

# ISOFOL MEDICAL

## AGENT phase III trial fails

Isofol Medical announced that the phase III trial AGENT had failed to reach its primary and most important secondary endpoints. This is a huge disappointment and reduces the company's valuation significantly (as arfolitixorin – the drug evaluated in the AGENT trial – was its only asset in clinical development). We have cut our fair value to SEK0-3 (14–26).

**AGENT phase III trial in mCRC failed to reach its endpoints.** The AGENT trial compared mFOLFOX-6 + bevacizumab (Avastin) in mCRC patients, but arfolitixorin replaced leucovorin; the aim was to reach an increase in ORR of >10% (primary endpoint) and to see a positive trend in the PFS (secondary endpoint). Unfortunately, the trial did not achieve either of these endpoints. Even though the data is not fully mature, the CEO stated that the ORR is; hence, it will not change over time. The PFS could change marginally as the data matures, we believe.

**Trial set to be completed in Q4 with full data read-out then.** We will not receive more detailed data or granularity on different subgroups, bio-markers or gene-expression data until later this year. The company stated that the trial will be completed in a responsible manner and the data submitted for publication as soon as possible.

**Arfolitixorin its only asset in clinical development.** As Arfolitixorin is Isofol Medical's most advanced asset and its only project in clinical development, we believe the steep share price fall (c85%) on the news was warranted. The failure of the trial and lack of data until Q4 also calls into question future developments and opportunities, in our view.

**Financial position decent – for now.** The company had cSEK332m in cash at end-Q1 (Q2 earnings not yet reported). However, cash will decline over time as the AGENT trial is completed and terminated. Even if the company scales back operations now because of the data read-out, cash will become an issue at some point.

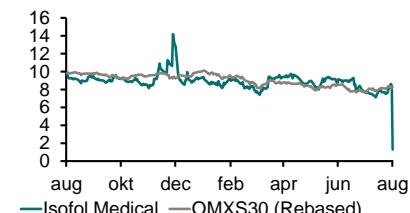
**How to proceed?** The answer to this question is still highly uncertain and will depend on the detailed data analysis of the AGENT trial. Depending on the final data read-out in Q4, we believe there could be subgroups of interest that make further development of arfolitixorin worth pursuing, but at this stage we have no such indications that we can factor into our model.

**Fair value cut to SEK0-3.** We estimate cash burn for the remainder of the year of cSEK130m (assuming some cost-cutting and rationalisation of operations when the AGENT trial is completed), meaning Isofol Medical should have cSEK200m at end-Q4. We have lowered our LOA for arfolitixorin from 23.2% to 6% as there could still be some value left in the project. In addition, we have lowered our penetration assumptions, as the drug does not seem to benefit the entire population of mCRC patients.

Year-end Dec	2018	2019	2020	2021	2022e	2023e	2024e
Revenue (SEKm)	nm	0	37	22	25	4	70
EBITDA adj (SEKm)	-90	-165	-183	-201	-161	-79	-4
EBIT adj (SEKm)	-90	-166	-185	-203	-163	-80	-6
PTP (SEKm)	-83	-160	-187	-199	-163	-83	-9
EPS rep (SEK)	-2.63	-5.04	-2.27	-1.24	-1.02	-0.52	-0.06
EPS adj (SEK)	-2.63	-5.04	-2.27	-1.24	-1.02	-0.52	-0.06
Revenue growth (%)	nm	nm	34607.5	-39.7	9.4	-84.9	1793.7

Source: Company (historical figures), DNB Markets (estimates)

### ISOFOL versus OMXS30 (12m)



Source: Factset

### SUMMARY

Share price (SEK) 1.30

Tickers ISOFOL SS

### CAPITAL STRUCTURE

NIBD adj end-2022e (SEKm) -242

Net debt/EBITDA adj (x) 1.50

Source: Company, DNB Markets (estimates)

Note: Unless otherwise stated, the share prices in this note are the last closing price.

### NEXT EVENT

Q2 2022 report 23/08/2022

### ESTIMATE CHANGES (SEK)

Year-end Dec	2022e	2023e	2024e
Sales (old)	24.52	90.40	438.2
Sales (new)	24.52	3.69	69.90
Change (%)	0.0	-95.9	-84.0
EPS adj (old)	-1.23	-0.67	1.59
EPS adj (new)	-1.02	-0.52	-0.06
Change (%)	nm	nm	-103.6

Source: DNB Markets,

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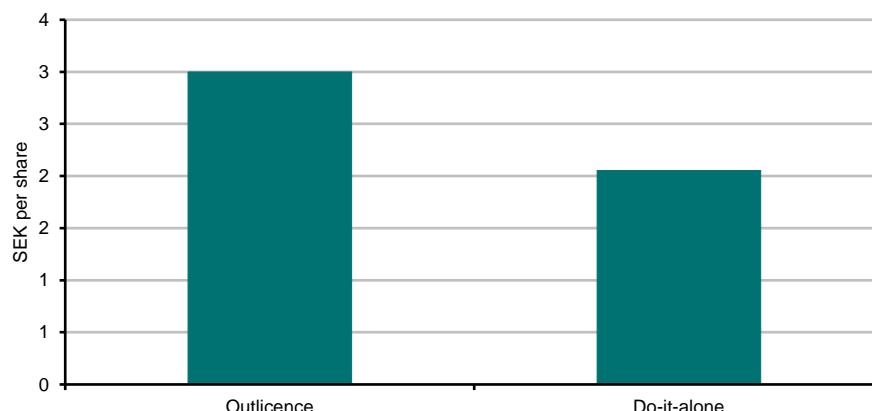
### ANALYSTS

Patrik Ling

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# Overview

## Valuation (SEK)



Source: DNB Markets

## Valuation methodology

- We continue to use a risk-adjusted DCF with two main scenarios: that the company 1) out-licenses the drug at some point; and 2) builds a proprietary organisation and takes arfolitixorin to market on its own. We discount the value in our model by a WACC of 10% and have cut the LOA to 6% (23.2%).
- We estimate the company will have cSEK200m in cash at end-2022.

Source: DNB Markets

## Downside risks to our fair value

- The risk is high that the company needs to wind down its operations completely after the failed AGENT trial.
- The company might run out of cash in the coming year.

Source: DNB Markets

## DNB Markets estimates

- We value the company at its expected cash position at the end of the year.
- We have not included any revenues from arfolitixorin in our model.

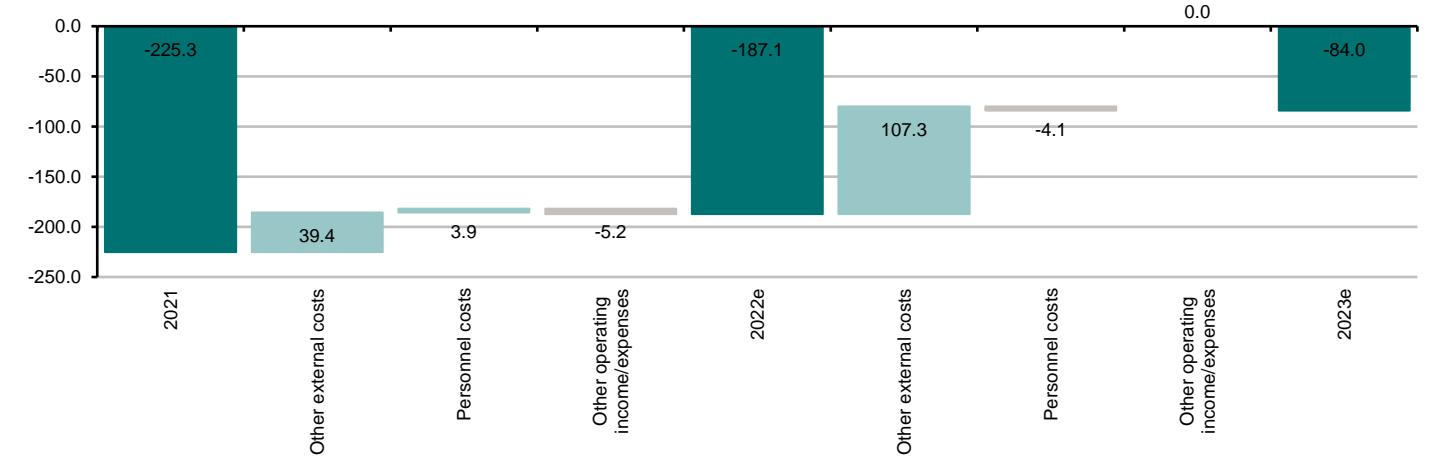
Source: DNB Markets

## Upside risks to our fair value

- If data evaluation from the finalised AGENT trial reveals subgroups where the drug works well, there could still be a potential market for arfolitixorin.
- An out-licensing deal for the further development of the drugs could happen if there is data indicating efficacy in certain subgroup(s).

Source: DNB Markets

## Operating cost base bridge 2021–2023e (SEKm)



Source: DNB Markets (forecasts), company (historical data)

# ESG overview

## Sustainability assessment

	Positive	Negative
Conclusions	<ul style="list-style-type: none"> <li>■ Isofol Medical is developing a new therapy for metastatic colorectal cancer, an area where there is a substantial unmet medical need.</li> <li>■ In this development stage, the company's operations pose no particular environmental risks.</li> </ul>	<ul style="list-style-type: none"> <li>■ The company has yet to publish any corporate social responsibility reports.</li> <li>■ Isofol Medical's business model for getting its product to the market is based on out-licensing the product to a global pharmaceutical company, which limits the company's ability to affect ESG policies and access to health.</li> <li>■ Developing new drugs is costly, time-consuming, and very risky.</li> <li>■ The company conducts testing on animals, which is a regulatory requirement to proceed to clinical trials in humans.</li> <li>■ Animal models do not always predict – in a representative way – the potential effects in humans, hence some risks remain.</li> </ul>
Actions being taken by company	<ul style="list-style-type: none"> <li>■ The company conducts its operations in accordance with health and safety regulations and offers employees a safe and healthy work environment.</li> <li>■ Isofol Medical works proactively to minimise its environmental footprint and to contribute to sustainable development.</li> </ul>	

## Key ESG drivers

Short-term	<ul style="list-style-type: none"> <li>■ The company has no products on the market and thus the environmental focus is more on supply and manufacturing of drug candidates for clinical trials rather than the market.</li> <li>■ 50% of the company's employees are women and 50% are men.</li> </ul>	<ul style="list-style-type: none"> <li>■ Board gender inequality – two of seven (c29%) members are women.</li> <li>■ Isofol Medical has yet to publish any corporate social responsibility reports.</li> </ul>
Long-term	<ul style="list-style-type: none"> <li>■ In our view, the management team is qualified to lead Isofol Medical at this stage as well as into the continued development of the company.</li> <li>■ Isofol Medical's aim is to contribute to sustainable development and work proactively to improve and minimise its environmental footprint.</li> </ul>	<ul style="list-style-type: none"> <li>■ Isofol Medical is to a great extent dependent on key personnel. The ability to recruit and retain qualified personnel is of the utmost importance to ensure the competence level in the company.</li> <li>■ The company's business model is based on out-licensing, which limits its impact on access to health and visibility in pricing matters.</li> </ul>

Source: DNB Markets

## Forecast changes – P&amp;L

(SEKm)	New			Old			Change		
	2022e	2023e	2024e	2022e	2023e	2024e	2022e	2023e	2024e
Revenues	25	4	70	25	90	438	0	-87	-368
Cost of sales	0	0	-1		-3	-26		3	25
Gross profit	25	4	69	25	87	413	0	-83	-344
Operating expenses	-187	-84	-75	-220	-194	-177	33	110	102
EBITDA	-161	-79	-4	-194	-105	237	33	27	-242
EBITDA adj	-161	-79	-4	-194	-105	237	33	27	-242
EBITDA margin (%)	nm	nm	nm	-790.8	-116.5	54.1	nm	nm	nm
Depreciation	-2	-2	-2	-2	-2	-2	0	0	0
EBITA	-163	-80	-6	-196	-107	236	33	27	-242
EBIT	-163	-80	-6	-196	-107	236	33	27	-242
EBIT adj	-163	-80	-6	-196	-107	236	33	27	-242
Net interest	0	0	0	0	0	0	0	0	0
Net financial items	-1	-2	-2	-1	-2	-2	0	0	0
PBT	-163	-83	-9	-196	-109	233	33	27	-242
Taxes	0	0	0		0	0		0	0
Net profit	-163	-83	-9	-196	-109	233	33	27	-242
Adjustments to net profit	0	0	0	0	0	0	0	0	0
Net profit adj	-163	-83	-9	-196	-109	233	33	27	-242
<i>Per share data (SEK)</i>									
EPS	-1.02	-0.52	-0.06	-1.23	-0.67	1.59	0.20	0.14	-1.65
EPS adj	-1.02	-0.52	-0.06	-1.23	-0.67	1.59	0.20	0.14	-1.65
<i>Other key metrics (%)</i>									
Revenue growth	9.4	-84.9	1793.7	9.4	268.6	384.7	0.0	-353.6	1409.0
EBIT adj growth	nm	nm	nm	-3.6	-45.3	-320.2	nm	nm	nm
EPS adj growth	nm	nm	nm	-1.1	-45.6	-338.4	nm	nm	nm
Capex	0	0	0		0	0		0	0
OpFCF	-161	-79	-4	-194	-105	237	33	27	-242
Working capital	13	13	13	13	13	13	0	0	0
NIBD adj	-242	-257	-256	-242	-257	-256	0	0	0

Source: DNB Markets

## Annual P&amp;L

(SEKm)	2015	2016	2017	2018	2019	2020	2021	2022e	2023e	2024e
<b>Revenues</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>37</b>	<b>22</b>	<b>25</b>	<b>4</b>	<b>70</b>
Cost of sales	0	0	0	0	0	0	0	0	0	-1
<b>Gross profit</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>37</b>	<b>22</b>	<b>25</b>	<b>4</b>	<b>69</b>
Operating expenses	-41	-64	-73	-90	-166	-222	-225	-187	-84	-75
<b>EBITDA</b>	<b>-40</b>	<b>-64</b>	<b>-72</b>	<b>-90</b>	<b>-165</b>	<b>-183</b>	<b>-201</b>	<b>-161</b>	<b>-79</b>	<b>-4</b>
Depreciation	0	0	0	0	-2	-2	-2	-2	-2	-2
<b>EBITA</b>	<b>-41</b>	<b>-64</b>	<b>-72</b>	<b>-90</b>	<b>-166</b>	<b>-185</b>	<b>-203</b>	<b>-163</b>	<b>-80</b>	<b>-6</b>
<b>EBIT</b>	<b>-41</b>	<b>-64</b>	<b>-72</b>	<b>-90</b>	<b>-166</b>	<b>-185</b>	<b>-203</b>	<b>-163</b>	<b>-80</b>	<b>-6</b>
Net interest	0	0	0	0	0	0	0	0	0	0
Net financial items	0	0	1	7	6	-2	4	-1	-2	-2
<b>PBT</b>	<b>-41</b>	<b>-64</b>	<b>-72</b>	<b>-83</b>	<b>-160</b>	<b>-187</b>	<b>-199</b>	<b>-163</b>	<b>-83</b>	<b>-9</b>
Taxes	0	0	0	0	0	0	0	0	0	0
Effective tax rate (%)	0	0	0	0	0	0	0	0	0	0
<b>Net profit</b>	<b>-41</b>	<b>-64</b>	<b>-72</b>	<b>-83</b>	<b>-160</b>	<b>-187</b>	<b>-199</b>	<b>-163</b>	<b>-83</b>	<b>-9</b>
Adjustments to net profit	0	0	0	0	0	0	0	0	0	0
Net profit adj	-41	-64	-72	-83	-160	-187	-199	-163	-83	-9
<i>Per share data (SEK)</i>										
EPS	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-1.24	-1.02	-0.52	-0.06
<b>EPS adj</b>	<b>-1.29</b>	<b>-2.03</b>	<b>-2.28</b>	<b>-2.63</b>	<b>-5.04</b>	<b>-2.27</b>	<b>-1.24</b>	<b>-1.02</b>	<b>-0.52</b>	<b>-0.06</b>
<i>Growth and margins (%)</i>										
Revenue growth	nm	171.9	-55.3	nm	nm	34607.5	-39.7	9.4	-84.9	1793.7
EPS adj growth	nm									
Gross margin	100.0	100.0	100.0	nm	100.0	100.0	100.0	100.0	100.0	98.6
EBITDA margin	nm									
EBITDA adj margin	nm									
Depreciation/revenues	-59.1	-26.0	-66.1	nm	-1452.3	-4.8	-7.1	-6.9	-45.6	-2.4
EBIT margin	nm									
EBIT adj margin	nm	nm	nm	nm	nm	-497.4	-905.4	-663.1	-2176.2	-8.7
PBT margin	nm									
Net profit margin	nm									

Source: Company (historical figures), DNB Markets (estimates)

## Adjustments to annual P&amp;L

(SEKm)	2015	2016	2017	2018	2019	2020	2021	2022e	2023e	2024e
<b>EBITDA</b>	<b>-40</b>	<b>-64</b>	<b>-72</b>	<b>-90</b>	<b>-165</b>	<b>-183</b>	<b>-201</b>	<b>-161</b>	<b>-79</b>	<b>-4</b>
EBITDA adj	-40	-64	-72	-90	-165	-183	-201	-161	-79	-4
<b>EBITA</b>	<b>-41</b>	<b>-64</b>	<b>-72</b>	<b>-90</b>	<b>-166</b>	<b>-185</b>	<b>-203</b>	<b>-163</b>	<b>-80</b>	<b>-6</b>
EBITA adj	-41	-64	-72	-90	-166	-185	-203	-163	-80	-6
<b>EBIT</b>	<b>-41</b>	<b>-64</b>	<b>-72</b>	<b>-90</b>	<b>-166</b>	<b>-185</b>	<b>-203</b>	<b>-163</b>	<b>-80</b>	<b>-6</b>
EBIT adj	-41	-64	-72	-90	-166	-185	-203	-163	-80	-6
<b>Net profit</b>	<b>-41</b>	<b>-64</b>	<b>-72</b>	<b>-83</b>	<b>-160</b>	<b>-187</b>	<b>-199</b>	<b>-163</b>	<b>-83</b>	<b>-9</b>
Tax adjustments	0	0	0	0	0	0	0	0	0	0
Net profit adj	-41	-64	-72	-83	-160	-187	-199	-163	-83	-9
<i>Per share data (SEK)</i>										
EPS	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-1.24	-1.02	-0.52	-0.06
Recommended adjustment	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EPS adj	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-1.24	-1.02	-0.52	-0.06

Source: Company (historical figures), DNB Markets (estimates)

## Cash flow

(SEKm)	2015	2016	2017	2018	2019	2020	2021	2022e	2023e	2024e
Net profit	-41	-64	-72	-83	-160	-187	-199	-163	-83	-9
Other non-cash adjustments	0	0	0	-11	3	4	-3	-4	-4	-4
Change in net working capital	4	7	10	2	11	25	15	0	0	0
<b>Cash flow from operations (CFO)</b>	<b>-37</b>	<b>-57</b>	<b>-62</b>	<b>-92</b>	<b>-144</b>	<b>-157</b>	<b>-185</b>	<b>-165</b>	<b>-85</b>	<b>-11</b>
Capital expenditure	0	-1	0	0	0	0	0	0	0	0
<b>Cash flow from investing (CFI)</b>	<b>0</b>	<b>-1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Free cash flow (FCF)</b>	<b>-37</b>	<b>-57</b>	<b>-62</b>	<b>-92</b>	<b>-144</b>	<b>-157</b>	<b>-185</b>	<b>-165</b>	<b>-85</b>	<b>-11</b>
Net change in debt	0	0	0	0	-1	-1	-2	0	0	0
Other	0	11	0	3	-1	-4	-2	0	0	1
<b>Cash flow from financing (CFF)</b>	<b>38</b>	<b>69</b>	<b>400</b>	<b>8</b>	<b>-1</b>	<b>146</b>	<b>448</b>	<b>173</b>	<b>0</b>	<b>1</b>
<b>Total cash flow (CFO+CFI+CFF)</b>	<b>1</b>	<b>12</b>	<b>338</b>	<b>-84</b>	<b>-146</b>	<b>-11</b>	<b>263</b>	<b>8</b>	<b>-85</b>	<b>-9</b>
<i>FCFF calculation</i>										
Free cash flow	-37	-57	-62	-92	-144	-157	-185	-165	-85	-11
Less: net interest	0	0	0	0	0	0	0	0	0	0
<i>Growth (%)</i>										
CFO	nm	-55.0	-8.8	-49.5	-56.4	-8.8	-18.2	10.7	48.6	87.3
CFI	nm	-432.8	89.7	100.0	nm	100.0	nm	nm	nm	nm
FCF	nm	-56.4	-7.6	-49.3	-56.8	-8.5	-18.2	10.7	48.6	87.3
CFF	nm	83.9	477.6	-98.1	-119.0	10014.5	206.8	-61.4	-99.7	198.2
FCFF	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm

Source: Company (historical figures), DNB Markets (estimates)

## Balance sheet

(SEKm)	2015	2016	2017	2018	2019	2020	2021	2022e	2023e	2024e
<b>Assets</b>	<b>10</b>	<b>23</b>	<b>362</b>	<b>289</b>	<b>146</b>	<b>148</b>	<b>401</b>	<b>406</b>	<b>321</b>	<b>312</b>
Other receivables	2	3	4	12	10	23	15	13	13	13
Cash and cash equivalents	7	19	357	273	127	116	379	387	303	293
<b>Current assets</b>	<b>9</b>	<b>22</b>	<b>361</b>	<b>284</b>	<b>137</b>	<b>140</b>	<b>395</b>	<b>400</b>	<b>316</b>	<b>306</b>
Property, plant and equipment	0	0	0	0	4	3	2	2	2	2
Other intangible assets	0	0	0	0	0	0	0	0	0	0
Non-current financial assets	0	0	0	4	5	5	5	4	4	4
<b>Non-current assets</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>4</b>	<b>9</b>	<b>8</b>	<b>7</b>	<b>5</b>	<b>5</b>	<b>6</b>
<b>Total assets</b>	<b>10</b>	<b>23</b>	<b>362</b>	<b>289</b>	<b>146</b>	<b>148</b>	<b>401</b>	<b>406</b>	<b>321</b>	<b>312</b>
<b>Equity and liabilities</b>	<b>10</b>	<b>23</b>	<b>362</b>	<b>289</b>	<b>146</b>	<b>148</b>	<b>401</b>	<b>406</b>	<b>321</b>	<b>312</b>
Total equity to the parent	2	6	343	265	105	67	318	326	241	232
<b>Total equity</b>	<b>2</b>	<b>6</b>	<b>343</b>	<b>265</b>	<b>105</b>	<b>67</b>	<b>318</b>	<b>326</b>	<b>241</b>	<b>232</b>
<b>Total current liabilities</b>	<b>8</b>	<b>17</b>	<b>18</b>	<b>24</b>	<b>39</b>	<b>80</b>	<b>83</b>	<b>80</b>	<b>80</b>	<b>80</b>
<b>Total non-current liabilities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total liabilities</b>	<b>8</b>	<b>17</b>	<b>18</b>	<b>24</b>	<b>42</b>	<b>82</b>	<b>83</b>	<b>80</b>	<b>80</b>	<b>80</b>
<b>Total equity and liabilities</b>	<b>10</b>	<b>23</b>	<b>362</b>	<b>289</b>	<b>146</b>	<b>148</b>	<b>401</b>	<b>406</b>	<b>321</b>	<b>312</b>
<b>Key metrics</b>										
Net interest bearing debt	-7	-19	-357	-273	-127	-116	-267	-242	-257	-256

Source: Company (historical figures), DNB Markets (estimates)

## Valuation ratios

(SEKm)	2015	2016	2017	2018	2019	2020	2021	2022e	2023e	2024e
<i>Enterprise value</i>										
Share price (SEK)			12.44	13.57	11.47	22.13	9.24	1.30	1.30	1.30
Net interest bearing debt	-7	-19	-357	-273	-127	-116	-267	-242	-257	-256
Adjustments to NIBD	0	0	0	0	0	0	0	0	0	0
Net interest bearing debt adj	-7	-19	-357	-273	-127	-116	-267	-242	-257	-256
<i>Valuation</i>										
EPS	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-1.24	-1.02	-0.52	-0.06
<b>EPS adj</b>	<b>-1.29</b>	<b>-2.03</b>	<b>-2.28</b>	<b>-2.63</b>	<b>-5.04</b>	<b>-2.27</b>	<b>-1.24</b>	<b>-1.02</b>	<b>-0.52</b>	<b>-0.06</b>
P/E			-5.5	-5.2	-2.3	-9.8	-7.5	-1.3	-2.5	-22.5
P/E adj			-5.5	-5.2	-2.3	-9.8	-7.5	-1.3	-2.5	-22.5
Average ROE	-1304.8%	-1637.6%	-41.1%	-27.3%	-86.5%	-218.4%	-103.3%	-50.8%	-29.2%	-3.6%

Source: Company (historical figures), DNB Markets (estimates)

## Key accounting ratios

	2015	2016	2017	2018	2019	2020	2021	2022e	2023e	2024e
<i>Profitability (%)</i>										
ROA	-434.2	-386.7	-37.4	-25.5	-73.6	-127.1	-72.3	-40.5	-22.8	-2.7
<i>Return on invested capital (%)</i>										
Net PPE/revenues	69.8	33.7	83.3		4143.9	8.8	7.8	6.7	44.4	2.3
Working capital/revenues	1198.0	632.5	1690.7		9380.4	63.1	67.7	53.9	357.9	18.9
<i>Cash flow ratios (%)</i>										
FCF/revenues	-19634.5	-11292.9	-27188.5		-134991.6	-422.0	-826.7	-674.6	-2305.2	-15.5
FCF yield (%)	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
CFO/revenues	-19561.1	-11149.2	-27155.5		-134672.0	-422.0	-826.7	-674.6	-2305.2	-15.5
CFO/capex	-26676.4	-7758.6	-82190.7		-42134.2					
CFO/current liabilities	-432.5	-337.3	-338.0	-391.4	-371.4	-195.6	-223.1	-207.1	-106.5	-13.5
Cash conversion ratio	90.4	89.8	85.9	111.1	90.3	83.7	93.2	101.2	102.7	126.4
Capex/revenues	73.3	143.7	33.0		319.6	0.0	0.0	0.0	0.0	0.0
Capex/depreciation	124.1	553.0	50.0	0.0	22.0	0.0	0.0	0.0	0.0	0.0
OpFCF margin	-21728.0	-12693.5	-31877.5		-154240.2	-492.6	-898.3	-656.2	-2130.6	-6.3
<i>Leverage and solvency (x)</i>										
Net debt/EBITDA	0.18	0.30	4.94	3.05	0.77	0.64	1.33	1.50	3.26	58.34

Source: Company (historical figures), DNB Markets (estimates)

## Important Information

Company: Isofol Medical  
 Coverage by Analyst: Patrik Ling  
 Date: 04-8-2022

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DNB Markets client	30%	7%	3%	3%	134

4 August 2022

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