

ESG insight



ISOFOL MEDICAL

Full steam ahead

Isofol Medical had a pivotal Q3 in terms of clinical and commercial milestones. We expect results from the interim readout in Q1 2021e and the DSMB to recommend an expansion of the study to demonstrate statistical significance on PFS. On the back of two successful licensing deals, securing a path to the market should now be able to continue unhindered. We have raised our fair value to SEK14–28 (SEK10–23).

Q3 operating loss of cSEK32m. Operating costs were cSEK50m, versus our estimated cSEK54m. The main deviation was the upfront payment from the Japan deal, which was c2% of the total deal value compared to our assumption of c6%. The end-Q3 cash position was cSEK154m.

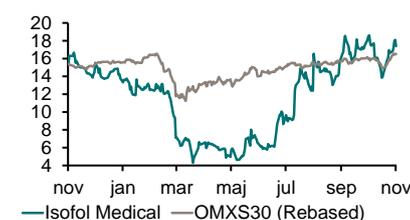
Inflection point in Q1 2020e. During Q3, 330 patients were included in the pivotal phase 3 study, enabling the start of the interim analysis. We expect the DSMB to announce its recommendation early in Q1 2021e. Of the three possible outcomes (close study due to futility, superiority (enough with 440 patients), or trending in statistical significance in PFS (expand study with 220 patients)), we believe the latter is the most likely outcome. The DSMB will only provide a recommendation on which pathway to take, and no other clinical information will be announced. If the study is expanded, we see a need for Isofol Medical to raise additional capital in H1 2021e.

Report cast some light on Japan deal structure, but visibility still low. Isofol Medical received an initial payment from Solasia in the form of an upfront payment (cSEK16m) and reimbursement relating to the study in Japan (cSEK2m). Going forward we expect additional reimbursements linked to the clinical development. We had hoped for some more flavour on the deal structure, but understand this is out of Isofol Medical's hands. We have updated our assumptions on milestones.

Canada now included in our forecasts. Our out-licensing scenario now assumes cUSD500m of milestones and sales-related payments for the US, EU5, Japan and Canada, with an average royalty rate of 20%. We assume an upfront payment of cSEK4m (c2% of total deal value, similar to Japan) in Q4 2020e. We highlight that the timing of milestones is uncertain and note our royalty rate could be somewhat on the low side. However, due to the low visibility we feel a cautious stance is warranted. The 'do-it-alone' scenario assumes Isofol Medical will launch in the US and EU5 on its own, and includes the licensing deals for Japan and Canada.

Fair value raised to SEK14–28 (SEK10–23). We have updated our assumptions for the Japan deal and included the Canada deal in our forecasts; as a result, we have raised our fair value.

ISOFOL versus OMXS30 (12m)



Source: Factset

SUMMARY

Share price (SEK)	17.4
Tickers	ISOFOL SS

CAPITAL STRUCTURE

NIBD adj end-2020e (SEKm)	0
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Source: Company, DNB Markets (estimates)

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

NEXT EVENT

Q4 2020 report	24/02/2021
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ESTIMATE CHANGES (SEK)

Year-end Dec	2020e	2021e	2022e
Sales (old)	54.11	0.11	5.11
Sales (new)	24.24	4.11	25.45
Change (%)	-55.2	3,738	398.4
EPS (old)	-1.84	-2.34	-0.88
EPS (new)	-2.18	-2.31	-0.89
Change (%)	nm	nm	nm

Source: DNB Markets,

This report has been commissioned and paid for by the company, and is deemed to constitute an acceptable minor non-monetary benefit as defined in MiFID II

Year-end Dec	2016	2017	2018	2019	2020e	2021e	2022e
Revenue (SEKm)	1	0	nm	0	24	4	25
EBITDA adj (SEKm)	-64	-72	-90	-165	-178	-189	-71
EBIT adj (SEKm)	-64	-72	-90	-166	-180	-191	-72
PTP (SEKm)	-64	-72	-83	-160	-180	-191	-72
EPS rep (SEK)	-2.03	-2.28	-2.63	-5.04	-2.18	-2.31	-0.89
EPS adj (SEK)	-2.03	-2.28	-2.63	-5.04	-2.18	-2.31	-0.89
Revenue growth (%)	171.9	-55.3	nm	nm	22550.5	-83.1	519.7

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

ANALYSTS

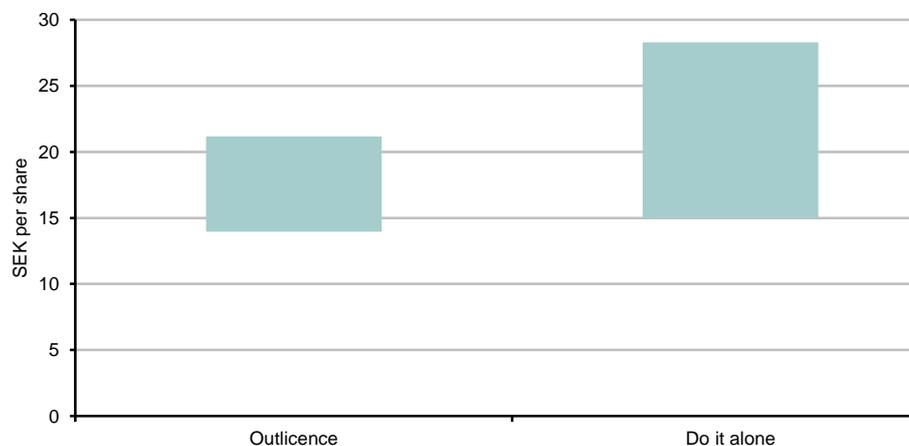
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Overview

Valuation (SEK)



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

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.
- 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.

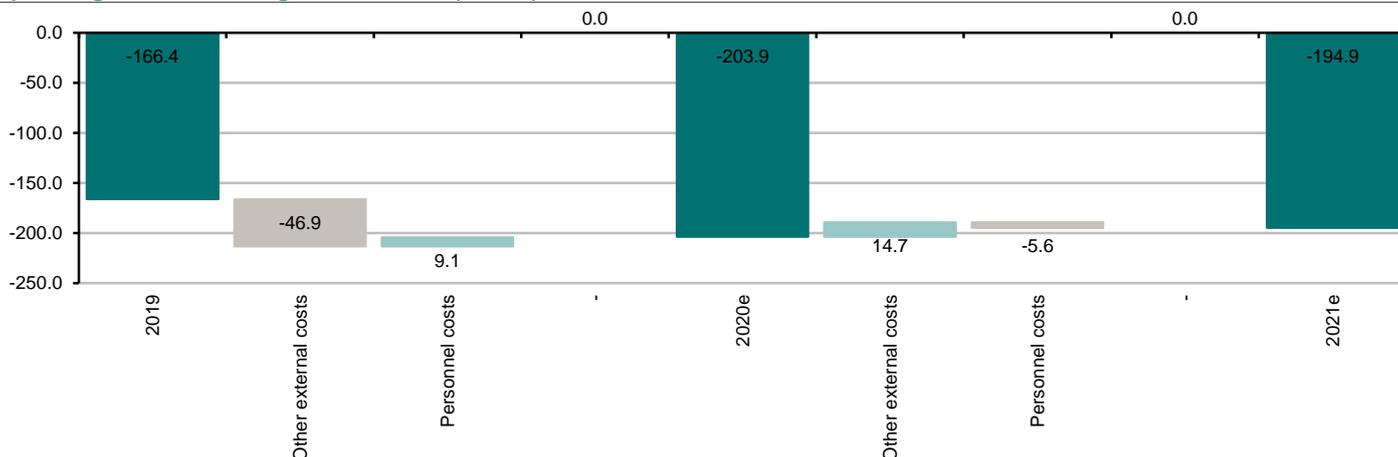
Source: DNB Markets

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 have factored into our calculations.
- Stronger data than expected 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 2019–2021e (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 current 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 impact 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 in order 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 does not yet have any products on the market and thus the environmental focus is more towards 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"> ■ 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

15 November 2020

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 both 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 current operations pose no particular environmental risk, nor require any permits. However, the company uses other services (i.e. contract manufacturing of drug substance 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		
	2020e	2021e	2022e	2020e	2021e	2022e	2020e	2021e	2022e
Revenues	24	4	25	54	0	5	-30	4	20
Cost of sales	0	0	0			-1			1
Gross profit	24	4	25	54	0	5	-30	4	21
Operating expenses	-204	-195	-98	-208	-196	-79	5	1	-19
EBITDA	-178	-189	-71	-153	-194	-72	-25	5	2
EBITDA adj	-178	-189	-71	-153	-194	-72	-25	5	2
EBITDA margin (%)	nm	nm	nm	-282.1	-181276.6	-1419.0	nm	nm	nm
Depreciation	-2	-2	-2	-2	-2	-2	0	0	0
EBITA	-180	-191	-72	-154	-196	-74	-25	5	2
EBIT	-180	-191	-72	-154	-196	-74	-25	5	2
EBIT adj	-180	-191	-72	-154	-196	-74	-25	5	2
Net interest	0	0	0	2	2	2	-2	-2	-2
Net financial items	0	0	0	2	2	2	-2	-2	-2
PBT	-180	-191	-72	-152	-193	-72	-28	3	-1
Taxes	0	0	0			0			0
Net profit	-180	-191	-72	-152	-193	-72	-28	3	-1
Adjustments to net profit	0	0	0	0	0	0	0	0	0
Net profit adj	-180	-191	-72	-152	-193	-72	-28	3	-1
<i>Per share data (SEK)</i>									
EPS	-2.18	-2.31	-0.89	-1.84	-2.34	-0.88	-0.33	0.03	-0.01
EPS adj	-2.18	-2.31	-0.89	-1.84	-2.34	-0.88	-0.33	0.03	-0.01
<i>Other key metrics (%)</i>									
Revenue growth	22550.5	-83.1	519.7	50467.3	-99.8	4672.9	-27916.8	16.7	-4153.2
EBIT adj growth	nm	nm	nm	-7.2	26.8	-62.1	nm	nm	nm
EPS adj growth	nm	nm	nm	-63.4	26.9	-62.3	nm	nm	nm
Capex	0	0	0	0	0	0	0	0	0
OpFCF	-178	-189	-71	-153	-194	-72	-25	5	2
Working capital	-39	-39	-39	-40	-40	-40	1	1	1
NIBD adj	0	0	0			0			0

Source: DNB Markets

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Annual P&L

(SEKm)	2013	2014	2015	2016	2017	2018	2019	2020e	2021e	2022e
Revenues	0	0	0	1	0	0	0	24	4	25
Cost of sales	0	0	0	0	0	0	0	0	0	0
Gross profit	0	0	0	1	0	0	0	24	4	25
Operating expenses	-35	-32	-41	-64	-73	-90	-166	-204	-195	-98
EBITDA	-35	-32	-40	-64	-72	-90	-165	-178	-189	-71
Depreciation	0	0	0	0	0	0	-2	-2	-2	-2
EBITA	-35	-32	-41	-64	-72	-90	-166	-180	-191	-72
EBIT	-35	-32	-41	-64	-72	-90	-166	-180	-191	-72
Net interest	0	0	0	0	1	7	6	0	0	0
Net financial items	0	0	0	0	1	7	6	0	0	0
PBT	-35	-32	-41	-64	-72	-83	-160	-180	-191	-72
Taxes	2	0	0	0	0	0	0	0	0	0
Effective tax rate (%)	5	0	0	0	0	0	0	0	0	0
Net profit	-34	-32	-41	-64	-72	-83	-160	-180	-191	-72
Adjustments to net profit	0	0	0	0	0	0	0	0	0	0
Net profit adj	-34	-32	-41	-64	-72	-83	-160	-180	-191	-72
<i>Per share data (SEK)</i>										
EPS	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.18	-2.31	-0.89
EPS adj	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.18	-2.31	-0.89
<i>Growth and margins (%)</i>										
Revenue growth	nm	nm	nm	171.9	-55.3	nm	nm	22550.5	-83.1	519.7
EPS adj growth	nm									
Gross margin	100.0	nm	100.0	100.0	100.0	nm	100.0	100.0	100.0	100.0
EBITDA margin	nm									
EBITDA adj margin	nm									
Depreciation/revenues	-153.9	nm	-59.1	-26.0	-66.1	nm	-1452.3	-7.2	-42.6	-6.9
EBIT margin	nm									
EBIT adj margin	nm	-741.3	-4644.6	-284.5						
PBT margin	nm									
Net profit margin	nm									

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

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Adjustments to annual P&L

(SEKm)	2013	2014	2015	2016	2017	2018	2019	2020e	2021e	2022e
EBITDA	-35	-32	-40	-64	-72	-90	-165	-178	-189	-71
EBITDA adj	-35	-32	-40	-64	-72	-90	-165	-178	-189	-71
EBITA	-35	-32	-41	-64	-72	-90	-166	-180	-191	-72
EBITA adj	-35	-32	-41	-64	-72	-90	-166	-180	-191	-72
EBIT	-35	-32	-41	-64	-72	-90	-166	-180	-191	-72
EBIT adj	-35	-32	-41	-64	-72	-90	-166	-180	-191	-72
Net profit	-34	-32	-41	-64	-72	-83	-160	-180	-191	-72
Tax adjustments	0	0	0	0	0	0	0	0	0	0
Net profit adj	-34	-32	-41	-64	-72	-83	-160	-180	-191	-72
<i>Per share data (SEK)</i>										
EPS	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.18	-2.31	-0.89
Recommended adjustment	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
EPS adj	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.18	-2.31	-0.89

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

Cash flow

(SEKm)	2013	2014	2015	2016	2017	2018	2019	2020e	2021e	2022e
Net profit	-34	-32	-41	-64	-72	-83	-160	-180	-191	-72
Other non-cash adjustments			0	0	0	-11	3	-1	2	2
Change in net working capital			4	7	10	2	11	11	0	0
Cash flow from operations (CFO)			-37	-57	-62	-92	-144	-168	-187	-69
Capital expenditure			0	-1	0	0	0	0	0	0
Cash flow from investing (CFI)			0	-1	0	0	0	0	0	0
Free cash flow (FCF)			-37	-57	-62	-92	-144	-168	-187	-69
Net change in debt			0	0	0	0	-1	-1	-1	0
Other			0	0	0	3	-1	-3	-5	-5
Cash flow from financing (CFF)			38	69	400	8	-1	147	179	-5
Total cash flow (CFO+CFI+CFF)			1	12	338	-84	-146	-21	-8	-74
<i>FCFF calculation</i>										
Free cash flow			-37	-57	-62	-92	-144	-168	-187	-69
Less: net interest	0	0	0	0	-1	-7	-6	0	0	0
Growth (%)										
CFO	nm	nm	nm	-55.0	-8.8	-49.5	-56.4	-16.9	-11.2	63.2
CFI	nm	nm	nm	-432.8	89.7	100.0	nm	100.0	nm	nm
FCF	nm	nm	nm	-56.4	-7.6	-49.3	-56.8	-16.6	-11.2	63.2
CFF	nm	nm	nm	83.9	477.6	-98.1	-119.0	10096.0	21.7	-102.9
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)	2013	2014	2015	2016	2017	2018	2019	2020e	2021e	2022e
Assets	25	9	10	23	362	289	146	140	132	58
Trade receivables	0	0	0	0	0	0	0	0	0	0
Other receivables	1	2	2	2	2	10	9	22	22	22
Current financial assets	0	0	1	1	1	1	1	3	3	3
Cash and cash equivalents	23	6	7	19	357	273	127	106	98	24
Current assets	25	8	9	22	361	284	137	131	123	49
Property, plant and equipment	0	0	0	0	0	0	4	4	4	4
Other intangible assets	1	1	0	0	0	0	0	0	0	0
Non-current financial assets	0	0	0	0	0	4	5	5	5	5
Non-current assets	1	1	1	1	1	4	9	9	9	9
Total assets	25	9	10	23	362	289	146	140	132	58
Equity and liabilities	25	9	10	23	362	289	146	140	132	58
Total equity to the parent	12	5	2	6	343	265	105	74	68	-7
Total equity	12	5	2	6	343	265	105	74	68	-7
Trade payables	4	2	5	12	13	12	20	34	34	34
Other payables and accruals	4	1	2	4	4	10	16	27	27	27
Short-term debt	5	0	1	1	1	1	2	4	4	4
Total current liabilities	13	4	8	17	18	24	39	64	64	64
Long-term debt	0	0	0	0	0	0	3	2	0	0
Total non-current liabilities	0	0	0	0	0	0	3	2	0	0
Total liabilities	13	4	8	17	18	24	42	66	65	65
Total equity and liabilities	25	9	10	23	362	289	146	140	132	58

Key metrics

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

Valuation ratios

(SEKm)	2013	2014	2015	2016	2017	2018	2019	2020e	2021e	2022e
<i>Enterprise value</i>										
Share price (SEK)					15.73	17.17	14.51	17.40	17.40	17.40
Net interest bearing debt adj	0	0	0	0	0	0	0	0	0	0
<i>Valuation</i>										
EPS	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.18	-2.31	-0.89
EPS adj	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-2.18	-2.31	-0.89
P/E					-6.9	-6.5	-2.9	-8.0	-7.5	-19.6
P/E adj					-6.9	-6.5	-2.9	-8.0	-7.5	-19.6
Average ROE		-383.1%	-1304.8%	-1637.6%	-41.1%	-27.3%	-86.5%	-200.8%	-269.5%	-237.9%

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

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Key accounting ratios

	2013	2014	2015	2016	2017	2018	2019	2020e	2021e	2022e
<i>Profitability (%)</i>										
ROA		-186.2	-434.2	-386.7	-37.4	-25.5	-73.6	-125.4	-140.2	-76.3
<i>Return on invested capital (%)</i>										
Net PPE/revenues	12.0		69.8	33.7	83.3		4143.9	15.6	91.8	14.8
Working capital/revenues	-6492.7		-3024.7	-2770.7	-6492.1		-26091.6	-160.5	-947.2	-152.9
<i>Cash flow ratios (%)</i>										
FCF/revenues			-19634.5	-11292.9	-27188.5		-134991.6	-694.8	-4559.7	-270.8
FCF yield (%)	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
CFO/revenues			-19561.1	-11149.2	-27155.5		-134672.0	-694.8	-4559.7	-270.8
CFO/capex			-26676.4	-7758.6	-82190.7		-42134.2			
CFO/current liabilities			-432.5	-337.3	-338.0	-391.4	-371.4	-261.7	-291.0	-107.1
Cash conversion ratio			90.4	89.8	85.9	111.1	90.3	93.7	98.2	95.2
Capex/revenues			73.3	143.7	33.0		319.6	0.0	0.0	0.0
Capex/depreciation			124.1	553.0	50.0	0.0	22.0	0.0	0.0	0.0
OpFCF margin	-33371.0		-21728.0	-12693.5	-31877.5		-154240.2	-734.1	-4602.0	-277.6
<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	-558.07	1361.45	-44216.52	-63753.00	130.95	13.32	26.47	-17790.75	-18900.45	-7066.06
Total debt/total capital (BV)	0.21	0.04	0.12	0.03	0.00	0.00	0.03	0.04	0.03	0.06
<i>Cash conversion cycle</i>										
Receivables turnover days	4811.3	nm	3167.7	1512.5	4019.8	nm	29834.5	329.9	1946.6	314.1
Credit period	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm

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

15 November 2020

Important Information

Company: Isofol Medical
 Coverage by Analyst: David Martinsson
 Date: 14/11/2020

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15 November 2020

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