ARO Medical ApS

Viengevej 100, 8240 Risskov

CVR no. 34 62 16 08

Annual report 2016

Approved at the annual general meeting of shareholders on 7 June 2017.

Chairman:

SØREN S. SKJÆRBÆK
V/BJARNE AARUP

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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 ARO Medical ApS for the financial year 1 January - 31 December 2016.

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 2016 and of the results of the Company's operations for the financial year 1 January - 31 December 2016.

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, 7 June 2017
Executive Board:

Bruce Harshaw Robie

Board of Directors:

Bruce Harshaw Robie	Michael Patrick McCarthy	Claus Asbjørn Andersson

Independent auditor's report

To the shareholders of ARO Medical ApS

Opinion

We have audited the financial statements of ARO Medical ApS for the financial year 1 January - 31 December 2016, which comprise an 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 2016 and of the results of the Company's operations for the financial year 1 January - 31 December 2016 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 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. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of matter in the financial statements

We refer to note 2 to the financial statements which states that the value of the Company's intangible assets comprising development projects in progress as well as patents and licences are subject to considerable uncertainty. We have not modified our auditor's report regarding this issue.

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 about 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 skepticism 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.

Independent auditor's report

- 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.
- 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 conclusion is 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 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 our procedures, 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, 7 June 2017
ERNST & YOUNG
Godkendt Revisionspartnerselskab
CVR no. 30 70 02 28

Henry Vesterholm
State Authorised Public Accountant

Jane Haugaard
State Authorised Public Accountant

Management's review

Company details

Name	ARO Medical ApS
Address, Postal code, City	Viengevej 100, 8240 Risskov
CVR no.	34 62 16 08
Established	12 July 2012
Registered office	Aarhus
Financial year	1 January - 31 December
E-mail	brobie@AROmedical.com
Board of Directors	Bruce Harshaw Robie Michael Patrick McCarthy Claus Asbjørn Andersson
Executive Board	Bruce Harshaw Robie
Auditors	Ernst & Young Godkendt Revisionspartnerselskab Værkmestergade 25, P.O. Box 330, 8100 Aarhus C, Denmark

Management's review

Management commentary

Business review

The objective of the Company is to develop back implants and related activities.

The Company was established on 12 July 2012 by a contribution of net assets totalling DKK 22,420 thousand comprising development projects, patents, trademark, etc. An additional amount of DKK 3,540 thousand was contributed by a cash capital increase in the Compay at 1 August 2012.

Recognition and measurement uncertainties

The Company's most significant assets comprise development project in progress as well as patents and licences. The carrying amount totalled DKK 30,830 thousand at 31 December 2016.

The Company is in the final steps of completing its first development project, with plans to commercialize the product in selected markets in 2017. The valuation thereof is subject to material uncertainty as the market interst in the product is unproven. Based on the current status, management is of the opinion that there is no indication of impairment and that consequently, there is no need for impairment write-down of the intabgible assets.

Financial review

The Company's income statement for 2016 showed a loss of DKK 1,932 thousand. The Company's equity totalled DKK 19,390 thousand at 31 December 2016.

As of December 2016, the Company had completed the initial clinical study of the ARO device, including one year follow-up. The clinical data shows that the device is safe, and meets the primary outcome measures of the study. Secondarily, it does not show a statistically significant improvement in comparison to historical controls, which may be due to the relatively small numbers of subjects in this study.

Events after the balance sheet date

No significant events have occurred subsequent to the financial year, which would influence the evaluation of this annual report.

Outlook

The Company continues to operate at a loss, and will be seeking to raise capital in 2017. The Company directs expenditures toward further development of clinical evidence, protection of associated intellectual property and preparation for commercialization. The Company does this in a virtual form, minimizing ongoing (fixed) expenses. Reliance on partners is required for the Company to continue to make progress.

In the long run, the Company expects to reward investors via the sale of the business and distribution of the received capital. It is unclear when that will occur.

Based on the financial condition of the Company, it is expected that the Company will either need to raise capital or sell the business in 2017. The ability to achieve either of these is uncertain, due to the environment surrounding Healthcare investments (with regard to raising additional capital) and the inherent nature of Mergers & Acquisitions.

Should the capital not be raised or the business not sold in 2017, the Company's activities will be adjusted accordingly.

Financial statements for the period 1 January - 31 December

Income statement

Note	DKK	2016	2015
	Gross margin	-452,030	-331,044
3	Staff costs	-84,296	-83,071
	Amortisation/depreciation and impairment of intangible assets	-1,310,769	-1,310,769
	Profit/loss before net financials	-1,847,095	-1,724,884
4	Financial income	3,663	303,224
5	Financial expenses	-633,661	-553,782
	Profit/loss before tax	-2,477,093	-1,975,442
6	Tax for the year	544,960	893,529
	Profit/loss for the year	-1,932,133	-1,081,913

		2016	2015
	Recommended appropriation of profit/loss		
	Other statutory reserves	1,327,461	0
	Retained earnings/accumulated loss	-3,259,594	-1,081,913
		-1,932,133	-1,081,913

Financial statements for the period 1 January - 31 December

Balance sheet

Note	DKK	2016	2015
	ASSETS		
	Fixed assets		
7	**Intangible assets**		
	Patents and licences	15,401,539	16,712,308
	Development projects in progress and prepayments for intangible assets	15,428,848	13,726,975
		30,830,387	30,439,283
	Total fixed assets	30,830,387	30,439,283
	Non-fixed assets		
	Receivables		
	Receivables from group entities	29,372	29,372
	Income taxes receivable	492,404	463,488
	Other receivables	26,790	31,344
		548,566	524,204
	Cash	273,826	1,919,635
	Total non-fixed assets	822,392	2,443,839
	TOTAL ASSETS	31,652,779	32,883,122
	EQUITY AND LIABILITIES		
	Equity		
8	Share capital	92,632	92,632
	Reserve for development costs	1,327,461	0
	Retained earnings	17,969,954	21,229,548
	Total equity	19,390,047	21,322,180
	Provisions		
	Deferred tax	6,243,813	6,296,369
	Total provisions	6,243,813	6,296,369
	Liabilities		
9	**Non-current liabilities other than provisions**		
	Other credit institutions	5,757,192	5,137,269
		5,757,192	5,137,269
	Current liabilities		
	Trade payables	122,216	92,526
	Other payables	139,511	34,778
		261,727	127,304
	Total liabilities other than provisions	6,018,919	5,264,573
	TOTAL EQUITY AND LIABILITIES	31,652,779	32,883,122

1 Accounting policies
2 Recognition and measurement uncertainties

Financial statements for the period 1 January - 31 December

Statement of changes in equity

DKK	Share capital	Reserve for development costs	Retained earnings	Total
Equity at 1 January 2016	92,632	0	21,229,548	21,322,180
Loss for the year	0	1,327,461	-3,259,594	-1,932,133
Equity at 31 December 2016	92,632	1,327,461	17,969,954	19,390,047

Financial statements for the period 1 January - 31 December

Notes to the financial statements

1 Accounting policies

The annual report of ARO Medical ApS for 2016 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.

Changes in accounting policies

Effective 1 January 2016, the Company has adopted act no. 738 of 1 June 2015. This implies the following changes in the recognition and measurement:

1. Reserve for development costs

Re 1: An amount corresponding to development costs recognised are in future tied up in a special reserve under equity called "Reserve for development costs". The amount is tied up in a special reserve, which cannot be used to distribute dividend or cover losses. If the development costs recognised are sold or in some other way no longer form part of the Company's operations, the reserve will be dissolved or reduced by a transfer directly to distributable reserves under equity. If the recognised development costs are written down, part of the reserve for development costs must be reversed. The reversed portion corresponds to the write-down of the development costs. If a write-down of the development costs is subsequently reversed, the reserve for development costs must be re-established. The reserve for development costs is also reduced by amortisation charges. In doing so, the equity reserve will not exceed the amount recognised in the balance sheet as development costs.

The above change does not affect the income statement or the balance sheet for 2016 or the comparative figures.

Apart from the above changes in accounting policy and new and changed presentation and disclosure requirements, which follow from act. no. 738 of 1 June 2015, the accounting policies are consistent with those of last year.

Reporting currency

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

Foreign currency translation

On initial recognition, transactions denominated in foreign currencies are translated at the exchange rate at the transaction date. Foreign exchange differences arising between the exchange rates at the transaction date and the date of payment are recognised in the income statement as financial income or financial expenses.

Receivables and payables and other monetary items denominated in foreign currencies are translated at the exchange rate at the balance sheet date. The difference between the exchange rates at the balance sheet date and the date at which the receivable or payable arose or was recognised in the most recent financial statements is recognised in the income statement as financial income or financial expenses.

Income statement

Revenue

Revenue 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.

Financial statements for the period 1 January - 31 December

Notes to the financial statements

1 Accounting policies (continued)

Gross margin

The items revenue, change in inventories of finished goods and work in progress, work performed for own account and capitalised, other operating income 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 include the year's expenses relating to the Company's core activities, including expenses relating to distribution, sale, advertising, administration, premises, bad debts, payments under operating leases, 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.

Depreciation

The item comprises depreciation of property, plant and equipment.

The basis of amortisation, which is calculated as cost less any residual value, is amortised on a straight line basis over the expected useful life. The expected useful lives of the assets are as follows:

Patents and licenses	16 years

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.

Balance sheet

Intangible assets

Other intangible assets include development projects and other acquired intangible rights, including software licences, distribution rights and development projects.

Other intangible assets are measured at cost less accumulated amortisation and impairment losses.

Development costs comprise expenses, salaries and amortisation directly or indirectly attributable to development activities.

Financial statements for the period 1 January - 31 December

Notes to the financial statements

1 Accounting policies (continued)

Development projects that are clearly defined and identifiable, where the technical feasibility, sufficient resources and a potential future market or development opportunities areidentifiable and where the Company intends to produce, market or use the project, are recognised as intangible assets provided that the cost can be measured reliably and that there is sufficient assurance that future earnings can cover production costs, selling costs and administrative expenses and development costs. Other development costs are recognised in the income statement as incurred.

Development costs that are recognised in the balance sheet are measured at cost less accumulated amortisation and impairment losses.

On completion of a development project, development costs are amortised on a straight-line basis over the estimated useful life. The amortisation period is usually 5 years.

Patents and licences are measured at cost less accumulated amortisation and impairment losses. Patents are amortised on a straight-line basis over the remaining term of the patent, and licences are amortised over the term of the licence. Consequently, the period of amortisation exceeds five years.

Gains and losses on the sale of intangible assets are recognised in the income statement under "Other operating income" or "Other operating expenses", respectively. Gains and losses are calculated as the difference between the selling price less selling expenses and the carrying amount at the time of sale.

Impairment of non-current assets

Intangible assets are subject to an annual test for indications of impairment other than the decrease in value reflected by depreciation or amortisation. Impairment tests are conducted in respect of individual assets or groups of assets generating separate cash flows when there is indications of impairment. The assets are written down to the higher of the value in use and net realisable value (recoverable amount) of the asset or group of assets if this is lower than the carrying amount.

Impairment tests are conducted on assets or groups of assets when there is evidence of impairment. The carrying amount of impaired assets is reduced to the higher of the net selling price and the value in use (recoverable amount).

The recoverable amount is the higher of the net selling price of an asset and its value in use. The value in use is calculated as the present value of the expected net cash flows from the use of the asset or the group of assets and the expected net cash flows from the disposal of the asset or the group of assets after the end of the useful life.

Previously recognised impairment losses are reversed when the reason for recognition no longer exists. Impairment losses on goodwill are not reversed.

Receivables

Receivables are measured at amortised cost.

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.

Financial statements for the period 1 January - 31 December

Notes to the financial statements

1 Accounting policies (continued)

Equity

Reserve for development costs

The reserve for development costs comprises recognised development costs incurred after 1 January 2016. The reserve cannot be used to distribute dividends or cover losses. The reserve will be reduced or dissolved if the recognised development costs are no longer part of the Company's operations by a transfer directly to the distributable reserves under equity.

Proposed dividends

Dividend proposed for the year is recognised as a liability once adopted at the annual general meeting (declaration date). Dividends expected to be distributed for the financial year are presented as a separate item under "Equity".

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 recognised at the date of borrowing at the net proceeds received less transaction costs paid. On subsequent recognition, financial liabilities are measured at amortised cost, corresponding to the capitalised value, using the effective interest rate. Accordingly, the difference between the proceeds and the nominal value is recognised in the income statement over the term of the loan. Financial liabilities also include the capitalised residual lease liability in respect of finance leases.

Other liabilities are measured at net realisable value.

Financial statements for the period 1 January - 31 December

Notes to the financial statements

2 Recognition and measurement uncertainties

The Company's most significant assets comprise development project in progress as well as patents and licences. The carrying amount totalled DKK 30,830 thousand at 31 December 2016.

As the Company is still in its development phase in relation to development projects and the use of the patents involved, the valuation thereof is subject to material uncertainty as this depends on the future outcome of clinical testing, etc. Based on the present stage of the development project and the clinical tests, etc. performed so far, Management is, however, of the opinion that there is no indication of impairment and that consequently, there is no need for impairment write-down of the intangible assets.

	DKK	2016	2015
3	**Staff costs**		
	Wages/salaries	163,264	160,500
	Other social security costs	5,066	5,462
	Other staff costs	-84,034	-82,891
		84,296	83,071
	Average number of full-time employees	1	1
4	**Financial income**		
	Other financial income	3,663	303,224
		3,663	303,224
5	**Financial expenses**		
	Other financial expenses	633,661	553,782
		633,661	553,782
6	**Tax for the year**		
	Estimated tax charge for the year	-492,404	-463,488
	Deferred tax adjustments in the year	-52,556	-741
	Change in tax rate	0	-429,300
		-544,960	-893,529

Financial statements for the period 1 January - 31 December

Notes to the financial statements

7 Intangible assets

DKK	Patents and licences	Development projects in progress and prepayments for intangible assets	Total
Cost at 1 January 2016	21,300,000	13,726,975	35,026,975
Additions in the year	0	1,701,873	1,701,873
Cost at 31 December 2016	21,300,000	15,428,848	36,728,848
Impairment losses and amortisation at 1 January 2016	4,587,692	0	4,587,692
Amortisation in the year	1,310,769	0	1,310,769
Impairment losses and amortisation at 31 December 2016	5,898,461	0	5,898,461
Carrying amount at 31 December 2016	15,401,539	15,428,848	30,830,387

8 Share capital

The share capital comprises 12,632 A shares and 80,000 Y shares.

Analysis of changes in the share capital over the past 4 years:

DKK	2016	2015	2014	2013
Opening balance	92,632	92,632	92,632	80,000
Capital increase	0	0	0	12,632
	92,632	92,632	92,632	92,632

9 Long-term liabilities

DKK	Total debt at 31/12 2016	Repayment, next year	Long-term portion	Outstanding debt after 5 years
Other credit institutions	5,757,192	0	5,757,192	0
	5,757,192	0	5,757,192	0