

FBC Device ApS

Viengevej 100, 8240 Risskov

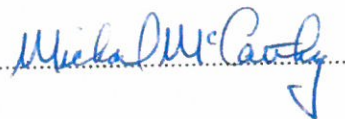
CVR no. 29 21 24 81

Annual report

for the year 1 January - 31 December 2018

Approved at the Company's annual general meeting on 22 May 2019

Chairman:

Michael McCarty

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working world



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Statement by the Board of Directors and the Executive Board

Today, the Board of Directors and the Executive Board have discussed and approved the annual report of FBC Device ApS for the financial year 1 January - 31 December 2018.

The annual report is prepared in accordance with the Danish Financial Statements Act.

In our opinion, the financial statements give a true and fair view of the financial position of the Company at 31 December 2018 and of the results of the Company's operations for the financial year 1 January - 31 December 2018.

Further, in our opinion, the Management's review gives a fair review of the matters discussed in the Management's review.

We recommend that the annual report be approved at the annual general meeting.

Risskov, 22 May 2019
Executive Board:



Finn Bjarke Christensen

Board of Directors:



Michael McCarthy
Chairman



Finn Bjarke Christensen



Lars Henning Stigel



Claus Asbjørn Andersson



Tonni Bülow-Nielsen



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Board of Directors:


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Chairman

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Claus Asbjørn Andersson

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Tonni Bülow-Nielsen

Independent auditor's report

To the shareholders of FBC Device ApS

Opinion

We have audited the financial statements of FBC Device ApS for the financial year 1 January - 31 December 2018, which comprise income statement, balance sheet, statement of changes in equity and notes, including accounting policies. The financial statements are prepared in accordance with the Danish Financial Statements Act.

In our opinion, the financial statements give a true and fair view of the financial position of the Company at 31 December 2018 and of the results of the Company's operations for the financial year 1 January - 31 December 2018 in accordance with the Danish Financial Statements Act.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and the additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the "Auditor's responsibilities for the audit of the financial statements" section of our report. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We are independent of the Company in accordance with the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants (IESBA Code) and the additional requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these rules and requirements.

Management's responsibilities for the financial statements

Management is responsible for the preparation of financial statements that give a true and fair view in accordance with the Danish Financial Statements Act and for such internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, Management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting in preparing the financial statements unless Management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance as to whether the financial statements as a whole are free from material misstatement, whether due to fraud or error and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

As part of an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- ▶ Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error as fraud may involve collusion, forgery, intentional omissions, misrepresentations or the override of internal control.
- ▶ Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.

Independent auditor's report

- ▶ Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- ▶ Conclude on the appropriateness of Management's use of the going concern basis of accounting in preparing the financial statements and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- ▶ Evaluate the overall presentation, structure and contents of the financial statements, including the note disclosures, and whether the financial statements represent the underlying transactions and events in a manner that gives a true and fair view.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Statement on the Management's review

Management is responsible for the Management's review.

Our opinion on the financial statements does not cover the Management's review, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the Management's review and, in doing so, consider whether the Management's review is materially inconsistent with the financial statements or our knowledge obtained during the audit, or otherwise appears to be materially misstated.

Moreover, it is our responsibility to consider whether the Management's review provides the information required under the Danish Financial Statements Act.

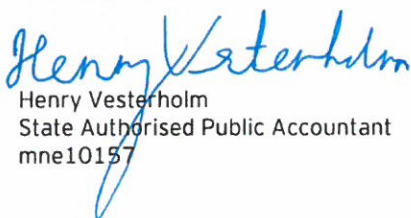
Based on the work we have performed, we conclude that the Management's review is in accordance with the financial statements and has been prepared in accordance with the requirements of the Danish Financial Statement Act. We did not identify any material misstatement of the Management's review.

Aarhus, 22 May 2019

ERNST & YOUNG

Godkendt Revisionspartnerselskab

CVR no. 30 70 02 28



Henry Vesterholm
State Authorised Public Accountant
mne10157



Jane Haugaard
State Authorised Public Accountant
mne29379



Management's review

Company details

Name	FBC Device ApS
Address, Postal code, City	Viengevej 100, 8240 Risskov
CVR no.	29 21 24 81
Registered office	Aarhus
Financial year	1 January - 31 December
Board of Directors	Michael McCarthy, Chairman Finn Bjarke Christensen Lars Henning Stigel Claus Asbjørn Andersson Tonni Bülow-Nielsen
Executive Board	Finn Bjarke Christensen
Auditors	Ernst & Young Godkendt Revisionspartnerselskab Værkmestergade 25, P.O. Box 330, 8100 Aarhus C, Denmark

Management commentary

Business review

The primary objective of the Company is to develop, utilise and market a new implant technology for diagnostic and therapeutic purposes.

Financial review

The income statement for 2018 shows a loss of DKK 5,282,040 against a loss of DKK 5,849,512 last year, and the balance sheet at 31 December 2018 shows equity of DKK 5,570,253.

Events after the balance sheet date

No events materially affecting the Company's financial position have occurred subsequent to the financial year-end.

Outlook

The capital increase made in 2018 ensures sufficient liquidity in the Company to carry out the research and development activities planned for 2019.

Through the investment agreement, considerable capital was injected into the Company, and Management is therefore in the opinion that the Company will be able to realise positive results in future.



Financial statements 1 January - 31 December

Income statement

Note	DKK	2018	2017
	Gross margin	-4,754,448	-5,706,563
2	Staff costs	-1,934,847	-1,639,672
	Profit/loss before net financials	-6,689,295	-7,346,235
	Financial income	0	355
	Financial expenses	-20,850	-10,911
	Profit/loss before tax	-6,710,145	-7,356,791
3	Tax for the year	1,428,105	1,507,279
	Profit/loss for the year	-5,282,040	-5,849,512
	Recommended appropriation of profit/loss		
	Retained earnings/accumulated loss	-5,282,040	-5,849,512
		-5,282,040	-5,849,512

Financial statements 1 January - 31 December

Balance sheet

Note	DKK	2018	2017
	ASSETS		
	Fixed assets		
	Investments		
	Other receivables	36,350	36,350
		<u>36,350</u>	<u>36,350</u>
	Total fixed assets	<u>36,350</u>	<u>36,350</u>
	Non-fixed assets		
	Receivables		
	Trade receivables	88,842	13,678
	Income taxes receivable	1,428,105	1,507,279
	Other receivables	305,628	386,207
		<u>1,822,575</u>	<u>1,907,164</u>
	Cash	4,540,424	4,765,604
	Total non-fixed assets	<u>6,362,999</u>	<u>6,672,768</u>
	TOTAL ASSETS	<u>6,399,349</u>	<u>6,709,118</u>
	EQUITY AND LIABILITIES		
	Equity		
4	Share capital	441,495	415,239
	Retained earnings	5,128,758	5,462,297
	Total equity	<u>5,570,253</u>	<u>5,877,536</u>
	Liabilities other than provisions		
	Current liabilities other than provisions		
	Trade payables	476,611	580,547
	Other payables	352,485	251,035
		<u>829,096</u>	<u>831,582</u>
	Total liabilities other than provisions	<u>829,096</u>	<u>831,582</u>
	TOTAL EQUITY AND LIABILITIES	<u>6,399,349</u>	<u>6,709,118</u>

1 Accounting policies

5 Contractual obligations and contingencies, etc.

6 Collateral

Financial statements 1 January - 31 December

Statement of changes in equity

DKK	Share capital	Retained earnings	Total
Equity at 1 January 2018	415,239	5,462,297	5,877,536
Capital increase	26,256	4,948,501	4,974,757
Transfer through appropriation of loss	0	-5,282,040	-5,282,040
Equity at 31 December 2018	441,495	5,128,758	5,570,253

Financial statements 1 January - 31 December

Notes to the financial statements

1 Accounting policies

The annual report of FBC Device ApS for 2018 has been prepared in accordance with the provisions in the Danish Financial Statements Act applying to reporting class B entities and elective choice of certain provisions applying to reporting class C entities.

The accounting policies used in the preparation of the financial statements are consistent with those of last year.

Reporting currency

The financial statements are presented in Danish kroner (DKK).

Income statement

Revenue

Revenue, which comprises implants, is measured at the fair value of the agreed consideration excluding VAT and taxes charged on behalf of third parties. All discounts and rebates granted are recognised in revenue.

Gross margin

The items revenue and external expenses have been aggregated into one item in the income statement called gross margin in accordance with section 32 of the Danish Financial Statements Act.

Other external expenses

Other external expenses comprise costs of premises, sale and distribution as well as office expenses, etc.

Staff costs

Staff costs include wages and salaries, including compensated absence and pension to the Company's employees, as well as other social security contributions, etc. The item is net of refunds from public authorities.

Financial income and expenses

Financial income and expenses are recognised in the income statements at the amounts that concern the financial year. Net financials include interest income and expenses as well as allowances and surcharges under the advance-payment-of-tax scheme, etc.

Tax

Tax for the year includes current tax on the year's expected taxable income and the year's deferred tax adjustments. The portion of the tax for the year that relates to the profit/loss for the year is recognised in the income statement, whereas the portion that relates to transactions taken to equity is recognised in equity.

Financial statements 1 January - 31 December

Notes to the financial statements

1 Accounting policies (continued)

Balance sheet

Receivables

Receivables are measured at amortised cost or at a lower net realisable value, corresponding to nominal amount less write-down for bad debt losses. Write-downs for bad debts are computed based on an individual assessment of each receivable.

The Company has chosen IAS 39 as interpretation for impairment of financial receivables.

An impairment loss is recognised if there is objective evidence that a receivable or a group of receivables is impaired. If there is objective evidence that an individual receivable has been impaired, an impairment loss is recognised on an individual basis.

Receivables in respect of which there is no objective evidence of individual impairment are tested for objective evidence of impairment on a portfolio basis. The portfolios are primarily based on the debtors' domicile and credit ratings in line with the Company's risk management policy. The objective evidence applied to portfolios is determined based on historical loss experience.

Impairment losses are calculated as the difference between the carrying amount of the receivables and the present value of the expected cash flows, including the realisable value of any collateral received. The effective interest rate for the individual receivable or portfolio is used as discount rate.

Income taxes

Current tax payables and receivables are recognised in the balance sheet as the estimated income tax charge for the year, adjusted for prior-year taxes and tax paid on account.

Deferred tax is measured according to the liability method on all temporary differences between the carrying amount and the tax base of assets and liabilities. However, deferred tax is not recognised on temporary differences relating to goodwill which is not deductible for tax purposes and on office premises and other items where temporary differences, apart from business combinations, arise at the date of acquisition without affecting either profit/loss for the year or taxable income. Where alternative tax rules can be applied to determine the tax base, deferred tax is measured based on Management's intended use of the asset or settlement of the liability, respectively.

Deferred tax is measured according to the tax rules and at the tax rates applicable at the balance sheet date when the deferred tax is expected to crystallise as current tax. Deferred tax assets are recognised at the expected value of their utilisation; either as a set-off against tax on future income or as a set-off against deferred tax liabilities in the same legal tax entity. Changes in deferred tax due to changes in the tax rate are recognised in the income statement.

Liabilities

Financial liabilities are measured at amortised cost, which essentially corresponds to the nominal value.

Other liabilities are measured at net realisable value.

Financial statements 1 January - 31 December

Notes to the financial statements

DKK	2018	2017
2 Staff costs		
Wages/salaries	1,825,573	1,547,267
Pensions	78,816	69,460
Other social security costs	20,098	13,487
Other staff costs	10,360	9,458
	<u>1,934,847</u>	<u>1,639,672</u>
 Average number of full-time employees	 <u>2</u>	 <u>2</u>
 3 Tax for the year		
Estimated tax charge for the year	-1,428,105	-1,507,279
	<u>-1,428,105</u>	<u>-1,507,279</u>

4 Share capital

The share capital comprises 441.495 shares of a nominal amount of DKK 1 each, of which 125,000 shares are Y-shares, 165,288 are A-shares, 98,695 are B-shares and 52,515 are C-shares. The A-shares carry preferential dividend rights.

Analysis of changes in the share capital over the past 5 years:

DKK	2018	2017	2016	2015	2014
Opening balance	415,239	388,983	388,983	344,649	290,288
Capital increase	26,256	26,256	0	44,334	54,361
	<u>441,495</u>	<u>415,239</u>	<u>388,983</u>	<u>388,983</u>	<u>344,649</u>

5 Contractual obligations and contingencies, etc.

Other financial obligations

The Company has entered into leases regarding premises with a notice of termination of six months. The lease liability amounts to DKK 69 thousand during the period of non-terminability.

6 Collateral

No mortgages or assets have been provided as security.