

ESG insight



ISOFOL MEDICAL

Fully focused on AGENT

Q4's operating loss was higher than expected, mainly due to continued higher R&D spending as well as costs related to the change of CEO. The 005-study has been concluded and the company's full attention should now be on bringing arfollitoxorin to market. We estimate continued high R&D spending going forward as more sites are expected to be opened. We have tweaked our estimated fair value to SEK14–42 (SEK18–49).

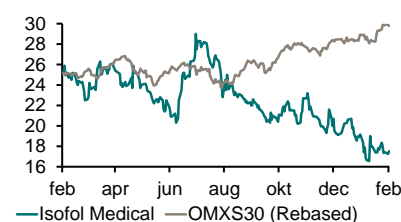
Isofol reported a Q4 operating loss of cSEK55m. The reported loss was above our estimate of cSEK38m due to increased spending on R&D and higher personnel costs. The increase in personnel costs was attributed mainly to a one-off due to the management change, with severance pay for the resigning CEO. The R&D increase related to the intensified work with the ongoing phase III study. Isofol had an end-Q3 cash position of cSEK127m with a quarterly burn rate of cSEK63m.

Continued progress in phase III study – first patient in Japan included. The ongoing phase III study AGENT is progressing and has randomised 200+ of the planned 440 patients. The first patient has been included in Japan and the study is now being run at 80+ clinics in the US, Canada, Europe, Australia, and Japan with the aim of adding 19 additional sites in Japan and Australia. At the current recruitment rate, we are likely to see 330 patients included in Q2 2020, which are required for the interim analysis. We are likely looking at a potential positive trigger with the communication of interim data around end-2020. The company is evaluating options to secure medium- and long-term financing and we see it as likely that a capital raise will occur following the interim readout.

ISO-CC-005 concluded – expects to present data at ESMO. During the quarter, Isofol decided to conclude its 005-study as the study had fulfilled its purpose of establishing an effective and safe dose for AGENT, as well as generating additional safety and efficacy data. The company plans to present data from the study at ESMO 2020 in September. We believe this is a sound decision as, given that the trial has achieved its objective, resources and focus can be dedicated fully to the development of the AGENT study.

We have adjusted our fair value assessment for Isofol to SEK14–42 (SEK18–49). Following the Q4 report, we have raised our R&D estimates to better reflect the ongoing clinical development. Increased spending on R&D is to be expected from a company at Isofol's stage of development, and we view it as positive that more resources are being committed to bring arfollitoxorin to market.

ISOFOL versus OMXS30 (12m)



Source: Factset

SUMMARY

Share price (SEK)	17.5
Tickers	ISOFOL SS, ISOFOL.ST

CAPITAL STRUCTURE

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

NEXT EVENT

Q1 2020 report	14/05/2020
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ESTIMATE CHANGES (SEK)

Year-end Dec	2020e	2021e	2022e
Sales (old)	0.00	0.00	
Sales (new)	0.11	0.11	0.11
Change (%)	nm	nm	nm
EPS (old)	-5.08	-3.94	
EPS (new)	-5.05	-5.08	-1.22
Change (%)	nm	nm	nm

Source: DNB Markets.

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Year-end Dec	2016	2017	2018	2019	2020e	2021e	2022e
Revenue (SEKm)	1	0	nm	0	0	0	0
EBITDA adj (SEKm)	-64	-72	-90	-165	-159	-160	-36
EBIT adj (SEKm)	-64	-72	-90	-166	-161	-161	-37
PTP (SEKm)	-64	-72	-83	-160	-160	-160	-36
EPS rep (SEK)	-2.03	-2.28	-2.63	-5.04	-5.05	-5.08	-1.22
EPS adj (SEK)	-2.03	-2.28	-2.63	-5.04	-5.05	-5.08	-1.22
Revenue growth (%)	171.9	-55.3	nm	nm	0.0	0.0	0.0

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

ANALYSTS

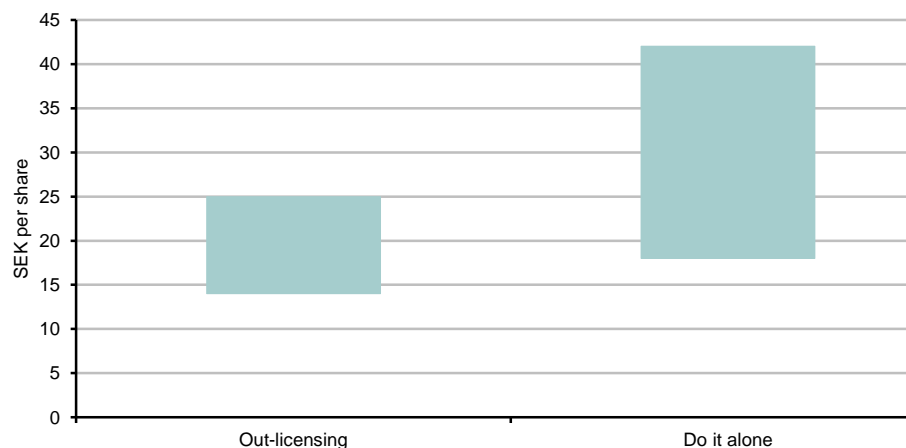
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Overview

Valuation (SEK)



Source: DNB Markets

Valuation methodology

- We continue to use a risk-adjusted DCF approach 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 USD300m 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

- Risks to our base case are mainly related to the clinical development of arfoltixorin. 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 at acceptable terms.
- There is a high execution risk in our 'do it alone' scenario, which includes the company building a proprietary sales organisation.

Source: DNB Markets

DNB Markets estimates

- We have included a price for arfoltixorin of USD3k per patient/month in the US and half of that 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, and Japan.

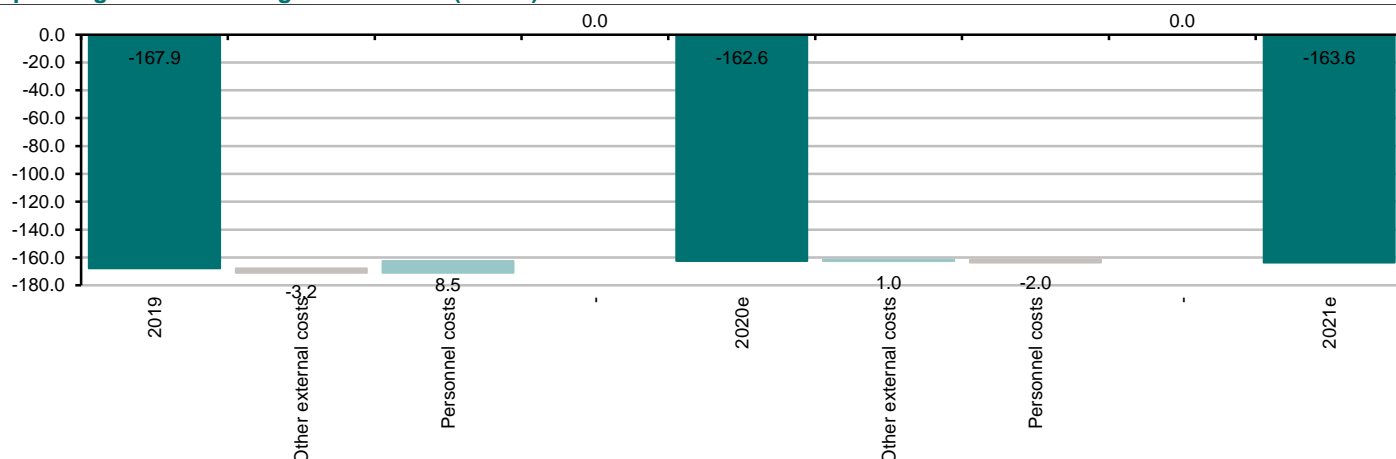
Source: DNB Markets

Upside risks to our fair value

- If the clinical development is more successful than we expect, there is potential for the company to charge more for arfoltixorin 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 at 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 focused towards supply and manufacturing of drug candidates for clinical trials rather than the market. ■ 62% of the company's employees are women and 38% are men. 	<ul style="list-style-type: none"> ■ Board gender inequality – 2 of 7 (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 outmost 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

19 February 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 in order to ensure that 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 also 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 harm to the reputation, 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 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 to include 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	0	0	0	0	0		0	0	
Cost of sales	0	0	0	0	0		0	0	
Gross profit	0	0	0	0	0		0	0	
Operating expenses	-161	-162	-38	-161	-125		0	-37	
EBITDA	-159	-160	-36	-161	-125		1	-36	
EBITDA adj	-159	-160	-36	-161	-125		1	-36	
EBITDA margin (%)	nm	nm	nm	high	high	nm	nm	nm	nm
Depreciation	-2	-2	-2	0	0		-1	-1	
EBITA	-161	-162	-38	-161	-125		0	-37	
Amortisation	0	1	1	0	1		0	0	
EBIT	-161	-161	-37	-161	-124		0	-37	
EBIT adj	-161	-161	-37	-161	-124		0	-37	
Net interest	1	1	1	1	1		0	0	
Net financial items	1	1	1	1	1		0	0	
PBT	-160	-160	-36	-160	-123		0	-37	
Taxes	0	0	0	0	0		0	0	
Net profit	-160	-160	-36	-160	-123		0	-37	
Adjustments to net profit	0	0	0	0	0		0	0	
Net profit adj	-160	-161	-37	-160	-124		0	-37	
<i>Per share data (SEK)</i>									
EPS	-5.05	-5.08	-1.22	-5.08	-3.94		0.03	-1.14	
EPS adj	-5.05	-5.08	-1.22	-5.08	-3.94		0.03	-1.14	
<i>Other key metrics (%)</i>									
Revenue growth	0.0	0.0	0.0	nm	nm	nm	nm	nm	nm
EBIT adj growth	nm	0.0	nm	7.3	-23.0	nm	nm	23.0	nm
EPS adj growth	nm	nm	nm	7.4	-22.4	nm	nm	nm	nm
Capex	0	0	0	0	0		0	0	
OpFCF	-160	-161	-37	-161	-125		1	-36	
Working capital	-28	-28	-28	0	0		-28	-28	
NIBD adj	0	0	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	0	0	0
Cost of sales	0	0	0	0	0	0	0	0	0	0
Gross profit	0	0	0	1	0	0	0	0	0	0
Operating expenses	-35	-32	-41	-64	-73	-90	-166	-161	-162	-38
EBITDA	-35	-32	-40	-64	-72	-90	-165	-159	-160	-36
Depreciation	0	0	0	0	0	0	-2	-2	-2	-2
EBITA	-35	-32	-41	-64	-72	-90	-166	-161	-162	-38
Amortisation	0	0	0	0	0	0	0	0	1	1
EBIT	-35	-32	-41	-64	-72	-90	-166	-161	-161	-37
Net interest	0	0	0	0	1	7	6	1	1	1
Net financial items	0	0	0	0	1	7	6	1	1	1
PBT	-35	-32	-41	-64	-72	-83	-160	-160	-160	-36
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	-160	-160	-36
Adjustments to net profit	0	0	0	0	0	0	0	0	0	0
Net profit adj	-34	-32	-41	-64	-72	-83	-160	-160	-161	-37
<i>Per share data (SEK)</i>										
EPS	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-5.05	-5.08	-1.22
EPS adj	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-5.05	-5.08	-1.22
<i>Growth and margins (%)</i>										
Revenue growth	nm	nm	nm	171.9	-55.3	nm	nm	0.0	0.0	0.0
EPS adj growth	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
Gross margin	100.0	nm	100.0	100.0	100.0	nm	100.0	100.0	100.0	100.0
EBITDA margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBITDA adj margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
Depreciation/revenues	-153.9	nm	-59.1	-26.0	-66.1	nm	-1452.3	-1452.3	-1452.3	-1452.3
EBIT margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBIT adj margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
PBT margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
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)	2013	2014	2015	2016	2017	2018	2019	2020e	2021e	2022e
EBITDA	-35	-32	-40	-64	-72	-90	-165	-159	-160	-36
Gains and losses	0	0	0	0	0	0	0	0	-1	-1
Other EBITDA adjustments					0	0	0	0	1	1
EBITDA adj	-35	-32	-40	-64	-72	-90	-165	-159	-160	-36
EBITA	-35	-32	-41	-64	-72	-90	-166	-161	-162	-38
Gains and losses	0	0	0	0	0	0	0	0	-1	-1
Other EBITA adjustments					0	0	0	0	1	1
EBITA adj	-35	-32	-41	-64	-72	-90	-166	-161	-162	-38
EBIT	-35	-32	-41	-64	-72	-90	-166	-161	-161	-37
Gains and losses	0	0	0	0	0	0	0	0	-1	-1
Other EBIT adjustments	0	0	0	0	0	0	0	0	1	1
EBIT adj	-35	-32	-41	-64	-72	-90	-166	-161	-161	-37
Net profit	-34	-32	-41	-64	-72	-83	-160	-160	-160	-36
Gains and losses	0	0	0	0	0	0	0	0	-1	-1
Other EBIT adjustments	0	0	0	0	0	0	0	0	1	1
Tax adjustments	0	0	0	0	0	0	0	0	0	0
Net profit adj	-34	-32	-41	-64	-72	-83	-160	-160	-161	-37
<i>Per share data (SEK)</i>										
EPS	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-5.05	-5.08	-1.22
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	-5.05	-5.08	-1.22

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	-160	-160	-36
Depreciation and amortisation	0	0	0	0	0	0	2	2	1	1
Other non-cash adjustments			0	0	0	-11	3	2	2	2
Change in net working capital			4	7	10	2	11	0	0	0
Cash flow from operations (CFO)	-33	-31	-37	-57	-62	-92	-144	-157	-158	-34
Capital expenditure			0	-1	0	0	0	0	0	0
Cash flow from investing (CFI)	0	0	0	-1	0	0	0	0	0	0
Free cash flow (FCF)	-33	-31	-37	-57	-62	-92	-144	-158	-159	-35
Net change in debt			0	0	0	0	-1	-1	-1	-1
Other	56	15	0	0	0	3	-1	-3	-3	-3
Cash flow from financing (CFF)	56	15	38	69	400	8	-1	195	195	-5
Total cash flow (CFO+CFI+CFF)	23	-17	1	12	338	-84	-146	38	37	-39
<i>FCFF calculation</i>										
Free cash flow	-33	-31	-37	-57	-62	-92	-144	-158	-159	-35
Less: net interest	0	0	0	0	-1	-7	-6	-1	-1	-1
Growth (%)										
CFO	nm	5.8	-16.2	-55.0	-8.8	-49.5	-56.4	-9.2	-0.6	78.3
CFI	nm	nm	nm	-432.8	89.7	100.0	nm	0.0	0.0	0.0
FCF	nm	5.8	-16.6	-56.4	-7.6	-49.3	-56.8	-9.1	-0.6	78.2
CFF	nm	-73.6	153.2	83.9	477.6	-98.1	-119.0	13352.2	0.0	-102.4
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	185	222	183
Trade receivables	0	0	0	0	0	0	0	0	0	0
Other receivables	1	2	2	2	2	10	9	9	9	9
Current financial assets	0	0	1	1	1	1	1	1	1	1
Cash and cash equivalents	23	6	7	19	357	273	127	165	201	162
Current assets	25	8	9	22	361	284	137	175	211	172
Property, plant and equipment	0	0	0	0	0	0	4	5	5	5
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	10	10	10
Total assets	25	9	10	23	362	289	146	185	222	183
Equity and liabilities	25	9	10	23	362	289	146	185	222	183
Total equity to the parent	12	5	2	6	343	265	105	143	180	141
Total equity	12	5	2	6	343	265	105	143	180	141
Trade payables	4	2	5	12	13	12	20	20	20	20
Other payables and accruals	4	1	2	4	4	10	16	16	16	16
Short-term debt	5	0	1	1	1	1	2	2	2	2
Total current liabilities	13	4	8	17	18	24	39	39	39	39
Long-term debt	0	0	0	0	0	0	3	3	3	3
Total non-current liabilities	0	0	0	0	0	0	3	3	3	3
Total liabilities	13	4	8	17	18	24	42	42	42	42
Total equity and liabilities	25	9	10	23	362	289	146	185	222	183

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)					21.90	23.90	20.20	17.50	17.50	17.50
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	-5.05	-5.08	-1.22
EPS adj	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-5.04	-5.05	-5.08	-1.22
P/E					-9.6	-9.1	-4.0	-3.5	-3.4	-14.4
P/E adj					-9.6	-9.1	-4.0	-3.5	-3.4	-14.4
Average ROE	-561.2%	-383.1%	-1304.8%	-1637.6%	-41.1%	-27.3%	-86.5%	-129.4%	-99.4%	-22.7%

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	-264.6	-186.2	-434.2	-386.7	-37.4	-25.5	-73.6	-96.9	-79.0	-18.0
<i>Return on invested capital (%)</i>										
Net PPE/revenues	12.0		69.8	33.7	83.3		4143.9	4463.6	4783.2	5102.8
Working capital/revenues	-6492.7		-3024.7	-2770.7	-6492.1		-26091.6	-26091.6	-26091.6	-26091.6
<i>Cash flow ratios (%)</i>										
FCF/revenues	-31819.3		-19634.5	-11292.9	-27188.5		-134991.6	-147331.8	-148266.4	-32378.5
CFO/revenues	-31819.3		-19561.1	-11149.2	-27155.5		-134672.0	-147012.1	-147946.7	-32058.9
CFO/capex			-26676.4	-7758.6	-82190.7		-42134.2	-45995.0	-46287.4	-10030.1
CFO/current liabilities	-249.2	-782.3	-432.5	-337.3	-338.0	-391.4	-371.4	-405.4	-408.0	-88.4
Cash conversion ratio	99.5	99.7	90.4	89.8	85.9	111.1	90.3	98.3	98.9	95.1
Capex/revenues			73.3	143.7	33.0		319.6	319.6	319.6	319.6
Capex/depreciation			124.1	553.0	50.0	0.0	22.0	22.0	22.0	22.0
OpFCF margin	-33371.0		-21728.0	-12693.5	-31877.5		-154240.2	-149300.0	-150234.6	-34346.7
<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	-558.07	1361.45	-44216.52	-63753.00	130.95	13.32	26.47	288.78	290.60	65.96
Total debt/total capital (BV)	0.21	0.04	0.12	0.03	0.00	0.00	0.03	0.03	0.02	0.03
<i>Cash conversion cycle</i>										
Receivables turnover days	4811.3	nm	3167.7	1512.5	4019.8	nm	29834.5	29834.5	29834.5	29834.5
Credit period	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm

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

19 February 2020

Important Information

Company: Isofol Medical
 Coverage by Analyst: Patrik Ling
 Date: 19/02/2020

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DNB Markets client	26%	10%	4%	3%	107

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