percent after it has initially been set. Gliolan sells for USD 4-5k, setting a price floor, and we had assumed that FG001 would be priced at USD 10,000 in the US, with FluoGuide initially accepting a lower share until a benefit from PTT can be demonstrated. However, the recent approval and reimbursement in Japan of Rakuten's Akalux-BioBlade for use in photoimmunotherapy (a process similar to PTT), priced at USD 125k, adds urgency to this issue. FluoGuide is therefore actively considering whether to alter its clinical programme, not in terms of the number or design of studies, but rather in terms of the order in which they should be conducted. For example, a PTT trial could potentially be conducted sooner.

A notable case of a drug that managed to increase its price is alemtuzumab, initially approved as Campath to treat CLL. With sales for CLL dwindling, Sanofi increased its pricing substantially by pulling it from the market and rebranding it Lemtrada, for use in MS. Although this is a somewhat controversial approach, we believe that such a strategy would be more readily justifiable for FluoGuide, although it would probably

necessitate dropping its initial indication for the rare brain cancer, glioblastoma. This could be potentially circumvented, after a fashion, by obtaining approval for other brain cancers.

Equity story intact, with potential upside from greater pricing power

With FluoGuide progressing on target and with strong data in hand to odate, we believe the equity story is fully intact. The prospect of reorganising the clinical programme to maximise pricing power and the potential to motivate much higher pricing sounds tantalising to us, so this is a development that we will be following closely.

Valuation:

Key figures				
(DKKm)	2020	2021E	2022E	2023E
Revenues (m)	3	8	0	0
Adj. EBIT	(22)	(31)	(65)	(78)
PTP (m)	(22)	(31)	(65)	(78)
EPS	(1.75)	(2.29)	(4.26)	(5.08)
EPS (adjusted)	(1.75)	(2.29)	(4.26)	(5.08)
DPS	0.00	0.00	0.00	0.00
Revenue growth (%)	0.0	0.0	0.0	0.0
EPS growth (%)	n.a.	n.a.	n.a.	n.a.
Operating margin (%)	0.0	0.0	0.0	0.0
ROCE (%)	(495.1)	(106.1)	(80.3)	(100.6)
Net Debt/EBITDA (x)	0.5	1.9	1.8	0.8
PER (adjusted)	(50.4)	(26.1)	(14.0)	(11.7)
Dividend yield (%)	0.0	0.0	0.0	0.0
Free Cash Flow Yield (%)	(1.0)	(4.2)	(6.5)	(7.9)
P/BV (x)	210.7	12.4	6.6	15.2
EV/EBIT (x)	(41.5)	(19.8)	(9.2)	(8.4)
EV/Sales (x)	n.m.	n.m.	n.m.	n.m.

Source: SEB

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