

Health Care
 Company update

This report was completed and disseminated at 16:45 CET on 29 April 2021



ISOFOL MEDICAL

Rights issue to secure arfolitixorin's route to filing

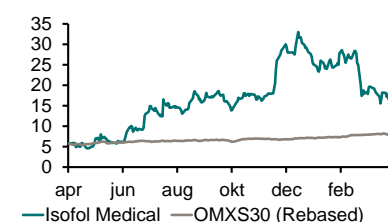
Isofol Medical plans to raise cSEK400m through a fully guaranteed rights issue, with an optional extra cSEK100m. Net proceeds are expected to be used to bring arfolitixorin beyond top-line results to submission to the FDA and EMA, as well as for pre-commercial activities and the exploration of additional indications. Top-line results are expected in H1 2022, with subsequent filing in H2 2022. As the terms of the rights issue have yet to be disclosed, our estimates are unchanged and we reiterate our SEK21–37 fair value.

cSEK400m rights issue and potential SEK100m over-allotment option. The company intends to carry out a fully guaranteed preferential issue, with the over-allotment conditional upon the rights issue being oversubscribed. The issue is subject to approval at an EGM, due to be held around 14 May 2021. The proceeds are planned to be used for: 1) taking main asset arfolitixorin beyond top-line results to filing; 2) CMC activities; 3) pre-commercial activities; 4) the exploration of additional indications; and 5) general corporate purposes. We note that the stock is down c19% on the news, but in our view it is difficult to assess what a 'reasonable' share price reaction is as we still do not know the terms of the rights issue.

Top-line results expected in H1 2022, with possibility of launch in 2023. The pivotal phase III study is fully recruited, and top-line results are expected in H1 2022, with regulatory submission to the FDA and EMA expected in H2 2022.

We reiterate our fair value of SEK21–37. A rights issue is already included in our SOTP valuation. However, as we do not yet know the subscription price or number of subsequent shares issued, it is difficult to estimate the impact on the fair value; therefore, our estimates are unchanged.

ISOFOL versus OMXS30 (12m)



Source: Factset

SUMMARY

Share price (SEK)	13.4
Tickers	ISOFOL SS

CAPITAL STRUCTURE

NIBD adj end-2021e (SEKm)	-109
Net debt/EBITDA adj (x)	0.58

Source: Company, DNB Markets (estimates)

NEXT EVENT

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ESTIMATE CHANGES (SEK)

Year-end Dec	2021e	2022e	2023e
Sales (old)	24.11	24.62	121.9
Sales (new)	24.11	24.62	121.9
Change (%)	0.0	0.0	0.0
EPS (old)	-2.30	-0.93	0.19
EPS (new)	-2.30	-0.93	0.19
Change (%)	nm	nm	0.0

Source: DNB Markets,

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Year-end Dec	2017	2018	2019	2020	2021e	2022e	2023e
Revenue (SEKm)	0	nm	0	37	24	25	122
EBITDA adj (SEKm)	-72	-90	-165	-183	-188	-71	22
EBIT adj (SEKm)	-72	-90	-166	-185	-190	-73	20
PTP (SEKm)	-72	-83	-160	-187	-190	-76	17
EPS rep (SEK)	-2.28	-2.63	-5.04	-2.27	-2.30	-0.93	0.19
EPS adj (SEK)	-2.28	-2.63	-5.04	-2.27	-2.30	-0.93	0.19
Revenue growth (%)	-55.3	nm	nm	34707.5	-35.3	2.1	395.1
EBITDA margin adj (%)	nm	nm	nm	nm	nm	nm	17.7
P/E adj (x)	nm	nm	nm	nm	nm	nm	71.7
ROE (%)	nm	nm	nm	nm	nm	nm	13.3

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

ANALYSTS

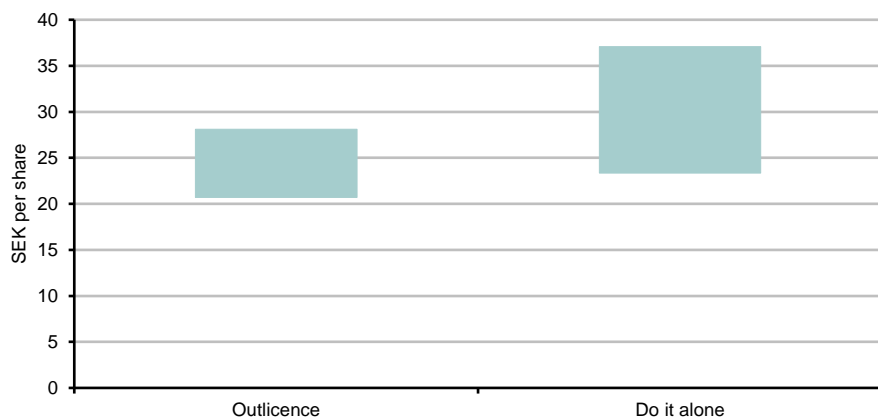
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Overview

Valuation (SEK)



Source: DNB Markets

Downside risks to our fair value

- The risks to our base case relate mainly to the clinical development of arfolitixorin. There is always a risk that development programmes experience delays or weaker data than expected.
- It might be more difficult than we expect to strike an out-licensing deal on acceptable terms.
- There is high execution risk in our 'do it alone' scenario, which includes the company building a proprietary sales organisation.
- The ongoing phase III trial is halted or delayed due to Covid-19.

Source: DNB Markets

DNB Markets estimates

- We have included a price for arfolitixorin of USD3k per patient per month in the US and half that amount elsewhere.
- We assume an overall penetration rate of 8–17% (depending on the scenario). This assumption is based on 365,000 patients treated with folate-based chemotherapy in the US, the five largest EU markets, Japan and Canada.

Source: DNB Markets

Valuation methodology

- We continue to use a risk-adjusted DCF with two main scenarios: 1) the company out-licenses the drug after phase III; and 2) it builds a sales organisation and takes the drug to market on its own. We discount the value in our model with a WACC of 10%, and the LOA is 23.2%.
- In our out-licensing scenario, we assume 20% royalties and USD500m of upfront and sales-related milestones.
- In our 'do it alone' scenario, we assume the company will launch in the US and EU5 on its own.

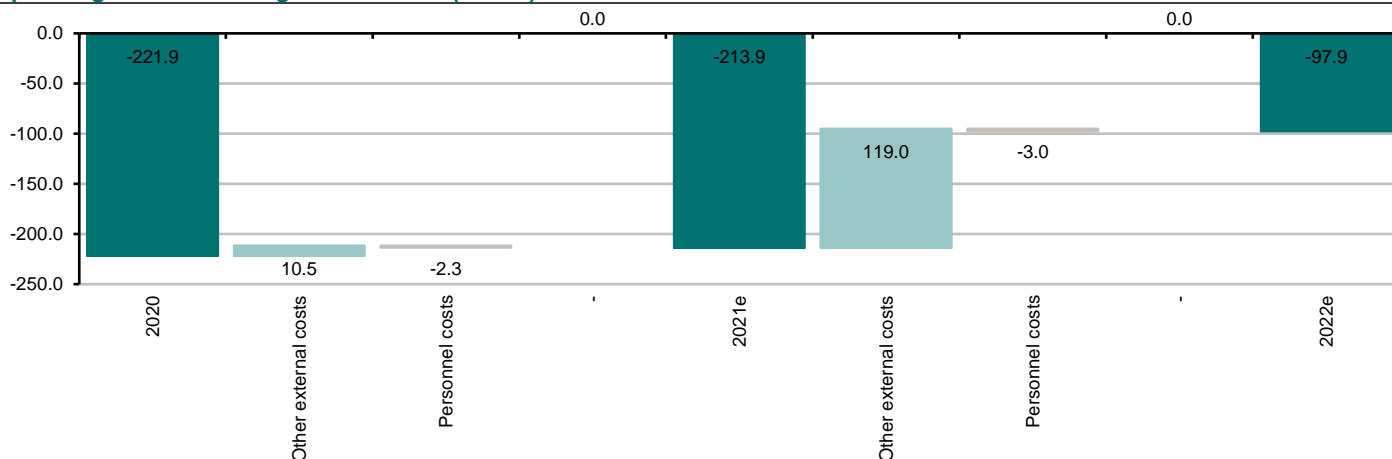
Source: DNB Markets

Upside risks to our fair value

- If the clinical development is more successful than we expect, there is the potential for the company to charge more for arfolitixorin than we forecast.
- Stronger than expected data could also increase the market penetration to well above the levels we assume.
- An out-licensing deal could be on better terms than we assume.

Source: DNB Markets

Operating cost base bridge 2020–2022e (SEKm)



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

ESG overview

Sustainability assessment

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

Key ESG drivers

Short-term	<ul style="list-style-type: none"> ■ 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. ■ 50% of the company's employees are women and 50% are men. 	<ul style="list-style-type: none"> ■ Board gender inequality – two of seven (c29%) members are women. ■ Isofol Medical has yet to publish any corporate social responsibility reports.
Long-term	<ul style="list-style-type: none"> ■ 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. ■ Isofol Medical's aim is to contribute to sustainable development and work proactively to improve and minimise its environmental footprint. 	<ul style="list-style-type: none"> ■ 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. ■ The company's business model is based on out-licensing, which limits its impact on access to health and visibility in pricing matters.

Source: DNB Markets

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Sustainability assessment

	Risk	Company's risk mitigation
Transition risks		
Policy and legal	<ul style="list-style-type: none"> Isofol Medical operates in a highly regulated environment and must comply with laws and regulations governing production, research, marketing, and reimbursement. 	<ul style="list-style-type: none"> The company carefully monitors all laws and regulations, to ensure it adheres to all requirements and stays on top of new regulations as they evolve.
Technology	<ul style="list-style-type: none"> Theft of sensitive patient data and intellectual property data through hacking. 	<ul style="list-style-type: none"> Appropriate data management, which is essential to secure the integrity of sensitive information.
Market	<ul style="list-style-type: none"> There is increasing pressure stemming from healthcare reforms and government initiatives to lower prices. 	<ul style="list-style-type: none"> Isofol Medical has performed a number of market surveys to determine a viable price for arfolitixorin and begun work on establishing the value to payers based on these pricing assumptions.
Reputation	<ul style="list-style-type: none"> The use of laboratory animals is a controversial matter and may cause reputational harm, despite being a regulatory requirement. 	<ul style="list-style-type: none"> The company complies with regulatory requirements and ensures experiments are designed with the intent to reduce and refine.
Physical risk		
Acute	<ul style="list-style-type: none"> Therapy-related severe adverse events. 	<ul style="list-style-type: none"> Isofol Medical designs clinical programmes to maximise the potential benefits for the intended patient populations while minimising risk.
Chronic	<ul style="list-style-type: none"> Emergence of new therapeutic approaches that pose a significant competitive risk against Isofol Medical's drug candidate. 	<ul style="list-style-type: none"> Mapping of the relevant competitive landscape. Incorporation of scientific advisory and competitive intelligence resources.

Source: DNB Markets

Sustainability assessment

	Opportunities	Company's utilisation of opportunity
Resource efficiency	<ul style="list-style-type: none"> The operations pose no particular environmental risk and require no permits. However, the company uses other services (i.e. contract manufacturing of drug substances for clinical trials, transportation etc.) where there could be a potential impact on the environment. 	<ul style="list-style-type: none"> The company works proactively to improve and reduce its environmental footprint as far as it is feasible and economically viable.
Products/Services	<ul style="list-style-type: none"> As the company does not have any sales at this time, its products do not have an environmental impact in terms of GHG emissions. 	<ul style="list-style-type: none"> Isofol Medical's areas of environmental impact pertain to the purchase of goods and services, energy consumption and transportation.
New markets	<ul style="list-style-type: none"> Isofol Medical aims to broaden the market potential for arfolitixorin by examining the possibility of including additional countries in the ongoing phase III study. 	<ul style="list-style-type: none"> The company filed a clinical trial notification with the Japanese regulatory authorities and received approval to commence its phase III clinical studies at Japanese sites.
Supply chain resilience	<ul style="list-style-type: none"> Not relevant at this time, as the company does not have any products on the market yet. 	<ul style="list-style-type: none"> Not relevant yet.

Source: DNB Markets

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Forecast changes – P&L

(SEKm)	New			Old			Change		
	2021e	2022e	2023e	2021e	2022e	2023e	2021e	2022e	2023e
Revenues	24	25	122	24	25	122	0	0	0
Cost of sales	0	0	-12		0	-12		0	0
Gross profit	24	25	110	24	25	110	0	0	0
Operating expenses	-214	-98	-90	-214	-98	-90	0	0	0
EBITDA	-188	-71	22	-188	-71	22	0	0	0
EBITDA adj	-188	-71	22	-188	-71	22	0	0	0
EBITDA margin (%)	nm	nm	17.7	-779.9	-290.3	17.7	nm	nm	0.0
Depreciation	-2	-2	-2	-2	-2	-2	0	0	0
EBITA	-190	-73	20	-190	-73	20	0	0	0
EBIT	-190	-73	20	-190	-73	20	0	0	0
EBIT adj	-190	-73	20	-190	-73	20	0	0	0
Net interest	0	-2	-2	0	-2	-2	0	0	0
Net financial items	0	-2	-2	0	-2	-2	0	0	0
PBT	-190	-76	17	-190	-76	17	0	0	0
Taxes	0	0	0		0	0		0	0
Net profit	-190	-76	17	-190	-76	17	0	0	0
Adjustments to net profit	0	0	0	0	0	0	0	0	0
Net profit adj	-190	-76	17	-190	-76	17	0	0	0
<i>Per share data (SEK)</i>									
EPS	-2.30	-0.93	0.19	-2.30	-0.93	0.19	0.00	0.00	0.00
EPS adj	-2.30	-0.93	0.19	-2.30	-0.93	0.19	0.00	0.00	0.00
<i>Other key metrics (%)</i>									
Revenue growth	-35.3	2.1	395.1	-35.3	2.1	395.1	0.0	0.0	0.0
EBIT adj growth	nm	nm	nm	2.8	-61.4	-127.1	nm	nm	nm
EPS adj growth	nm	nm	nm	1.4	-59.5	-120.2	nm	nm	nm
Capex	0	0	0	0	0	0	0	0	0
OpFCF	-188	-71	22	-188	-71	22	0	0	0
Working capital	-55	-55	-55	-55	-55	-55	0	0	0
NIBD adj	-109	-171	-187	-109	-171	-187	0	0	0

Source: DNB Markets

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Annual P&L

(SEKm)	2014	2015	2016	2017	2018	2019	2020	2021e	2022e	2023e
Revenues	0	0	1	0	0	0	37	24	25	122
Cost of sales	0	0	0	0	0	0	0	0	0	-12
Gross profit	0	0	1	0	0	0	37	24	25	110
Operating expenses	-32	-41	-64	-73	-90	-166	-222	-214	-98	-90
EBITDA	-32	-40	-64	-72	-90	-165	-183	-188	-71	22
Depreciation	0	0	0	0	0	-2	-2	-2	-2	-2
EBITA	-32	-41	-64	-72	-90	-166	-185	-190	-73	20
EBIT	-32	-41	-64	-72	-90	-166	-185	-190	-73	20
Net interest	0	0	0	1	7	6	-2	0	-2	-2
Net financial items	0	0	0	1	7	6	-2	0	-2	-2
PBT	-32	-41	-64	-72	-83	-160	-187	-190	-76	17
Taxes	0	0	0	0	0	0	0	0	0	0
Effective tax rate (%)	0	0	0	0	0	0	0	0	0	0
Net profit	-32	-41	-64	-72	-83	-160	-187	-190	-76	17
Adjustments to net profit	0	0	0	0	0	0	0	0	0	0
Net profit adj	-32	-41	-64	-72	-83	-160	-187	-190	-76	17
<i>Per share data (SEK)</i>										
EPS	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-2.30	-0.93	0.19
EPS adj	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-2.30	-0.93	0.19
<i>Growth and margins (%)</i>										
Revenue growth	nm	nm	171.9	-55.3	nm	nm	34707.5	-35.3	2.1	395.1
EPS adj growth	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
Gross margin	nm	100.0	100.0	100.0	nm	100.0	100.0	100.0	100.0	90.0
EBITDA margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	17.7
EBITDA adj margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	17.7
Depreciation/revenues	nm	-59.1	-26.0	-66.1	nm	-1452.3	-4.8	-7.3	-7.1	-1.4
EBIT margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	16.3
EBIT adj margin	nm	nm	nm	nm	nm	nm	-495.7	-787.1	-297.4	16.3
PBT margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	14.2
Net profit margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm

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

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Adjustments to annual P&L

(SEKm)	2014	2015	2016	2017	2018	2019	2020	2021e	2022e	2023e
EBITDA	-32	-40	-64	-72	-90	-165	-183	-188	-71	22
EBITDA adj	-32	-40	-64	-72	-90	-165	-183	-188	-71	22
EBITA	-32	-41	-64	-72	-90	-166	-185	-190	-73	20
EBITA adj	-32	-41	-64	-72	-90	-166	-185	-190	-73	20
EBIT	-32	-41	-64	-72	-90	-166	-185	-190	-73	20
EBIT adj	-32	-41	-64	-72	-90	-166	-185	-190	-73	20
Net profit	-32	-41	-64	-72	-83	-160	-187	-190	-76	17
Tax adjustments	0	0	0	0	0	0	0	0	0	0
Net profit adj	-32	-41	-64	-72	-83	-160	-187	-190	-76	17
<i>Per share data (SEK)</i>										
EPS	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-2.30	-0.93	0.19
Recommended adjustment	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EPS adj	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-2.30	-0.93	0.19

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

Cash flow

(SEKm)	2014	2015	2016	2017	2018	2019	2020	2021e	2022e	2023e
Net profit	-32	-41	-64	-72	-83	-160	-187	-190	-76	17
Other non-cash adjustments		0	0	0	-11	3	4	2	2	2
Change in net working capital		4	7	10	2	11	25	0	0	0
Cash flow from operations (CFO)		-37	-57	-62	-92	-144	-157	-186	-72	21
Capital expenditure		0	-1	0	0	0	0	0	0	0
Cash flow from investing (CFI)		0	-1	0	0	0	0	0	0	0
Free cash flow (FCF)		-37	-57	-62	-92	-144	-157	-186	-72	21
Net change in debt		0	0	0	0	-1	-1	-1	0	0
Other		0	0	0	3	-1	-4	-5	-5	-5
Cash flow from financing (CFF)		38	69	400	8	-1	146	179	134	-5
Total cash flow (CFO+CFI+CFF)		1	12	338	-84	-146	-11	-7	62	16
<i>FCFF calculation</i>										
Free cash flow		-37	-57	-62	-92	-144	-157	-186	-72	21
Less: net interest	0	0	0	-1	-7	-6	2	0	2	2
Growth (%)										
CFO	nm	nm	-55.0	-8.8	-49.5	-56.4	-8.7	-18.9	61.2	128.9
CFI	nm	nm	-432.8	89.7	100.0	nm	100.0	nm	nm	nm
FCF	nm	nm	-56.4	-7.6	-49.3	-56.8	-8.4	-18.9	61.2	128.9
CFF	nm	nm	83.9	477.6	-98.1	-119.0	10007.1	22.8	-25.1	-103.9
FCFF	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm

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

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Balance sheet

(SEKm)	2014	2015	2016	2017	2018	2019	2020	2021e	2022e	2023e
Assets	9	10	23	362	289	146	148	141	203	219
Trade receivables	0	0	0	0	0	0	0	0	0	0
Other receivables	2	2	2	2	10	9	20	20	20	20
Current financial assets	0	1	1	1	1	1	3	3	3	3
Cash and cash equivalents	6	7	19	357	273	127	116	109	171	187
Current assets	8	9	22	361	284	137	140	133	195	210
Property, plant and equipment	0	0	0	0	0	4	3	3	3	3
Other intangible assets	1	0	0	0	0	0	0	0	0	0
Non-current financial assets	0	0	0	0	4	5	5	5	5	5
Non-current assets	1	1	1	1	4	9	8	8	8	8
Total assets	9	10	23	362	289	146	148	141	203	219
Equity and liabilities	9	10	23	362	289	146	148	141	203	219
Total equity to the parent	5	2	6	343	265	105	67	61	123	139
Total equity	5	2	6	343	265	105	67	61	123	139
Trade payables	2	5	12	13	12	20	42	42	42	42
Other payables and accruals	1	2	4	4	10	16	34	34	34	34
Short-term debt	0	1	1	1	1	2	4	4	4	4
Total current liabilities	4	8	17	18	24	39	80	80	80	80
Long-term debt	0	0	0	0	0	3	1	0	0	0
Total non-current liabilities	0	0	0	0	0	3	1	0	0	0
Total liabilities	4	8	17	18	24	42	82	80	80	80
Total equity and liabilities	9	10	23	362	289	146	148	141	203	219
<i>Key metrics</i>										
Net interest bearing debt	-6	-7	-19	-357	-273	-127	-116	-109	-171	-187

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

Valuation ratios

(SEKm)	2014	2015	2016	2017	2018	2019	2020	2021e	2022e	2023e
<i>Enterprise value</i>										
Share price (SEK)				15.73	17.17	14.51	28.00	13.44	13.44	13.44
Net interest bearing debt	-6	-7	-19	-357	-273	-127	-116	-109	-171	-187
Adjustments to NIBD	0	0	0	0	0	0	0	0	0	0
Net interest bearing debt adj	-6	-7	-19	-357	-273	-127	-116	-109	-171	-187
<i>Valuation</i>										
EPS	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-2.30	-0.93	0.19
EPS adj	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.27	-2.30	-0.93	0.19
P/E				-6.9	-6.5	-2.9	-12.4	-5.9	-14.5	71.7
P/E adj				-6.9	-6.5	-2.9	-12.4	-5.9	-14.5	71.7
Average ROE	-383.1%	-1304.8%	-1637.6%	-41.1%	-27.3%	-86.5%	-218.2%	-297.4%	-82.3%	13.3%

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

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Key accounting ratios

	2014	2015	2016	2017	2018	2019	2020	2021e	2022e	2023e
<i>Profitability (%)</i>										
ROA	-186.2	-434.2	-386.7	-37.4	-25.5	-73.6	-127.0	-131.2	-44.0	8.2
<i>Return on invested capital (%)</i>										
Net PPE/revenues		69.8	33.7	83.3		4143.9	8.7	13.5	13.2	2.7
Working capital/revenues		-3024.7	-2770.7	-6492.1		-26091.6	-148.4	-229.3	-224.5	-45.3
<i>Cash flow ratios (%)</i>										
FCF/revenues		-19634.5	-11292.9	-27188.5		-134991.6	-420.5	-772.7	-293.4	17.1
FCF yield (%)	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
CFO/revenues		-19561.1	-11149.2	-27155.5		-134672.0	-420.5	-772.7	-293.4	17.1
CFO/capex		-26676.4	-7758.6	-82190.7		-42134.2				
CFO/current liabilities		-432.5	-337.3	-338.0	-391.4	-371.4	-195.5	-232.5	-90.2	26.0
Cash conversion ratio		90.4	89.8	85.9	111.1	90.3	83.7	98.2	95.4	120.1
Capex/revenues		73.3	143.7	33.0		319.6	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
OpFCF margin		-21728.0	-12693.5	-31877.5		-154240.2	-490.9	-779.9	-290.3	17.7
<i>Leverage and solvency (x)</i>										
Interest cover	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBIT/interest payable	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBITA adj/interest payable	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
Cash coverage	1361.45	-44216.52	-63753.00	130.95	13.32	26.47	-73.20	-18800.45	-28.62	8.65
Net debt/EBITDA	0.20	0.18	0.30	4.94	3.05	0.77	0.64	0.58	2.40	-8.65
Total debt/total capital (BV)	0.04	0.12	0.03	0.00	0.00	0.03	0.04	0.03	0.02	0.02
<i>Cash conversion cycle</i>										
Receivables turnover days	nm	3167.7	1512.5	4019.8	nm	29834.5	200.2	309.4	302.9	61.2
Credit period	nm	nm	nm	nm	nm	nm	nm	nm	nm	1258.6

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

29 April 2021

Important Information

Company: Isofol Medical
 Coverage by Analyst: David Martinsson
 Date: 29/04/2021

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29 April 2021

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