

Blusense Diagnostics ApS

Fruebjergvej 3
2100 Copenhagen
Denmark

CVR no. 36 05 91 84

Annual report 2018

The annual report was presented and approved at the
Company's annual general meeting on

29 May 2019

Jørgen Bek Weiss Hansen
chairman

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Statement by the Board of Directors and the Executive Board

The Board of Directors and the Executive Board have today discussed and approved the annual report of Blusense Diagnostics ApS for the financial year 1 January – 31 December 2018.

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

In our opinion, the financial statements give a true and fair view of the Company's assets, liabilities and financial position 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.

Copenhagen 29 May 2019
Executive Board:

Filippo Giacomo Bosco
CEO

Robert Burger

Marco Donolato

Board of Directors:

Leif Helth Jensen
Chairman

Marco Donolato
Vice chairman

Chih-Liu Lin
Board member

Konstantinos Piliounis
Board member

Shi-Chi Ho
Board member

Filippo Giacomo Bosco
Board member

Chen Shang-Hao
Board member

Independent auditor's report

To the shareholders of Blusense Diagnostics ApS

Opinion

We have audited the financial statements of Blusense Diagnostics ApS for the financial year 1 January – 31 December 2018 comprising 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 Company's assets, liabilities and financial position 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 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.

Management's responsibility 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 that 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 in Denmark will always detect a material misstatement when it exists. Misstatements may 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 made on the basis of these 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 company 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 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 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 Statements Act. We did not identify any material misstatement of the Management's review.

Copenhagen, 29 May 2019

KPMG

Statsautoriseret Revisionspartnerselskab

CVR no. 25 57 81 98

Morten Høgh-Petersen
State Authorised
Public Accountant
mne34283

Blusense Diagnostics ApS
Annual report 2018
CVR no. 36 05 91 84

Management's review

Company details

Blusense Diagnostics ApS
Fruebjergvej 3
2100 Copenhagen
Denmark

Telephone: +45 39 17 97 14
Website: www.blusense-diagnostics.com
E-mail: info@blusense-diagnostics.com

CVR no.: 36 05 91 84
Established: 1 August 2014
Registered office: Copenhagen
Financial year: 1 January – 31 December

Board of Directors

Leif Helth Jensen, Chairman
Marco Donolato, Vice chairman
Chih-Liu Lin, Board member
Konstantinos Piliounis, Board member
Shi-Chi Ho, Board member
Filippo Giacomo Bosco, Board member
Chen Shang-Hao, Board member

Executive Board

Filippo Giacomo Bosco, CEO
Robert Burger
Marco Donolato

Auditor

KPMG
Statsautoriseret Revisionspartnerselskab
Dampfaergevej 28
DK-2100 Copenhagen
Denmark

Management's review

Operating review

Principal activities

Blusense Diagnostics is a young and dynamic medTech company, born as a spin-off from the Technical University of Denmark (DTU), one of the leading technical universities of Northern Europe. The technological innovation is based on the opto-magnetic readout which is part of Blusense's core IP.

Blusense has developed an innovative nanotechnology-based point-of-care blood testing platform for the diagnostics of infectious diseases. The platform is based on a reader (BluBox), and single-use blood test cartridges (ViroTrack), specifically designed for targeting different viruses. Blusense is currently marketing a quantitative Dengue antigen test (ViroTrack Acute Dengue NS1 Ag) and is developing Dengue and Zika antibody serological tests (ViroTrack Combo Dengue NS1/IgG/IgM, ViroTrack Sero Dengue IgG/IgM Ab and ViroTrack Sero Zika IgG/IgM Ab). Both, BluBox and ViroTrack Acute Dengue NS1 Ag are regulatory approved and registered in three South East Asian countries, namely Malaysia, Thailand and Vietnam.

The combination of superparamagnetic nanoparticles (MNP), microfluidics, optics and an affordable high-tech detection module allows to accurately quantify virtually any biomarker from a single drop of blood. The core technology's versatility has allowed Blusense's scientists to validate the biodetection protocols over a large panel of relevant immunoassays, which are deemed critical in the rapid diagnosis of severe tropical diseases. Therefore, the opportunities for diagnostics go beyond Dengue and Zika and have the potential to be scaled to other infectious diseases, including Chikungunya, Yellow Fever, Leptospirosis and other hemorrhagic fevers. BluBox offers full laboratory diagnostics capabilities within a small, affordable and portable device, proven to meet the standards of hospital diagnostics tools. Blusense's value proposition has been endorsed by key opinion leaders across the world. The device with its related consumables can be deployed throughout the Asia-Pacific and South American region, mainly distributed in de-centralized clinical settings, such as primary health centres and small clinics.

Management's review

Operating review

Knowhow and employees

With a highly skilled and very international mix of founders and employees, BluSense Diagnostics employed more than 25 full time employees over the year. The employees have strong technical backgrounds, several of them holding PhD's in nanotechnology, engineering or biochemistry. Thanks to its highly qualified portfolio of scientists and technicians, BluSense has been able to quickly move from product conception towards functioning prototypes, and finally towards product validation in the field.

BluSense is maintaining a quality management system according to ISO13485:2016, in order to ensure the highest quality standards for development and production of all products.

As a global-born start-up, BluSense has operations in Denmark, Taiwan, and Malaysia, with scientific and technological partners in several countries worldwide. BluSense is particularly active in the South East Asian region, where most of its clinical validation activities take place. BluSense has started moving towards the Latin American market, which holds great opportunities for BluSense products.

The headquarters is located at Symbion Science Park in the heart of the Medicon Valley in central Copenhagen. Core R&D related to microfluidics and biochemistry development are fully performed in these laboratories with a strong focus on building in-house knowhow in core areas such as biochemical conjugation protocols, advanced microfluidics design and prototyping, as well as product validation.

BluSense established a subsidiary in Taiwan, BluSense Biotech Ltd., in Q4 2015, located at the centre of the ICT industrial park in Guishan near Taipei City, Taiwan. BluSense Biotech Ltd. occupies 400 m2 of office and laboratory space in the facilities of Quanta Storage International. Currently, BluSense Biotech Ltd. employs a team of 11 people, 8 of whom are highly qualified engineers with an average of 11 years of industry experience. BluSense Biotech Ltd. is fully dedicated to the design, development and large-scale manufacturing of BluBox. Furthermore, BluSense incorporated a 100% subsidiary in Kuala Lumpur, BluSense Health SND Bdh, which is used as regional hub for running clinical studies.

BluSense's technical and scientific achievements have been published in several peer-reviewed scientific journals and have been presented at international conferences. Thanks to a broad appeal of BluSense's technology, several joint projects with universities worldwide allow BluSense to remain at the forefront of innovative research, adding new inventions and new technologies to its portfolio of diagnostics products.

Finally, BluSense has been a success case in raising public grants from the European funding agencies, obtaining the very competitive Horizon 2020 SME Phase-II grant, which has been running from May 2018 and will terminate in 2020.

Development in activities and financial position

In march 2019 4 million euro was additionally invested in the company. The investment has secured that the current activity is funded until spring 2020.

Financial statements 1 January – 31 December

Income statement

DKK'000	Note	2018	2017
Gross loss		-9,396	-8,750
Staff costs	2	-12,746	-8,865
Depreciation, amortisation and impairment		-445	-270
Operating loss		-22,587	-17,885
Financial income		69	148
Financial expenses		-263	-88
Loss before tax		-22,781	-17,825
Tax on profit/loss for the year		4,003	3,329
Loss for the year		-18,778	-14,496
Proposed distribution of loss			
Retained earnings		-18,778	-14,496
		-18,778	-14,496

Financial statements 1 January – 31 December

Balance sheet

DKK'000	Note	31/12 2018	31/12 2017
ASSETS			
Fixed assets			
Property, plant and equipment			
Property, plant and equipment		<u>760</u>	<u>968</u>
Investments			
Investments in group entities	3	1,912	1,902
Deposits		<u>424</u>	<u>301</u>
		<u>2,336</u>	<u>2,203</u>
Total fixed assets		<u>3,096</u>	<u>3,171</u>
Current assets			
Receivables			
Trade receivables		30	1,105
Other receivables		190	135
Corporation tax		<u>4,003</u>	<u>3,329</u>
		<u>4,223</u>	<u>4,569</u>
Cash at bank and in hand		<u>6,670</u>	<u>8,617</u>
Total current assets		<u>10,893</u>	<u>13,186</u>
TOTAL ASSETS		<u><u>13,989</u></u>	<u><u>16,357</u></u>

Financial statements 1 January – 31 December

Balance sheet

DKK'000	Note	<u>31/12 2018</u>	<u>31/12 2017</u>
EQUITY AND LIABILITIES			
Equity			
Contributed capital		278	185
Share premium		52,230	38,343
Retained earnings		<u>-44,615</u>	<u>-25,837</u>
Total equity		<u>7,893</u>	<u>12,691</u>
Liabilities			
Current liabilities			
Banks, current liabilities		61	0
Trade payables		944	2,977
Other payables		2,373	669
Deferred income		<u>2,718</u>	<u>20</u>
		<u>6,096</u>	<u>3,666</u>
Total liabilities		<u>6,096</u>	<u>3,666</u>
TOTAL EQUITY AND LIABILITIES		<u>13,989</u>	<u>16,357</u>
Contractual obligations, contingencies, etc.	4		

Financial statements 1 January – 31 December

Statement of changes in equity

DKK'000	<u>Contributed capital</u>	<u>Share premium</u>	<u>Retained earnings</u>	<u>Total</u>
Equity at 1 January 2018	185	38,343	-25,837	12,691
Cash capital increase	93	13,887	0	13,980
Transferred over the distribution of loss	<u>0</u>	<u>0</u>	<u>-18,778</u>	<u>-18,778</u>
Equity at 31 December 2018	<u><u>278</u></u>	<u><u>52,230</u></u>	<u><u>-44,615</u></u>	<u><u>7,893</u></u>

Financial statements 1 January – 31 December

Notes

1 Accounting policies

The annual report of Blusense Diagnostics ApS for 2018 has been prepared in accordance with the provisions applying to reporting class B entities under the Danish Financial Statements Act with opt-in from higher reporting classes.

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

Omission of consolidated financial statements

Pursuant to section 110(1) of the Danish Financial Statements Act, no consolidated financial statements have been prepared.

Gross Profit

Pursuant to Section 32 of the Danish Financial Statements Act, the Company has decided only to disclose gross profit.

Revenue

Income from the sale of goods is recognised in revenue when delivery and transfer of risk to the buyer have taken place, and the income may be measured reliably and is expected to be received.

Other external costs

Other external costs comprise distribution costs and costs related to sales, sales campaigns, administration, office premises, operating leases, etc.

Staff costs

Staff costs comprise wages and salaries, including holiday allowance, pension and other social security costs, etc., to the Company's employees, excluding reimbursements from public authorities.

Financial income and expenses

Financial income and expenses comprise interest income and expense..

Tax on profit/loss for the year

Tax for the year comprises current corporation tax for the year and changes in deferred tax, including changes in tax rates. The tax expense relating to the profit/loss for the year is recognised in the income statement, and the tax expense relating to amounts directly recognised in equity is recognised directly in equity.

Property, plant and equipment

Fixtures and fittings, tools and equipment are measured at cost less accumulated depreciation and impairment losses.

Financial statements 1 January – 31 December

Notes

1 Accounting policies (continued)

Cost comprises the purchase price and any costs directly attributable to the acquisition until the date on which the asset is available for use. Indirect production overheads and borrowing costs are not recognised in cost.

The basis of depreciation is cost less any projected residual value after the end of the useful life. Depreciation is provided on a straight-line basis over the estimated useful life. The estimated useful lives are as follows:

Equipment	3-5 years
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The useful life and residual value are reassessed annually. Changes are treated as accounting estimates, and the effect on depreciation is recognised prospectively.

Gains and losses on the disposal of equipment are stated as the difference between the selling price less selling costs and the carrying amount at the date of disposal. Gains and losses are recognised in the income statement as other operating income or other operating costs, respectively.

Investments in group entities

Equity investments in group entities and associates are measured at cost. When the cost exceeds the recoverable amount, write-down is made to this lower value. The cost is reduced by dividends received exceeding accumulated earnings after the acquisition date.

Receivables

Receivables are measured at amortised cost.

Write-down is made for bad debt losses where there is an objective indication that a receivable or a portfolio of receivables has been impaired. If there is an objective indication that an individual receivable has been impaired, write-down is made on an individual basis.

Other receivables and deposits are recognised at amortised cost.

Cash and cash equivalents

Cash and cash equivalents comprise cash.

Equity

Dividends

The expected dividends payment for the year is disclosed as a separate item under equity.

Financial statements 1 January – 31 December

Notes

1 Accounting policies (continued)

Liabilities

Financial liabilities are recognised at cost at the date of borrowing, corresponding to the proceeds received less transaction costs paid. In subsequent periods, the financial liabilities are measured at amortised cost using the effective interest method. Accordingly, the difference between cost and the nominal value is recognised in the income statement over the term of the loan together with interest expenses.

Other liabilities are measured at net realisable value.

Prepayments and deferred income

Deferred income comprises advance invoicing regarding income in subsequent years.

Corporation tax and deferred tax

Current tax payable and receivable is recognised in the balance sheet as tax computed on the taxable income for the year, adjusted for tax on the taxable income of prior years and for tax paid on account.

2 Staff costs

DKK'000	2018	2017
Wages and salaries	11,975	8,554
Pensions	56	37
Other social security costs	158	55
Other staff costs	557	219
	<u>12,746</u>	<u>8,865</u>
Average number of full-time employees	<u>24</u>	<u>16</u>

3 Investments

Investment in subsidiaries comprise of investments in:

BluSense Biotech Ltd., Taiwan 100%
Blusense Health Sdn. Bhd., Malaysia 100%

4 Contractual obligations, contingencies, etc.

The Company has a rental contract with a 6-month notice period, corresponding to DKK 830 thousand.