EQUITY RESEARCH – COMMISSIONED RESEARCH
Research report prepared by DNB Markets, a division of DNB Bank ASA
Health Care
Company update
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31 January 2020

ESG insight

ISOFOL MEDICAL

Update on clinical development

Isofol Medical yesterday gave an update on several of its clinical programmes. The AGENT study has randomised 200+ patients and is rapidly approaching interim analysis in Q4 2020e. The company also reported the phase I/IIa study ISC-CC-005 had been concluded and a gene expression analysis method had been validated. We reiterate our SEK18–49 fair value.

AGENT study progressing to plan; interim analysis rapidly approaching. The ongoing phase III AGENT is progressing according to plan and has randomised 200+ of the planned 440 patients. The trial is rapidly approaching the next milestone of 330 treated patients, when the interim analysis will start. The interim analysis is expected to commence in Q4 2020 and it will take an independent Data Safety Monitoring Board (DSMB) c12 weeks to review safety and efficacy with three possible outcomes: 1) stop the study due to excessive toxicity; 2) consider stopping the trial due to overwhelming efficacy and submit a New Drug Application (NDA); or 3) increase the sample size to reach statistical significance on PFS. Given there have been no safety concerns, and as recent as December 2019 the DSMB recommended the continuation of the study, we find it unlikely it will be terminated based on excessive toxicity. We view the third outcome as the most likely. Once all 330 are recruited, they will be followed for 16 weeks and it will take the DSMB 12 weeks to review, so we are likely looking at a potential positive trigger around end-2020.

Phase I/IIa-study ISC-CC-005 has concluded. The original aim of the trial was to determine an effective and safe dose of arfolitixorin for the AGENT study. The study was expanded to determine the safety profile of arfolitixorin in combination with 5-FU, oxaliplatin and bevacizumab, which is now used in the ongoing phase III study. The study has fulfilled its purpose and final analysis has started with the data expected to be presented at ESMO 2020 (September 2020). We view this as a sound decision as the trial has achieved its objective and resources can be fully committed to the development of the AGENT study.

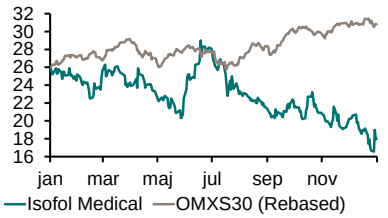
Method for gene expression analysis validated. The analysis included academic data from c450 patients treated with 5-FU and leucovorin containing regimens and indicates there is a difference in progression-free survival between patients that have a high expression of certain folate genes and patients with lower expression. The validation was requested by regulatory authorities to be used on clinical practice. With a validated method, Isofol Medical now has a biomarker that can be used when stratifying patients and exploring other cancer indications where 5-FU is standard of care.

We reiterate our fair value of SEK18–49. We have raised our R&D estimates slightly to reflect the ongoing clinical development; however, this does not affect our fair value.

Year-end Dec	2015	2016	2017	2018	2019e	2020e	2021e
Revenue (SEKm)	0	1	0	nm	nm	nm	nm
EBITDA adj (SEKm)	-40	-64	-72	-90	-150	-161	-125
EBIT adj (SEKm)	-41	-64	-72	-90	-150	-161	-124
PTP (SEKm)	-41	-64	-72	-83	-149	-160	-123
EPS rep (SEK)	-1.29	-2.03	-2.28	-2.63	-4.73	-5.08	-3.94
EPS adj (SEK)	-1.29	-2.03	-2.28	-2.63	-4.73	-5.08	-3.94
Revenue growth (%)	nm	171.9	-55.3	nm	nm	nm	nm

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

ISOFOL versus OMXS30 (12m)



Source: Factset

SUMMARY

Share price (SEK)	18.0
Tickers	ISOFOL SS, ISOFOL.ST

CAPITAL STRUCTURE

NIBD adj end-2019e (SEKm)	0

Source: Company, DNB Markets (estimates)

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

NEXT EVENT

Q4 2019 report	19/02/2020

ESTIMATE CHANGES (SEK)

Year-end Dec	2019e	2020e	2021e
Sales (old)	0.00	0.00	0.00
Sales (new)	0.00	0.00	0.00
Change (%)	nm	nm	nm
EPS (old)	-4.73	-4.73	-3.94
EPS (new)	-4.73	-5.08	-3.94
Change (%)	nm	nm	nm

Source: DNB Markets,

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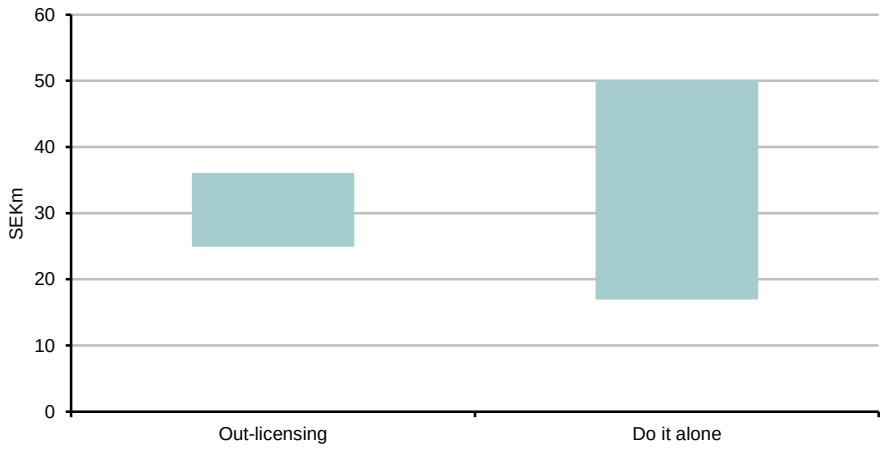
ANALYSTS
Patrik Ling
David Martinsson

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 launches 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 than expected data.
- 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 arfolitixorin 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.

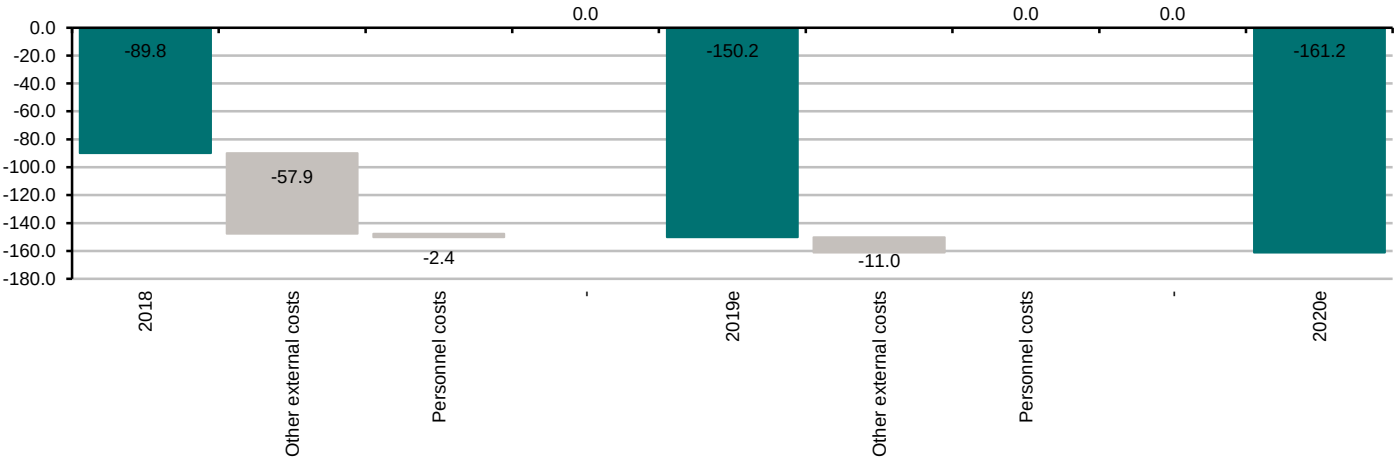
Source: DNB Markets

Upside risks to our fair value

- If the clinical development is more successful than we expect, there is the potential for the company to charge more for arfolitixorin than we have factored into our calculations.
- Stronger than expected data 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 2018–2020e (SEKm)



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

ESG overview

Sustainability assessment

	Positive	Negative
Conclusions	■ 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.	■ 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	■ 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.	■ 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	■ The company does not yet have any products on the market and thus the environmental focus is more focused on 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.	■ Board gender inequality – two of seven (c29%) members are women. ■ Isofol Medical has yet to publish any corporate social responsibility reports.
Long-term	■ The management team is qualified for leading 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.	■ Isofol Medical is to a great extent dependent on key personnel. The ability to recruit and retain qualified personnel is of 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

Sustainability assessment

	Risk	Company's risk mitigation
Transition risks		
Policy and legal	■ Isofol Medical operates in a highly regulated environment and must comply with laws and regulations governing production, research, marketing and reimbursement.	■ 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	■ Theft of sensitive patient data and intellectual property data through hacking.	■ Appropriate data management, which is essential to secure the integrity of sensitive information.
Market	■ There is increasing pressure stemming from healthcare reforms and government initiatives to lower prices.	■ 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	■ The use of laboratory animals is a controversial matter and could cause harm to the reputation, despite being a regulatory requirement.	■ The company complies with regulatory requirements and ensures experiments are designed with the intent to reduce and refine.
Physical risk		
Acute	■ Therapy-related severe adverse events.	■ Isofol Medical designs clinical programmes to maximise the potential benefits for the intended patient populations while minimising risk.
Chronic	■ Emergence of new therapeutic approaches that pose a significant competitive risk against Isofol Medical's drug candidate.	■ 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	■ 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.	■ The company works proactively to improve and reduce its environmental footprint as far as it is feasible and economically viable.
Products/Services	■ As the company does not have any sales at this time, its products do not have an environmental impact in terms of GHG emissions.	■ Isofol Medical's areas of environmental impact pertain to the purchase of goods and services, energy consumption and transportation.
New markets	■ Isofol Medical aims to broaden the market potential for arfolitixorin by examining the possibility to include additional countries in the ongoing phase III study.	■ 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	■ Not relevant at this time, as the company does not have any products on the market yet.	■ Not relevant yet.

Source: DNB Markets

Forecast changes – P&L

	New			Old			Change		
(SEKm)	2019e	2020e	2021e	2019e	2020e	2021e	2019e	2020e	2021e
Revenues	0	0	0	0	0	0	0	0	0
Cost of sales	0	0	0	0	0	0	0	0	0
Gross profit	0	0	0	0	0	0	0	0	0
Operating expenses	-150	-161	-125	-150	-150	-125	0	-11	0
EBITDA	-150	-161	-125	-150	-150	-125	0	-11	0
EBITDA adj	-150	-161	-125	-150	-150	-125	0	-11	0
EBITDA margin (%)	nm	nm	nm	high	high	high	nm	nm	nm
Depreciation	0	0	0	0	0	0	0	0	0
EBITA	-150	-161	-125	-150	-150	-125	0	-11	0
Amortisation	0	0	1	0	0	1	0	0	0
EBIT	-150	-161	-124	-150	-150	-124	0	-11	0
EBIT adj	-150	-161	-124	-150	-150	-124	0	-11	0
Net interest	1	1	1	1	1	1	0	0	0
Net financial items	1	1	1	1	1	1	0	0	0
PBT	-149	-160	-123	-149	-149	-123	0	-11	0
Taxes	0	0	0	0	0	0	0	0	0
Net profit	-149	-160	-123	-149	-149	-123	0	-11	0
Adjustments to net profit	0	0	0	0	0	0	0	0	0
Net profit adj	-149	-160	-124	-149	-149	-124	0	-11	0
Per share data (SEK)									
EPS	-4.73	-5.08	-3.94	-4.73	-4.73	-3.94	0.00	-0.35	0.00
EPS adj	-4.73	-5.08	-3.94	-4.73	-4.73	-3.94	0.00	-0.35	0.00
Other key metrics (%)									
Revenue growth	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBIT adj growth	nm	nm	nm	67.2	0.0	-17.3	nm	nm	nm
EPS adj growth	nm	nm	nm	80.0	0.0	-16.7	nm	nm	nm
Capex	0	0	0	0	0	0	0	0	0
OpFCF	-150	-161	-125	-150	-150	-125	0	-11	0
Working capital	0	0	0	0	0	0	0	0	0
NIBD adj	0	0	0	0	0	0	0	0	0

Source: DNB Markets

Annual P&L

(SEKm)	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
Revenues	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
Cost of sales	0	0	0	0	0	0	0	0	0
Gross profit	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**
Operating expenses	-35	-32	-41	-64	-73	-90	-150	-161	-125
EBITDA	**-35**	**-32**	**-40**	**-64**	**-72**	**-90**	**-150**	**-161**	**-125**
Depreciation	0	0	0	0	0	0	0	0	0
EBITA	**-35**	**-32**	**-41**	**-64**	**-72**	**-90**	**-150**	**-161**	**-125**
Amortisation	0	0	0	0	0	0	0	0	1
EBIT	**-35**	**-32**	**-41**	**-64**	**-72**	**-90**	**-150**	**-161**	**-124**
Net interest	0	0	0	0	1	7	1	1	1
Net financial items	0	0	0	0	1	7	1	1	1
PBT	**-35**	**-32**	**-41**	**-64**	**-72**	**-83**	**-149**	**-160**	**-123**
Taxes	2	0	0	0	0	0	0	0	0
Effective tax rate (%)	5	0	0	0	0	0	0	0	0
Net profit	**-34**	**-32**	**-41**	**-64**	**-72**	**-83**	**-149**	**-160**	**-123**
Adjustments to net profit	0	0	0	0	0	0	0	0	0
Net profit adj	-34	-32	-41	-64	-72	-83	-149	-160	-124
Per share data (SEK)									
EPS	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-4.73	-5.08	-3.94
EPS adj	**-1.07**	**-1.00**	**-1.29**	**-2.03**	**-2.28**	**-2.63**	**-4.73**	**-5.08**	**-3.94**
Growth and margins (%)									
Revenue growth	nm	nm	nm	171.9	-55.3	nm	nm	nm	nm
EPS adj growth	nm	nm	nm	nm	nm	nm	nm	nm	nm
Gross margin	100.0	nm	100.0	100.0	100.0	nm	nm	nm	nm
EBITDA margin	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBITDA adj margin	nm	nm	nm	nm	nm	nm	nm	nm	nm
Depreciation/revenues	-153.9	nm	-59.1	-26.0	-66.1	nm	nm	nm	nm
EBIT margin	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBIT adj margin	nm	nm	nm	nm	nm	nm	nm	nm	nm
PBT margin	nm	nm	nm	nm	nm	nm	nm	nm	nm
Net profit margin	nm	nm	nm	nm	nm	nm	nm	nm	nm

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

Adjustments to annual P&L

(SEKm)	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
EBITDA	**-35**	**-32**	**-40**	**-64**	**-72**	**-90**	**-150**	**-161**	**-125**
Gains and losses	0	0	0	0	0	0	0	0	-1
Other EBITDA adjustments					0	0	0	0	1
EBITDA adj	-35	-32	-40	-64	-72	-90	-150	-161	-125
EBITA	**-35**	**-32**	**-41**	**-64**	**-72**	**-90**	**-150**	**-161**	**-125**
Gains and losses	0	0	0	0	0	0	0	0	-1
Other EBITA adjustments					0	0	0	0	1
EBITA adj	-35	-32	-41	-64	-72	-90	-150	-161	-125
EBIT	**-35**	**-32**	**-41**	**-64**	**-72**	**-90**	**-150**	**-161**	**-124**
Gains and losses	0	0	0	0	0	0	0	0	-1
Other EBIT adjustments	0	0	0	0	0	0	0	0	1
EBIT adj	-35	-32	-41	-64	-72	-90	-150	-161	-124
Net profit	**-34**	**-32**	**-41**	**-64**	**-72**	**-83**	**-149**	**-160**	**-123**
Gains and losses	0	0	0	0	0	0	0	0	-1
Other EBIT adjustments	0	0	0	0	0	0	0	0	1
Tax adjustments	0	0	0	0	0	0	0	0	0
Net profit adj	-34	-32	-41	-64	-72	-83	-149	-160	-124
Per share data (SEK)									
EPS	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-4.73	-5.08	-3.94
Recommended adjustment	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	-4.73	-5.08	-3.94

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

Cash flow

(SEKm)	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
Net profit	-34	-32	-41	-64	-72	-83	-149	-160	-123
Depreciation and amortisation	0	0	0	0	0	0	0	0	-1
Other non-cash adjustments			0	0	0	-7	0	0	0
Change in net working capital			4	7	10	2	0	0	0
Cash flow from operations (CFO)	**-33**	**-31**	**-37**	**-57**	**-62**	**-88**	**-149**	**-160**	**-124**
Capital expenditure			0	-1	0	0	0	0	0
Cash flow from investing (CFI)	**0**	**0**	**0**	**-1**	**0**	**0**	**0**	**0**	**0**
Free cash flow (FCF)	**-33**	**-31**	**-37**	**-57**	**-62**	**-88**	**-149**	**-160**	**-124**
Other	56	15	0	0	0	3	0	0	-12
Cash flow from financing (CFF)	**56**	**15**	**38**	**69**	**400**	**4**	**0**	**200**	**188**
Total cash flow (CFO+CFI+CFF)	**23**	**-17**	**1**	**12**	**338**	**-84**	**-150**	**39**	**63**
FCFF calculation									
Free cash flow	-33	-31	-37	-57	-62	-88	-149	-160	-124
Less: net interest	0	0	0	0	-1	-7	-1	-1	-1
Growth (%)									
CFO	nm	5.8	-16.2	-55.0	-8.8	-43.4	-68.7	-7.4	22.5
CFI	nm	nm	nm	-432.8	89.7	100.0	nm	0.0	0.0
FCF	nm	5.8	-16.6	-56.4	-7.6	-43.2	-68.8	-7.4	22.5
CFF	nm	-73.6	153.2	83.9	477.6	-99.0	-109.5	53327.7	-6.0
FCFF	nm	nm	nm	nm	nm	nm	nm	nm	nm

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

Balance sheet

(SEKm)	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
Assets	**25**	**9**	**10**	**23**	**362**	**289**	**289**	**289**	**289**
Trade receivables	0	0	0	0	0	0	0	0	0
Other receivables	1	2	2	2	2	0	0	0	0
Current financial assets	0	0	1	1	1	0	0	0	0
Cash and cash equivalents	23	6	7	19	357	273	123	163	226
Current assets	**25**	**8**	**9**	**22**	**361**	**273**	**123**	**163**	**226**
Property, plant and equipment	0	0	0	0	0	0	0	0	0
Other intangible assets	1	1	0	0	0	0	0	0	0
Non-current financial assets	0	0	0	0	0	4	4	4	4
Non-current assets	**1**	**1**	**1**	**1**	**1**	**4**	**4**	**4**	**4**
Total assets	**25**	**9**	**10**	**23**	**362**	**289**	**289**	**289**	**289**
Equity and liabilities	**25**	**9**	**10**	**23**	**362**	**289**	**289**	**289**	**289**
Total equity to the parent	12	5	2	6	343	265	115	155	230
Total equity	**12**	**5**	**2**	**6**	**343**	**265**	**115**	**155**	**230**
Trade payables	4	2	5	12	13	0	0	0	0
Other payables and accruals	4	1	2	4	4	0	0	0	0
Short-term debt	5	0	1	1	1	0	0	0	0
Total current liabilities	**13**	**4**	**8**	**17**	**18**	**0**	**0**	**0**	**0**
Total non-current liabilities	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Total liabilities	**13**	**4**	**8**	**17**	**18**	**0**	**0**	**0**	**0**
Total equity and liabilities	**25**	**9**	**10**	**23**	**362**	**289**	**289**	**289**	**289**
Key metrics									

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

Valuation ratios

(SEKm)	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
Enterprise value									
Share price (SEK)					21.90	23.90	20.20	18.00	18.00
Net interest bearing debt adj	0	0	0	0	0	0	0	0	0
Valuation									
EPS	-1.07	-1.00	-1.29	-2.03	-2.28	-2.63	-4.73	-5.08	-3.94
EPS adj	**-1.07**	**-1.00**	**-1.29**	**-2.03**	**-2.28**	**-2.63**	**-4.73**	**-5.08**	**-3.94**
P/E					-9.6	-9.1	-4.3	-3.5	-4.6
P/E adj					-9.6	-9.1	-4.3	-3.5	-4.6
Average ROE	-561.2%	-383.1%	-1304.8%	-1637.6%	-41.1%	-27.3%	-78.6%	-118.8%	-64.1%

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

Key accounting ratios

	2013	2014	2015	2016	2017	2018	2019e	2020e	2021e
Profitability (%)									
ROA	-264.6	-186.2	-434.2	-386.7	-37.4	-25.5	-51.8	-55.6	-42.8
Return on invested capital (%)									
Net PPE/revenues	12.0		69.8	33.7	83.3				
Working capital/revenues	-6492.7		-3024.7	-2770.7	-6492.1				
Cash flow ratios (%)									
FCF/revenues	-31819.3		-19634.5	-11292.9	-27188.5				
CFO/revenues	-31819.3		-19561.1	-11149.2	-27155.5				
CFO/capex			-26676.4	-7758.6	-82190.7		-198845.3	-213512.0	-165512.0
CFO/current liabilities	-249.2	-782.3	-432.5	-337.3	-338.0				
Cash conversion ratio	99.5	99.7	90.4	89.8	85.9	106.5	99.8	99.9	100.6
Capex/revenues			73.3	143.7	33.0				
Capex/depreciation			124.1	553.0	50.0	0.0	47.8	47.8	47.8
OpFCF margin	-33371.0		-21728.0	-12693.5	-31877.5				
Leverage and solvency (x)									
Interest cover	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBIT/interest payable	nm	nm	nm	nm	nm	nm	nm	nm	nm
EBITA adj/interest payable	nm	nm	nm	nm	nm	nm	nm	nm	nm
Cash coverage	-558.07	1361.45	-44216.52	-63753.00	130.95	13.32	271.45	291.38	226.16
Cash conversion cycle									
Receivables turnover days	4811.3	nm	3167.7	1512.5	4019.8				
Credit period	nm	nm	nm	nm	nm				

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

Important Information

Company: Isofol Medical
Coverage by Analyst: Patrik Ling
Date: 31/01/2020

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% of total	56%	23%	14%	6%	
DNB Markets client	28%	8%	4%	2%	108

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