# BluSense Diagnostics ApS

Fruebjergvej 3 DK-2100 Copenhagen

CVR no. 36 05 91 84

**Annual report 2021** 

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

28 June 2022

Jørgen Bek Weiss Hansen

Chairman of the annual general meeting

BluSense Diagnostics ApS Annual report 2021 CVR no. 36 05 91 84

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Copenhagen, 28 June 2022

**Executive Board:** 

# 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 2021.

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 2021 and of the results of the Company's operations for the financial year 1 January – 31 December 2021.

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.

Maarten Nicolaas Walter van der Linden CEO

Board of Directors:

Leif Helth Jensen Chairman

Ulrik Falk

Wei-Chin Lee

Hans-Joachim Maria Diedenhofen

Michael Jürgen Lutz

Achim Plum

Shih-Chih Ho



## 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 2021 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 2021 and of the results of the Company's operations for the financial year 1 January – 31 December 2021 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' International Code of Ethics for Professional Accountants (IESBA Code) and the additional ethical requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Material uncertainty related to going concern

We note that there is a material uncertainty concerning the Company's ability to continue as a going concern. We draw attention to Note 2, which describes the current financing situation of the Company, in which additional investment is needed to be able to fund its planned operations during the coming year. Management expects that the Company will be able to raise capital to continue its operations. Our opinion is not qualified in respect of this matter.

#### 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.



## Independent auditor's report

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.
- 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

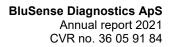
Management is responsible for the Management's review.

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.





# Independent auditor's report

Copenhagen, 28 June 2022 **KPMG** Statsautoriseret Revisionspartnerselskab CVR no. 25 57 81 98

Morten Høgh-Petersen State Authorised Public Accountant mne34283

#### **BluSense Diagnostics ApS**

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# **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

Registered office: Copenhagen Financial year: 1 January – 31 December

#### **Board of Directors**

Leif Helth Jensen, Chairman Ulrik Falk Wei-Chin Lee Hans-Joachim Maria Diedenhofen Michael Jürgen Lutz Achim Plum Shih-Chih Ho

#### **Executive Board**

Maarten Nicolaas Walter van der Linden, CEO Robert Burger

#### **Auditor**

KPMG Statsautoriseret Revisionspartnerselskab Dampfærgevej 28 DK-2100 København Ø CVR no. 25 57 81 98

#### **BluSense Diagnostics ApS**

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## **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's diagnostic tests are based on its proprietary technology called Immuno Magnetic Assay (IMA). IMA is compatible with virtually any biomarker and more than 20 peer-reviewed papers have been published in scientific journals demonstrating the application of IMA for a wide range of applications. The versatility of the technology will allow BluSense to rapidly expand the test portfolio to other diseases such as COVID-19, yellow fever or chagas. All of the new tests will be compatible with BluBox such that customers can easily perform new test as they become available without the need to change hardware.

BluSense currently has four CE marked products on the market: BluBox, ViroTrack Acute Dengue NS1, ViroTrack Comob Dengue and ViroTrack Sero Covid Total Ab. In 2021 in response to the COVID-19 pandemic, BluSense launched ViroTrack Sero Covid Total Ab, a test to quantify the amount of antibodies against COVID-19 of an individual following vaccination or infection with the virus. The test has been launched in Italy, Ireland and Germany so far and the company expects to enter other EU and non-EU markets within 2022.

#### **Development in activities and financial position**

The Company's income statement for 2021 shows a profit of DKK -26,528 thousand as against DKK -23,380 thousand in 2020. Equity in the Company's balance sheet at 31 December 2021 stood at DKK 27,219 thousand as against DKK 5,319 thousand at 31 December 2020.

The company is currently in negotiations with current and potential new investors to close a round of financing within 2022 which will allow to company to launch several new products, scale up manufacturing as well as sales and marketing related activities to reach break-even.

#### Events after the balance sheet date

BluSense CE marked ViroTrack Sero COVID-19 Total Ab HDR, a test with a larger dynamic range to measure the concentration of antibodies against COVID-19 following immunization with a booster shot in May 2022 and will launch it in selected markets from May 2022.

In march 2022 DKK 3.3 million was additionally invested in the company.

No other events have occurred after the balance sheet date that could significantly affect the Company's financial position, including the outbreak of the Corona virus.

# **Income statement**

DKK'000	Note	2021	2020
Gross loss		-12,489	-8,577
Staff costs  Depreciation, amortisation and impairment losses	3	-18,762 -653	-19,581 -622
Loss before financial income and expenses		-31,904	-28,780
Other financial income Other financial expenses		-130	-104
Loss before tax		-32,028	-28,880
Tax on profit/loss for the year	4	5,500	5,500
Loss for the year		-26,528	-23,380
Proposed distribution of loss			
Retained earnings		-26,528	-23,380
		-26,528	-23,380

## **Balance sheet**

DKK'000	Note	31/12 2021	31/12 2020
ASSETS			
Fixed assets			
Property, plant and equipment			
Property, plant and equipment in progress		1,349	1,521
Leasehold improvements		37	0
		1,386	1,521
Investments	5		
Equity investments in group entities		1,902	1,902
Deposits		530	698
		2,432	2,600
Total fixed assets		3,818	4,121
Current assets			
Inventories			
Raw materials and consumables		1,365	0
Receivables			
Trade receivables		477	807
Other receivables		556	386
Corporation tax		5,506	5,504
Prepayments		3,032	0
		9,571	6,697
Cash at bank and in hand		23,510	9,743
Total current assets		34,446	16,440
TOTAL ASSETS		38,264	20,561

### **Balance sheet**

DKK'000	Note	31/12 2021	31/12 2020
EQUITY AND LIABILITIES			
Equity			
Contributed capital		574	374
Share premium		149,125	100,897
Retained earnings		-122,480	-95,952
Total equity		27,219	5,319
Liabilities			
Non-current liabilities			
Convertible and profit-sharing debt instruments		0	9,288
Current liabilities			
Banks, current liabilities		6	13
Convertible and profit-sharing debt instruments		3,684	0
Trade payables		1,702	676
Payables to group entities		952	854
Other payables		3,463	3,718
Deferred income		1,238	693
		11,045	5,954
Total liabilities		11,045	15,242
TOTAL EQUITY AND LIABILITIES		38,264	20,561
Disclosure of material uncertainties regarding going concern	2		

Contractual obligations, contingencies, etc. 6

# Statement of changes in equity

DKK'000	Contributed capital	Share premium	Retained earnings	Total
Equity at 1 January 2021	374	100,897	-95,952	5,319
Cash capital increase	200	48,228	0	48,428
Transferred over the distribution of loss	0	0	-26,528	-26,528
Equity at 31 December 2021	574	149,125	-122,480	27,219

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# Financial statements 1 January – 31 December

#### **Notes**

#### 1 Accounting policies

The annual report of BluSense Diagnostics ApS for 2021 has been prepared in accordance with the provisions applying to reporting class B entities under the Danish Financial Statements Act with opt-in of specific provisions for reporting class C.

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.

#### Foreign currency translation

On initial recognition, transactions denominated in foreign currencies are translated at the exchange rates 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, payables and other monetary items denominated in foreign currencies are translated at the exchange rates 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 latest financial statements is recognised in the income statement as financial income or financial expenses.

#### Income statement

#### **Gross loss**

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

#### 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.

#### Cost of sales

Cost of sales comprises costs incurred to generate revenue for the year. This item also comprises direct costs for goods for resale and changes to inventory of goods for resale.

#### Other external costs

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

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## Financial statements 1 January – 31 December

#### **Notes**

#### 1 Accounting policies (continued)

#### 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 and transactions denominated in foreign currencies.

Dividends from equity investments in group entities measured at cost are recognised as income in the Parent Company's income statement in the financial year when the dividends are declared.

#### Tax on 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.

#### **Balance sheet**

#### Property, plant and equipment

Equipment is measured at cost less accumulated depreciation and impairment losses.

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

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.

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# Financial statements 1 January – 31 December

#### **Notes**

#### 1 Accounting policies (continued)

#### Investments

Equity investments in group entities and participating interests (including associates) are measured at cost. In case of indication of impairment, an impairment test is conducted. 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.

Deposits are recognised at amortised cost.

#### **Inventories**

Inventories are measured at cost in accordance with the FIFO method. Where the net realisable value is lower than cost, inventories are written down to this lower value.

Goods for resale and raw materials and consumables are measured at cost, comprising purchase price plus delivery costs.

Finished goods and work in progress are measured at cost, comprising the cost of raw materials, consumables, direct wages and salaries and indirect production overheads. Indirect production overheads comprise indirect materials and wages and salaries as well as the maintenance of depreciation of production machinery, buildings and equipment as well as factory administration and management. Borrowing costs are not included in cost.

The net realisable value of inventories is calculated as the sales amount less costs of completion and costs necessary to make the sale and is determined taking into account marketability, obsolescence and development in expected selling price.

#### 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.

#### **Prepayments**

Prepayments comprise prepayment of costs incurred relating to subsequent financial years.

#### Cash at bank and in hand

Cash and cash equivalents comprise cash.

#### **Notes**

#### 1 Accounting policies (continued)

#### 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.

Deferred tax is measured using the balance sheet liability method on all temporary differences between the carrying amount and the tax value of assets and liabilities based on the planned use of the asset or settlement of the liability. However, deferred tax is not recognised on temporary differences relating to goodwill non-deductible for tax purposes and on office premises and other items where the temporary differences arise at the date of acquisition without affecting either profit/loss or taxable income.

Deferred tax assets, including the tax value of tax loss carryforwards, are recognised at the expected value of their utilisation within the foreseeable future; 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. Any deferred net assets are measured at net realisable value.

Deferred tax is measured in accordance with 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. Changes in deferred tax as a result of changes in tax rates are recognised in the income statement or equity, respectively.

#### 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.

#### **Deferred income**

Deferred income comprises advance invoicing regarding income in subsequent years.

#### 2 Material uncertainties regarding going concern

The operations of the Company have been funded by the shareholders through new investments and debt converted to share capital during 2021. However, the Company is still in a phase where significant investments are being made, and the Company therefore needs new financing in 2022 to be able to fund its future activities.

The current investors have indicated that they are willing to ensure funding that will last until the end of the year, based on the current business plan.

The Company has historically shown ability to raise capital. It is Management's assessment that the Company, also in the future, will be able to ensure new funding to secure the continued operations. The accounts are on this basis prepared with continued operation in mind.

#### **Notes**

	DKK'000	2021	2020
3	Staff costs		
	Wages and salaries	18,100	18,743
	Pensions	105	148
	Other social security costs	130	238
	Other staff costs	427	452
		18,762	19,581
	Average number of full-time employees	35	40
4	Tax on loss for the year		
	Current tax for the year	-5,500	-5,500
		-5,500	-5,500

#### 5 Investments

Investment in subsidiaries comprise of investments in:

BluSense Biotech Ltd., Taiwan 100%

#### 6 Contractual obligations, contingencies, etc.

The Company has a rental contract with a six-month notice period, corresponding to DKK 1,094 thousand (2020: DKK 1,066 thousand).

The Company has other leasing obligations with an average lease period of 4 months corrresponding to DKK 69 thousand (2020: DKK 66 thousand).