# Nanovi A/S

Diplomvej 378, st., DK-2800 Kongens Lyngby CVR no. 34 88 90 31

# Annual report 2020

Approved at the Company's annual general meeting on 27 May 2021

Chair of the meeting ·····





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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 Nanovi A/S for the financial year 1 January - 31 December 2020.

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 2020 and of the results of the Company's operations for the financial year 1 January - 31 December 2020.

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.

Kgs. Lyngby, 27 May 2021 Executive Board:

Jesper Boysen

Board of Directors:

Simon Hes Vengsted Hoffmann

Chair

Jespe

Ole Kri

Michael Sa

Thomas Lars Andresen



### Independent auditor's report

To the shareholders of Nanovi A/S

#### Opinion

We have audited the financial statements of Nanovi A/S for the financial year 1 January - 31 December 2020, 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 2020 and of the results of the Company's operations for the financial year 1 January - 31 December 2020 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.



#### 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 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.

Copenhagen, 27 May 2021 EY Godkendt Revisionspartnerselskab CVR no. 30 70 02 28

Rasmus Bloch Jespersen State Authorised Public Accountant mne35503



## Management's review

Company details	
Name Address, Postal code, City	Nanovi A/S Diplomvej 378, st., DK-2800 Kongens Lyngby
CVR no. Established Registered office Financial year	34 88 90 31 12 December 2012 Lyngby-Taarbæk 1 January - 31 December
Board of Directors	Simon Hesse Vangsted Hoffmann, Chair Ole Kring Thomas Lars Andresen Jesper Boysen Michael Sandhu
Executive Board	Jesper Boysen
Auditors	EY Godkendt Revisionspartnerselskab Dirch Passers Allé 36, P.O. Box 250, 2000 Frederiksberg, Denmark
Bankers	Jyske Bank



#### Management's review

#### **Business review**

Nanovi is a Danish medical device company focused on the development and commercialization of liquid implantable medical devices that can open new therapeutic opportunities in the fields of imageguided high precision radiation and surgery. It is our mission to empower healthcare providers for the benefit of patients in support also of optimal efficiency in healthcare.

Based on a unique proprietary biomaterial technology and two associated implantable medical device platforms, we are building a portfolio of liquid soft tissue markers for use in human and veterinary patients.

BioXmark® is our first liquid soft tissue marker commercialized for human use. This marker enhances target visibility on medical imaging and offers unique options for high precision diagnostic and interventional radiation therapy across multiple cancer indications. PetXmark<sup>™</sup> was introduced as a novel soft tissue marker for use on the veterinarian radiation therapy market in the US in 2019.

In development, we have an innovative liquid soft tissue marker intended to enhance target visibility and treatment precision for new opportunities in image guided conventional and robotic surgery.

Nanovi has a broad patent portfolio, which has been co-invented with and fully licensed from the Danish Technical University's (DTU) Department of Health Technology.

#### Activities and achievements in 2020

In February, Nanovi met an important milestone with the grant of regulatory approval to CE mark BioXmark<sup>®</sup>. The CE mark opened for commercial introduction of the product across the EU and the subsequent receipt of the first commercial orders from leading cancer clinics. In parallel, results from several both clinical and non-clinical studies have been published by radiation oncology partners over the course of the year, further supporting the clinical value of BioXmark<sup>®</sup>.

Inevitably, the covid-19 crisis had a negative impact on Nanovi's commercial activities and on the start of new post-market clinical studies with BioXmark<sup>®</sup>. Most importantly, access to physical meetings with hospitals and cancer clinics to present BioXmark<sup>®</sup> has been closed all over Europe since March 2020. Further, the leading annual European conference in the field of radiation therapy, ESTRO 2020, was postponed twice and finally held as a purely virtual conference in late November/early December.

Despite the crisis, we have been able to keep our organization intact and even add new competences to ensure a continued strengthening of our operational and managerial set-up in preparation of a US regulatory approval of BioXmark<sup>®</sup>. The company's IP portfolio has also been expanded and substantially strengthened in 2020.

In Q4, we raised a total of DKK 36.5 million in a combined equity and loan funding to support expanded commercialization of BioXmark, advance the process towards regulatory approval of the product in the US and accelerate pipeline development.



#### Management's review

#### Financial review

In 2020, Nanovi's revenue amounted to DKK 111,120 (2019: DKK 394,489). The revenue was generated from sales of BioXmark<sup>®</sup> following market introduction of the product in Europe in Q2. In comparison, revenue in 2019 was solely from sales of PetXmark<sup>™</sup> in the US, where new orders were paused in 2020 due to the covid-19 crises.

Result before net financials was DKK -12,050,702 compared to DKK -11,886,253 in 2019. This was the outcome of a tight cost control during the covid-19 crises, counterbalancing the addition of new competences in the organization and the start of European sales and marketing operations.

Net financial items in 2020 amounted to DKK -754,777 compared to DKK -1,664,275 in 2019. The fall in financial expenses was a consequence of the conversion of two convertible loans to equity in H2 2019. Net results for 2020 was DKK -11,115,202 (2019: DKK -11,708,528).

Nanovi's balance sheet per 31 December 2020 shows a positive equity capital of DKK 18,183,443 (31 December 2019: DKK 12,963,293) and a cash position of DKK 42,838,896 (31 December 2019: DKK 17,860,352).

#### Events after the balance sheet date

In the first months of 2021, Nanovi has increased sales, further expanded the organization and advanced on its prioritized regulatory and development projects. No other material events to report.

#### Outlook

In 2021, sales of BioXmark are expected to increase as a growing number of European cancer clinics start using the product. Sales of PetXmark<sup>™</sup> are also expected to grow.

Operational expenses are also expected to increase to accelerate the company's commercial, development and regulatory activities, including the process for US approval of BioXmark® and advancement of pipeline projects.



## Income statement

Note	DKK	2020	2019
	Revenue Cost of sales	111,120 -44,476	394,489 -220,226
7 7	Gross profit Distribution costs Administrative expenses	66,644 -1,448,821 -2,985,448	174,263 -912,796 -2,351,602
72	Operating profit/loss Research and development costs	-4,367,625 -7,683,077	-3,090,135 -8,796,118
3	Profit/loss before net financials Financial income Financial expenses	-12,050,702 7,167 -761,944	-11,886,253 18,858 -1,683,133
	Profit/loss before tax Tax for the year	-12,805,479 1,690,277	-13,550,528 1,842,000
	Profit/loss for the year	-11,115,202	-11,708,528
	Recommended appropriation of profit/loss		
	Retained earnings/accumulated loss	-11,115,202	-11,708,528
		-11,115,202	-11,708,528



## Balance sheet

Note	ДКК	2020	2019
	ASSETS Fixed assets		
4	Property, plant and equipment		
	Other fixtures and fittings, tools and equipment	601,192	806,907
		601,192	806,907
	Investments		
	Deposits	85,526	85,526
		85,526	85,526
	Total fixed assets	686,718	892,433
	Non-fixed assets Inventories		
	In-process devices and raw material	1,160,662	681,052
	Finished goods	322,861	0
		1,483,523	681,052
	Receivables		
	Trade receivables	317,881	524,879
	Income taxes receivable	1,912,174	1,841,999
	Other receivables Prepayments	527,058 691,279	691,803 29,054
	repayments	i	
		3,448,392	3,087,735
	Cash	42,838,896	17,860,352
	Total non-fixed assets	47,770,811	21,629,139
	TOTAL ASSETS	48,457,529	22,521,572



#### Balance sheet

Note	ДКК	2020	2019
5	EQUITY AND LIABILITIES Equity Share capital Share premium account Retained earnings	3,360,181 0 14,823,262	2,913,685 0 10,049,608
	Total equity	18,183,443	12,963,293
6	Liabilities other than provisions Non-current liabilities other than provisions		
	Lease liabilities Loans Other payables	330,021 26,931,892 711,204	481,577 6,546,887 223,294
		27,973,117	7,251,758
	Current liabilities other than provisions Lease liabilities Other credit institutions Prepayments received from customers Trade payables Other payables	115,829 299,756 0 955,965 929,419	219,031 299,089 22,418 1,171,639 594,344
		2,300,969	2,306,521
		30,274,086	9,558,279
	TOTAL EQUITY AND LIABILITIES	48,457,529	22,521,572

- Accounting policies
  Contractual obligations and contingencies, etc.
  Contingent assets
  Collateral



## Statement of changes in equity

DKK	Share capital	Share premium account	Retained earnings	Total
Equity at 1 January 2019	1,565,141	0	-8,632,311	-7,067,170
Capital increase	1,348,544	30,798,483	0	32,147,027
Expenses, capital increase	0	-408,036	0	-408,036
Transfer through appropriation				
of loss	0	0	-11,708,528	-11,708,528
Transferred from share				
premium account	0	-30,390,447	30,390,447	0
Equity at 1 January 2020	2,913,685	0	10,049,608	12,963,293
Capital increase	446,496	16,073,856	0	16,520,352
Expenses, capital increase	0	-185,000	0	-185,000
Transfer through appropriation				
of loss	0	0	-11,115,202	-11,115,202
Transferred from share				
premium account	0	-15,888,856	15,888,856	0
Equity at 31 December 2020	3,360,181	0	14,823,262	18,183,443



#### Notes to the financial statements

1 Accounting policies

The annual report of Nanovi A/S for 2020 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).

#### 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.

#### Public grants

Public grants to cover expenses are recognised in the income statement when it is deemed likely that all grant criteria have been met. Grants which must be repaid under certain circumstances are recognised only where they are not expected to be repaid.

#### Income statement

#### Revenue

The Company has chosen IAS 11/IAS 18 as interpretation for revenue recognition.

Income from the sale of finished goods is recognised in revenue when the most significant rewards and risks have been transferred to the buyer and provided the income can be measured reliably and payment is expected to be received. The date of the transfer of the most significant rewards and risks is based on standardised terms of delivery based on Incoterms<sup>®</sup> 2010.

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.

#### **Distribution costs**

Distribution costs comprise costs related to the distribution of goods sold in the year and to sales campaigns, etc. carried out in the year, including costs related to sales staff, advertising and exhibitions.

#### Administrative expenses

Administrative expenses include expenses incurred in the year for company management and administration, including expenses relating to administrative staff, general management, office premises and expenses as well as amortisation/depreciation of assets used for administrative purposes.



Notes to the financial statements

1 Accounting policies (continued)

#### Development costs

The item includes research and development costs, including IPR costs, that do not qualify for capitalisation.

#### 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.

#### 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, foreign exchange rate differences, as well as allowances and surcharges under the advance-payment-of-tax scheme, etc.

#### Balance sheet

#### Property, plant and equipment

Items of property, plant and equipment are measured at cost less accumulated depreciation and impairment losses. Cost includes the acquisition price and costs directly related to the acquisition until the time at which the asset is ready for use.



Notes to the financial statements

#### 1 Accounting policies (continued)

#### Leases

The Company has chosen IAS 17 as interpretation for classification and recognition of leases.

On initial recognition, leases for assets that transfer substantially all the risks and rewards incident to the ownership to the Company (finance leases) are measured in the balance sheet at the lower of fair value and the present value of the future lease payments. In calculating the net present value, the interest rate implicit in the lease or the incremental borrowing rate is used as the discount factor. Assets held under finance leases are subsequently accounted for in the same way as the Company's other assets.

The capitalised residual lease liability is recognised in the balance sheet as a liability, and the interest element of the lease payment is recognised in the income statement over the term of the lease.

Leases that do not transfer substantially all the risks and rewards incident to the ownership to the Company are classified as operating leases. Payments relating to operating leases and any other rent agreements are recognised in the income statement over the term of the lease. The Company's aggregate liabilities relating to operating leases and other rent agreements are disclosed under "Contingent liabilities".

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

The cost of raw materials and consumables comprises the cost of acquisition plus delivery costs.

#### Receivables

Receivables are measured at amortised cost.

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.

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.

Cash

Cash comprises cash in banks accounts.

#### 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.



#### Notes to the financial statements

#### 1 Accounting policies (continued)

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.

#### Lease liabilities

Lease liabilities are measured at the net present value of the remaining lease payments including any guaranteed residual value based on the interest rate implicit in the lease.

#### Convertible loans

Convertible loans are broken down into a liability element and an equity element based on the relevant instrument of debt. On initial recognition, the liability is recognised at the fair value of a similar liability without a conversion right. The remaining amount of the convertible loan is recognised as equity. On subsequent recognition, the liability is measured at amortised cost until converted or repaid. The equity element is not re measured after initial recognition.

#### Prepayments received from customers

Prepayments received from costumors concerning income in subsequent financial years are recognized as prepayments under liabilities.



761,944

1,683,133

## Financial statements 1 January - 31 December

Notes to the financial statements

	DKK	2020	2019
2	Depreciation of property, plant and equipment Depreciation of property, plant and equipment	212,328	211,020
		212,328	211,020

Depreciation of property, plant and equipment is recognised in the income statement under the following items:

	Development costs	212,328	211,020
		212,328	211,020
3	Financial expenses		
	Other interest expenses	671,722	1,677,876
	Exchange losses	90,222	5,257

4 Property, plant and equipment

DKK	Other fixtures and fittings, tools and equipment
Cost at 1 January 2020 Additions in the year	1,059,985 6,613
Cost at 31 December 2020	1,066,598
Impairment losses and depreciation at 1 January 2020 Amortisation/depreciation in the year	253,078 212,328
Impairment losses and depreciation at 31 December 2020	465,406
Carrying amount at 31 December 2020	601,192
Property, plant and equipment include finance leases with a carrying amount totalling	601,192



5

## Financial statements 1 January - 31 December

## Notes to the financial statements

DKK				2020	2019
Share capital					
Analysis of the share capital:					
320,000 A- shares of DKK 1. 3,040,181 B- shares of DKK				320,000 040,181	320,000 2,593,685
			3,	360,181	2,913,685
Analysis of changes in the share of	apital over the past 5	years:			
DKK	2020	2019	2018	2017	2016
Opening balance Capital increase	2,913,685 446,496	1,565,141 1,348,544	1,065,141 500,000	731,808 333,333	731,808 0
	3,360,181	2,913,685	1,565,141	1,065,141	731,808

In 2020, the Company completed a cash capital increase through subscription of 446,496 B-shares of nominally DKK 1 at a subscription price of DKK 37 per B-share.

## 6 Non-current liabilities other than provisions

DKK	Total debt at	Repayment,	Long-term	Outstanding debt
	31/12 2020	next year	portion	after 5 years
Lease liabilities	445,850	115,829	330,021	0
Loans	27,231,648	299,756	26,931,892	8,319,417
Other payables	711,204	0	711,204	0
	28,388,702	415,585	27,973,117	8,319,417



	DKK	2020	2019
7	Staff costs and incentive programmes Wages/salaries Other social security costs Other staff costs	7,858,941 69,729 65,632	7,000,670 54,101 65,716
		7,994,302	7,120,487
	Staff costs are recognised as follows in the financial statements: Distribution Administration Development	1,199,244 1,056,456 5,738,602	593,433 1,035,086 5,491,968
		7,994,302	7,120,487
	Average number of full-time employees	11	8

Incentive programmes

According to the Company's articles of associations, the company has established a equity-settled warrant incentive program for board members, management and employees. At 31 December 2020 the number of outstanding warrants was 237,152. Each warrant carries the right to subscribe for one A-share of nominally DKK 1 in the Company by way of cash payment of the exercise price, which ranges from DKK 1-15 per A-share of nominally DKK 1. The warrant program is not recognized in the financial statements.

8 Contractual obligations and contingencies, etc.

Other financial obligations	Other	financial	obligations
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Other rent and lease liabilities:

DKK	2020	2019
Rent and lease liabilities	193,000	187,000

9 Contingent assets

The Company has tax loss carry-forwards totalling DKK 27,952 thousand. The nominal value thereof is 22%, totalling DKK 6,149 thousand which has not been recognized in the balance sheet due to uncertainty as to the application of tax losses.

10 Collateral

The Company has not provided any security or other collateral in assets at 31 December 2020.