



# **Second Quarter & First Half Year Report 2020**



# Q2 and H1'2020 Highlights

- Strategic review completed: clinical development strategy revised, and cost-saving initiatives implemented
- Pivotal Phase 2b PARADIGME trial of Betalutin® progressing in 3<sup>rd</sup>-line follicular lymphoma (3L FL)
  - o COVID-19 continued to have a negative impact on PARADIGME patient recruitment during Q3
  - o 56 patients enrolled as of August 26<sup>th</sup>, 2020
- After positive Type C meeting with the FDA, protocol amendments are being implemented to PARADIGME in the local countries to enlarge the eligible patient population and increase the rate of enrolment into the study
- Dr Lars Nieba appointed as interim Chief Executive Officer and Malene Brondberg as Chief Financial Officer
- Planned restructuring completed
  - o Corporate and personnel reorganisation implemented, headcount reduced by approx. 20%
  - o Cost savings of approx. NOK 35 million in connection with the restructuring on an annual basis
- Betalutin® granted Fast Track designation in the US and Orphan Drug designation in the European Union for Marginal Zone Lymphoma (MZL)

#### Events after Q2'2020

- Result of PARADIGME Interim Analysis: recommendation to focus on single arm investigating the "40/15" dosing regimen
  - o Comprehensive review of data by Independent Review Committee
  - Both dosing regimens were well-tolerated and associated to a manageable safety profile
  - Both arms were actively based on efficacy measures of Complete Response, Partial Response and Stable Diseases
  - o "40/15" arm demonstrated consistency across all sub-groups
  - "100/20" arm to be discontinued dosed patients to be monitored for the remainder of the trial
- Although we see improvements in certain geographies, the negative impact due to COVID-19 continues to impact PARADIGME patient recruitment during Q3. The target patient population is a high-risk group for COVID-19
- Target to announce three-month top-line data from PARADIGME in H2'2021, based on enrolment of 130 patients
- Dr Christine Wilkinson Blanc appointed Chief Medical Officer

Lars Nieba, interim CEO of Nordic Nanovector, said: "The management team together with the board have taken a range of actions during the last several months to increase focus, improve patient recruitment while at the same time conserve cash. These initiatives along with the positive PARADIGME interim analysis and on-going protocol amendments have put Nordic Nanovector in a significantly improved position to deliver the three-month top line data from PARADIGME in H2'2021. "

# **Key figures Nordic Nanovector Group**

Amounts in MNOK	Second	Second Quarter		First Half Year		
(except earnings/loss per share)	2020	2019	2020	2019	2019	
Total revenues	0.0	0.0	0.0	0.0	0.0	
Total operating expenses	113.4	111.0	239.3	200.9	440.4	
Operating profit (loss)	-113.4	-111.0	-239.3	-200.9	-440.4	
Net financial items	-11.0	0.9	21.5	-0.5	7.7	
Total comprehensive income (loss) for the period	-125.6	-110.4	-217.2	-202.0	-433.2	
Basic and diluted earnings (loss) per share	-1.88	-2.05	-3.3	-3.75	-7.66	
Number of employees	44	49	44	49	48	
Net change in bank deposits, cash and equivalents	-138.0	-95.0	-224.6	3.5	30.8	
Cash and equivalents at beginning of period	384.3	538.5	470.8	440.1	440.1	
Cash and equivalents at end of period	246.2	443.5	246.2	443.5	470.8	

# Operational review

#### Introduction

Nordic Nanovector is developing, and aims to commercialise, its wholly owned lead product candidate Betalutin® (177Lu lilotomab satetraxetan) as a new, targeted, single agent and one-time treatment for patients with non-Hodgkin's lymphoma (NHL).

Betalutin® has been designed to offer a new chemotherapy-free treatment modality for NHL patients, many of whom become resistant to rituximab (RTX)-based regimens. Betalutin® is a radioimmunotherapy that targets the CD37 receptor on the surface of B-cell tumours, and represents an alternative target to CD20, upon which the current standard-of-care NHL therapies (such as RTX) are focused.

It has been reported that 40-60% of NHL patients treated with an RTX-containing regimen are either refractory to therapy or develop resistance within five years<sup>1</sup> and are in urgent need of new treatment options.

The company is advancing Betalutin® in PARADIGME, a pivotal, global, randomised Phase 2b trial in 3<sup>rd</sup>-line relapsed/refractory follicular lymphoma (3L R/R FL) as a first-to-market indication based on compelling clinical data from earlier studies. The company is also investigating the potential of Betalutin® in earlier lines of treatment for FL and in other significant NHL types.

Betalutin® has been granted Fast Track designation in the US for the treatment of FL after at least two prior systemic therapies and Orphan Drug designation for FL in the US and Europe. Betalutin® has also been granted Fast Track designation in the US and Orphan Drug designation for marginal zone lymphoma (MZL) in Europe.

Beyond Betalutin®, the company leverages its R&D expertise and proprietary technologies to evaluate opportunities with other CD37-targeting immunotherapies across NHL and other haematological cancer indications.

<sup>1</sup>Abdollahi, S., et al., The Impact of Rituximab Resistance on Overall Survival Rate in Low-Grade Follicular Lymphoma. Blood, 2008. 112(11): p. 3783-3783.

#### **Operational review**

So far, 2020 has been a challenging year for Nordic Nanovector, particularly as the measures taken by many governments in response to the COVID-19 pandemic have negatively impacted patient enrolment. Execution of virtually all non COVID-19 related clinical studies have been hit hard globally due to COVID-19. The PARADIGME trial has been impacted too, resulting in a significant reduction in enrolment rate during Q2'2020. The company reports that 56 patients have been enrolled as of August 26<sup>th</sup>, 2020.

Against this backdrop, Nordic Nanovector undertook a thorough review of its strategy and clinical operations. This process, now complete, resulted in a range of actions focused on the execution and recruitment of PARADIGME as well as to reduce the overall cost structure of the company.

#### Strategic review - focus on PARADIGME and initiatives to accelerate patient enrolment

The assessment of the clinical strategy by the management team, working with the board's Clinical Strategy Committee and the Scientific Advisory Board, resulted in several important decisions, the most important of which was to focus resources on completing the PARADIGME trial in patients with 3L R/R FL in a timely manner.

In this process, the PARADIGME trial protocol was reviewed and several modifications that are projected to improve the enrolment rate and improve the chances of a successful outcome were identified. As a result, the company engaged in discussions with the US Food and Drug Administration (FDA) to gain feedback on e.g. protocol amendments to broaden the inclusion criteria and thereby expanding the pool of eligible patients. The company received positive feedback from the FDA regarding these proposals.

One of the measures to improve the recruitment rate is to allow for FL patients who have undergone stem cell transplant (SCT) to be included in the trial. In some countries (e.g. UK, Italy, Turkey, Israel and Spain), SCT is frequently

used for treating R/R FL and patients, previously excluded from participation in PARADIGME, who have had a SCT make up the majority of 3L FL patients in these countries. Once these and other ways to expand the inclusion criteria have been implemented, it is projected that the pool of eligible patients will expand significantly.

Following positive feedback from FDA and the outcome of a planned Interim Analysis on PARADIGME, the company has made the necessary protocol amendments and is seeking approvals from the regulators in each of the 24 countries in where PARADIGME is active. It is anticipated that it will take two to three months to gain approval for these protocol amendments in all countries. In the meantime, patient enrolment continues under the original protocol.

Furthermore, and as previously reported, the company has taken actions to improve the execution of PARADIGME, including enhancing the working relationship with the Clinical Research Organisation (CRO) managing the implementation of the trial, and improving patient referral networks and interactions with study investigators and Key Opinion Leaders (KOLs). These actions are expected to further improve recruitment once the amended protocol is approved by the various countries.

### **PARADIGME Interim Analysis**

In August, Nordic Nanovector announced that, following a planned Interim Analysis of PARADIGME, the Independent Review Committee (IRC) recommended the company to focus the study on one of the two dosage arms being investigated: the dosing regimen of 15 MBq/kg Betalutin® following a pre-dose of 40 mg lilotomab – the "40/15" arm.

The arm evaluating the regimen of 20 MBq/kg Betalutin® following a pre-dose of 100 mg/m2 lilotomab ("100/20") will be discontinued. Patients already dosed on the higher dose will continue to be monitored until completion. The resulting data will be added to the final data set for regulatory submission.

The Interim Analysis confirmed activity across both arms in this very difficult to treat patient population. Betalutin®, as a single administration, was found to be active based on key efficacy measures (Complete Response, Partial Response and Stable Disease). Betalutin® also demonstrated a well-tolerated and manageable safety profile in both arms, again confirming findings from earlier clinical studies.

Based on a comprehensive assessment, the IRC determined that the interim data set supported the selection of only the 40/15 dosage arm for the remainder of the PARADIGME trial. The 40/15 dose demonstrated consistency across all patient sub-groups and was selected to advance to completion.

The recommendation from the IRC to advance the 40/15 arm of PARADIGME provides Nordic Nanovector with a clear path for the late-stage clinical development of Betalutin® in patients with 3L FL, especially those who are elderly and fragile and have no or limited treatment options.

The decision to focus PARADIGME on a single arm, when combined with the implementation of the protocol amendments and the other initiatives to broaden the patient inclusion criteria, are expected to significantly improve the rate of enrolment into PARADIGME over the remainder of the trial's duration, despite the evolving COVID-19 situation

Nordic Nanovector is targeting three-month top-line data from PARADIGME in H2'2021, paving the way for a planned regulatory filing with Betalutin® in 2022.

#### **Exploring the opportunity with Marginal Zone Lymphoma**

An additional opportunity that the company is evaluating is the possible use of Betalutin® as a single-agent treatment for advanced marginal zone lymphoma (MZL), a rare type of indolent NHL. Betalutin® demonstrated a very promising clinical effect in nine MZL patients in the Phase 1/2a LYMRIT 37-01 trial. This indication was also granted Fast-track designation in the U.S. and Orphan Drug designation in the European Union during H1'2020. This decision reflects the clear need for new therapeutic options for MZL patients who no longer respond to anti-CD20 immunotherapy.

The evaluation is ongoing, however, further development of Betalutin® in MZL will be dependent on available funds to support the clinical development plan.

#### Archer-1 and LYMRIT 37-05 to be paused

Given the clear strategic focus on PARADIGME, the company has taken the decision to pause enrolment in the Archer-1 and LYMRIT 37-05 trials after the current cohorts have been completed. Once these studies have been paused and the data analysed, the company will re-assess the plans to progress Betalutin® in both 2L FL and diffuse large B-cell lymphoma (DLBCL), respectively.

#### Cost-saving initiatives and corporate restructuring to extend the cash runway

Nordic Nanovector has completed significant restructuring during H1'2020 designed to extend cash resources into 2021, improve organisational efficiency and focus the business on delivering results from PARADIGME.

Investment and human resources have been prioritised on core clinical operations and CMC (Chemistry, Manufacturing and Controls), with spending on CMC better aligned with clinical progress and investment into commercialisation of Betalutin® delayed into 2021.

Headcount was reduced by approximately 20%, with a number of roles being consolidated. Talented staff has been reassigned to new functional roles.

Overall, the restructuring is expected to result in approximately NOK 35 million in savings on an annual basis. There have been up-front costs associated with the implementation of these measures during Q2, which means the impact of cost savings will materialise during the second half of the year.

#### **Management Changes**

As previously communicated, the following changes have been made in the management team; Dr Lars Nieba has been appointed interim CEO, Malene Brondberg has been appointed as CFO and most recently Christine Wilkinson Blanc has been appointed as CMO.

## Financial review

The interim consolidated financial statements for Nordic Nanovector Group<sup>1</sup> as of June 30<sup>th</sup>, 2020 have been prepared in accordance with the International Accounting Standard (IFRS) 34 interim financial reporting.

#### Interim consolidated statement of profit or loss

(Figures in brackets = same period 2019 unless stated otherwise)

Revenues in the second quarter of 2020 amounted to NOK 0.0 million (NOK 0.0 million). Revenues for the first half of 2020 amounted to NOK 0.0 million (NOK 0.0 million).

Total operating expenses for the quarter came to NOK 113.4 million (NOK 111.0 million). Payroll and related expenses were NOK 20.2 million (NOK 19.7 million). Other expenses amounted to NOK 89.5 million during the quarter (NOK 87.8 million). Total operating expenses for the first half of 2020 increased to NOK 239.3 million (NOK 200.9 million). The increase being driven by clinical and manufacturing development activities to prepare for Biologics License Application (BLA) readiness for Betalutin®.

Research and development (preclinical, clinical, medical affairs, regulatory and CMC activities) expenses accounted for 82 % of total operating expenses in the first half of 2020 (77 %).

<sup>&</sup>lt;sup>1</sup> "the group" embraces Nordic Nanovector ASA ("the parent company" or "the company") and its wholly owned subsidiaries

Operating loss for the quarter was NOK 113.4 million (loss of NOK 111.0 million). Operating loss for the first half of 2020 was NOK 239.3 million (NOK 200.9 million).

Net financial items for the second quarter came to negative NOK 11.0 million (NOK 0.9 million), mainly due to currency fluctuations on bank deposits. Net financial items for the first half amounted to NOK 21.5 million (negative 0.5 million), mainly driven by increased value of cash deposited in foreign currency.

Nordic Nanovector's comprehensive loss for the quarter amounted to NOK 125.6 million (loss of NOK 110.4 million), due to the reasons stated above. Comprehensive loss for the first half was NOK 217.2 (NOK 202.0 million).

### **Financial position**

Total assets at June 30<sup>th</sup>, 2020, amounted to NOK 285.2 million, down from NOK 515.7 million at year-end 2019.

Total shareholders' equity at June 30<sup>th</sup>, 2020, was NOK 161.8 million (NOK 388.0 million at year-end 2019), corresponding to an equity ratio of 56.7% (75.2 % at year-end 2019).

Total liabilities at the end of the second quarter were NOK 123.4 million, down from NOK 127.7 million from year-end 2019, driven by decrease in account payables.

#### Cash flow

Net cash flow from operating activities in the second quarter and first half of 2020 was negative NOK 123.2 million (negative NOK 102.2 million), and negative NOK 239.2 million (negative 210.5 million), respectively, mainly reflecting the impact of higher clinical and manufacturing development activities and fluctuations in the working capital.

Net cash flow from investing activities in the second quarter and first half was NOK 0.0 million (NOK 0.2 million) and NOK 0.0 (NOK 0.1 million), respectively.

Net cash flow from financing activities for the second quarter of 2020 was negative NOK 3.5 million (NOK 7.0 million). Net cash flow from financing activities for the first half 2020 was negative NOK 7.0 million (NOK 216.8 million), driven by change in lease liabilities.

Exchange rate fluctuations in the second quarter and first half 2020 was NOK negative 11.3 (NOK 0.1) and 21.7 million (negative NOK 3.1 million), respectively.

Cash and cash equivalents amounted to NOK 246.2 million at the end of June 2020, compared to NOK 470.8 million at the end of December 2019.

#### **Risks and uncertainties**

The company has seen a slowdown in patient enrolment into the PARADIGME study during 2020. This is due to measures taken by many governments to contain the COVID-19 pandemic. The slower than anticipated rate of recruitment into PARADIGME led the company to take a range of measures to extend its cash runway, including reducing its headcount by approximately 20%.

The uncertainty around the duration, severity and geographic scope of the COVID-19 outbreak could cause further delays in patient enrolment into the company's clinical studies due to re-prioritisation of hospital activities, healthcare staff or patients being affected by the virus, or supply issues due to restriction of movement.

If the COVID-19 situation continues it may impact the enrolment, important regulatory meetings, the monitoring of patients and their motivation to attend visits at the company's clinical trial centres.

The COVID-19 outbreak has also impacted financial markets and caused investors to be much more selective in where they allocate funds. This could limit the company's ability to raise funds in the future resulting in the company needing to streamline its activities based on its financial resources.

## Outlook

The company is targeting the readout of three-month top line data from PARADIGME in H2'2021. This timeline assumes the efficient implementation of the protocol amendments and other initiatives to increase the rate of enrolment and the impact of the COVID pan-epidemic on patient recruitment to slowly subside over the next few months.

The steps the company has taken to conserve cash, including reducing headcount and pausing certain clinical trials, will extend the cash runway into 2021. The company expects to see the impact of these cost-saving initiatives emerge over the remainder of 2020.

Following a broad range of actions carried out by the management team during the course of 2020, the company now believes it is in a much-improved position to deliver the pivotal results from PARADIGME in a timely manner. This would be a key milestone for Nordic Nanovector as the company seeks to bring this exciting new targeted NHL treatment to patients and maximise the value of Betalutin®.

#### **Responsibility statement**

The Board of Directors and the CEO of Nordic Nanovector ASA have today considered and approved the condensed financial statements as at June 30<sup>th</sup>, 2020 and for the six-month period ended June 30<sup>th</sup>, 2020. The half year report has been prepared in accordance with IAS 34 Interim Financial Reporting as endorsed by the EU and additional Norwegian regulations.

We confirm, to the best of our knowledge, that:

- the condensed consolidated financial statements for the six months ending June 30<sup>th</sup>, 2020 have been prepared in accordance with applicable financial reporting standards
- the information provided in the financial statements gives a true and fair view of the group's assets, liabilities, financial position and result for the period
- the financial review includes a fair review of significant events during the first six months of the year and their impact on the financial statements, any major related party transactions, and a description of the principal risk and uncertainties for the remaining six months of the year

Oslo, August 26 <sup>th</sup> , 2020	
The Board of Directors Nordic Nanovector ASA	
Jan H. Egberts Chairperson of the Board	Jean-Pierre Bizzari Board Member
Rainer Boehm Board Member	Joanna Horobin Board Member
Per Samuelsson Board Member	Karin Meyer Board Member
Hilde Hermansen Steineger Board Member	Lars Nieba Interim CEO

# Interim condensed consolidated statement of profit or loss and other comprehensive income Nordic Nanovector Group

A 12 NOV 4 000		Second Quarter		First Ha	ılf Year	Full Year
Amounts in NOK 1 000	Note	2020	2019	2020	2019	2019
Revenues		0	0	0	0	0
Total revenues		0	0	0		0
Payroll and related expenses	4, 5	20 201	19 680	39 982	42 096	96 409
Depreciation	,	3 723	3 544	7 437	4 627	12 659
Other operating expenses	4, 6	89 452	87 755	191 834	154 209	331 284
Total operating expenses	,	113 376	110 979	239 253	200 932	440 352
Operating profit (loss)		-113 376	-110 979	-239 253	-200 932	-440 352
Net finance income	9	-10 960	868	21 469	-525	7 693
Loss before income tax		-124 336	-110 111	-217 784	-201 457	-432 659
Income tax		-291	-234	-585	-397	-938
Loss for the period		-124 627	-110 345	-218 369	-201 854	-433 <b>597</b>
Loss for the period		-124 027	-110 343	-218 309	-201 034	-433 337
Other comprehensive income (loss), net of income tax to be reclassified to profit and loss in subsequent periods Translation effects Other comprehensive income (loss), net of income tax not to be reclassified to profit and loss in		-959	-58	1 131	-185	326
subsequent periods Re-measurement gains (losses) on defined benefit plans		0	0	0	0	101
Total comprehensive income (loss) for the period		-125 586	-110 403	-217 238	-202 039	-433 170
Loss for the period attributable to owners of the company		-124 627	-110 345	-218 369	-201 854	-433 597
Total comprehensive income (loss) for the period attributable to owners of the company		-125 586	-110 403	-217 238	-202 039	-433 170
Earnings (loss) per share Basic and diluted earnings (loss) per share in NOK	8	-1.88	-2.05	-3.30	-3.75	-7.66

The interim financial information has not been subject to audit.

# Interim condensed consolidated statement of financial position Nordic Nanovector Group

Amounts in NOK 1 000	Note	30.06 2020	31.12 2019
ASSETS			
Non-current assets			
Property, plant and equipment		2 104	2 648
Right-of-use-assets		11 019	17 747
Total non-current assets		13 123	20 395
Current assets			
Receivables			
Other current receivables	4	25 793	24 499
Total receivables		25 793	24 499
Cash and cash equivalents		246 243	470 824
Total current assets		272 036	495 323
TOTAL ASSETS		285 159	515 718
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	7	13 232	13 229
Share premium	7	135 336	335 336
Other paid in capital	5, 6	60 035	69 025
Retained earnings		-46 819	-29 582
Total shareholders' equity		161 784	388 008
LIABILITIES			
Non-current liabilities			
Lease liability		3 479	4 571
Net employee defined benefit liabilities		3 769	3 348
Total non-current liabilities		7 248	7 919
Current liabilities			
Accounts payable		27 823	45 956
Tax payable		1 191	949
Other current liabilities		87 113	72 886
Total current liabilities		116 127	119 791
Total liabilities		123 375	127 710
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		285 159	515 718

The interim financial information has not been subject to audit.

# Interim condensed consolidated statement of changes in equity Nordic Nanovector Group

For the period ended 30.06.2020								
Amounts in NOK 1 000	Note	Share capital	Share premium	Other paid in capital	Accumulated losses	Trans- lation effects	Remeasure- ment gains (losses)	Total equity
Balance at 31.12 2018		9 886	593 399	56 320	-295 209	3	-1 206	363 193
Loss for the period					-433 597			-433 597
Other comprehensive income (loss) for the year, net of income tax						326	101	427
Total comprehensive income for the period		0	0	0	-433 597	326	101	-433 170
Recognition of share-based payments	5, 6			12 705				12 705
Issue of ordinary shares	7	3 207	464 865					468 072
Issue of ordinary shares under share options and RSUs	5, 6, 7	136	15 450					15 586
Share issue costs			-38 378					-38 378
Reclassification of accumulated losses			-700 000		700 000			0
Balance at 31.12.2019		13 229	335 336	69 025	-28 806	329	-1 105	388 008
Loss for the period					-218 369			-218 369
Other comprehensive income (loss) for the year, net of income tax						1 131	0	1 131
Total comprehensive income for the period		0	0	0	-218 369	1 131	0	-217 238
Recognition of share-based payments	5, 6			-8 990				-8 990
Issue of ordinary shares under share options and RSUs	5, 6, 7	4						4
Reclassification of accumulated losses			-200 000		200 000			0
Balance at 30.06.2020		13 232	135 336	60 035	-47 175	1 461	-1 105	161 784

Amounts in NOK 1 000	Note	Share capital	Share premium	Other paid in capital	Accumulated losses	Trans- lation effects	Remeasure- ment gains (losses)	Total equity
Balance at 31.12 2018		9 886	593 399	56 320	-295 209	3	-1 206	363 193
Loss for the period					-201 854			-201 854
Other comprehensive income (loss) for the year, net of income tax						-185		-185
Total comprehensive income for the period		0	0	0	-201 854	-185	0	-202 039
Recognition of share-based payments Issue of ordinary shares	5, 6 7	1 002	224 544	5 999				5 999 225 546
Issue of ordinary shares under share options and RSUs	5, 6, 7	135	15 369					15 503
Share issue costs			-20 762					-20 762
Balance at 30.06.2019		11 023	812 550	62 319	-497 064	-181	-1 206	387 440

The interim financial information has not been subject to audit.

# Interim condensed consolidated statement of cash flow Nordic Nanovector Group

Amounts in NOK 1 000	Note	Second	Second Quarter		lf Year	Full Year
		2020	2019	2020	2019	2019
Cash flow from operating activities						
Loss for the period before income tax		-124 336	-110 111	-217 784	-201 457	-432 659
Adjustments for:						
Interests paid		138	246	313	310	771
Interest received		-42	-272	-203	-463	-5 611
Share option and PSU expenses employees	5	-1 295	2 876	-9 414	5 135	11 271
Restricted share units (RSUs) expenses board	6	143	468	424	865	1 434
Taxes paid		0	-3	-433	-320	-805
Depreciation		3 723	3 544	7 437	4 627	12 659
Currency (gains) losses not related to operating activities		11 269	-76	-21 656	2 984	-1 907
Changes in working capital and non-cash adjustments		-12 802	1 096	2 076	-22 168	4 226
Net cash flow from operating activities		-123 202	-102 232	-239 240	-210 487	-410 621
Cash flow from investing activities						
Investments in property, plant and equipment and intangible assets		-54	-115	-165	-353	-1 066
Interests received		42	272	203	463	5 611
Net cash flow from investing activities		-12	157	38	110	4 545
Cash flows from financing activities						
Net proceeds from equity issue	7	4	9 992	4	220 288	445 279
Change in lease liabilities	,	-3 400	-2 718	-6 726	-3 154	-9 584
Interests paid		-138	-246	-313	-310	-771
Net cash flow from financing activities		-3 534	7 028	-7 035	216 824	434 924
a services			, 320	, 300		.01027
Effects of exchange rate changes on cash and cash equivalents		-11 269	76	21 656	-2 984	1 907
Net change in bank deposits, cash and equivalents		-138 017	-94 971	-224 581	3 463	30 755
Cash and equivalents at beginning of period		384 260	538 503	470 824	440 069	440 069
Cash and equivalents at end of period		246 243	443 532	246 243	443 532	470 824

The interim financial information has not been subject to audit.

# Notes to the condensed interim financial statements for the Second Quarter & First Half year report 2020

## Note 1. General information

Nordic Nanovector (the group) consists of Nordic Nanovector ASA and its subsidiaries. Nordic Nanovector ASA ("the company") is a limited company incorporated and based in Oslo, Norway. The address of the registered office is *Kjelsåsveien 168 B, 0884 Oslo*.

The figures in this Second Quarter & First Half 2020 report are non-audited figures.

These financial statements were approved for issue by the board of directors on August 26<sup>th</sup>, 2020.

#### Note 2. Basis for preparation and significant accounting policies

The principal accounting policies applied in the preparation of these financial statements can be found in the group's Annual Report 2019. These policies have been consistently applied in all periods presented. Amounts are in Norwegian kroner (NOK) unless stated otherwise. The functional currency of the group is NOK.

#### Basis of preparation of the annual accounts

The Nordic Nanovector Group's interim consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS), which have been adopted by the EU and are mandatory for financial years beginning on or after January 1<sup>st</sup>, 2020, and Norwegian disclose requirements listed in the Norwegian Accounting Act. The interim consolidated financial statements have been prepared on the historical cost basis, with the exception of receivables and other financial liabilities which are recognised at amortised cost.

## Note 3. Critical accounting judgments and key sources of estimation uncertainty

#### Critical accounting estimates and judgments

Management makes estimates and assumptions that affect the reported amounts of assets and liabilities within the next financial year. Estimates and judgments are evaluated on an on-going basis and are based on historical experience and other factors, including expectations of future events that are considered to be relevant.

In preparing these condensed interim financial statements, the significant judgements made by management in applying the group's accounting policies and the key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31<sup>st</sup>, 2019.

### Note 4. Government grants

Government grants have been recognised in profit or loss as a reduction of the related expenses with the following amounts:

Amounts in NOK 1 000	Second	Quarter	First Half Year		
Amounts in NOK 1 000	2020	2019	2020	2019	
Payroll and related expenses	98	564	305	1 018	
Other operating expenses	1 840	2 850	3 570	5 025	

Grants receivable presented as other current receivables in the statement of financial position:

Amounts in NOK 1 000	30.06.2020	31.12.2019
Grants receivable	12 088	10 213

- 1) R&D projects have been approved for SkatteFUNN grants for the period 2017 through 2020. For the financial period ended June 30<sup>th</sup>, 2020, the company has recognised NOK 2.4 million compared to NOK 4.4 million for the same period in 2019. The amount was recognised partly as a reduction of payroll and related expenses and partly as a reduction of other operating expenses. The reduction reflects the changes introduced in 2020 by the Norwegian government for the SkatteFunn scheme.
- 2) The company has finalised the discovery phase of its Alpha37 R&D collaboration with Orano Med. Alpha37 leverages Nordic Nanovector's chimeric anti-CD37 antibody, NNV003, chelated with the alpha particle generating radionuclide <sup>212</sup>Pb; preparations for an IND application for potential treatment of NHL and chronic lymphocytic leukaemia (CLL) are now advancing. In 2019, Nordic Nanovector was granted EUR 0.6 million from Eurostars in funding for this project. For the financial period ended June 30<sup>th</sup>, 2020, the company recognised NOK 1.5 million partly as a reduction of payroll and related expenses and other operating expenses, compared to NOK 0.0 million for the same period in 2019.
- 3) The company received a new grant in 2016 of up to NOK 15 million from the Research Council of Norway's User-driven Research-based Innovation programme (in Norwegian; Brukerstyrt innovasjonsarena, BIA). The project period was from 2016 to August 2019. The purpose of the grant was to support research and development of novel targeted therapeutics for leukaemia and NHL. The grant was distributed to the company over the course of three years and eight months. For the financial period ended June 30th, 2019, the company recognised NOK 1.1 million classified partly as a reduction of payroll and related expenses, and partly as a reduction of other operating expenses.
- 4) In 2016, The Research Council awarded a grant supporting a PhD for the period 2016 through 2019 of NOK 2.2 million. For the financial period ended June 30<sup>th</sup>, 2019, the company recognised NOK 0.3 million as a reduction of payroll and related expenses, and partly as a reduction of other operating expenses.
- 5) In 2019, The Research Council awarded miscellaneous de minimis aid for first half of 2019 up to NOK 0.2 million.

## Note 5. Employee share incentive programmes

#### **Performance Share Units (PSUs)**

The board of directors of Nordic Nanovector ASA decided on March 24<sup>th</sup>, 2020 to grant 561 500 PSUs to current and newly hired employees.

#### **Overview of outstanding PSUs**

	Year to date 2020
	Number of PSUs
Balance at 01.01.2020	775 250
Granted during the period	561 500
Exercised during the period	0
Forfeited	-536 000
Balance at 30.06.2020	800 750

Hereof vested PSUs	0
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For further information about the PSU programme see note 6.3.1 to the company's annual accounts included in the company's annual report for 2019.

#### **Share options**

The share option programme was discontinued in 2017 and no options have been granted in the 2018, 2019 or 2020, but options granted under the programme will remain valid with its existing terms.

### Overview of outstanding options

	Year to date 2020				
	Number of options	Weighted average exercise price, NOK			
Balance at 01.01.2020	1 805 126	47.35			
Granted during the year	0	0			
Exercised during the year	0	0			
Forfeited	-438 787	68.14			
Balance at 30.06.2020	1 366 339	40.68			
Hereof vested options	1 334 231	39.48			

For further information about the share option programme see note 6.3.3 to the company's annual accounts included in the company's annual report for 2019.

### Note 6. Restricted Stock Units (RSUs)

#### Allocation of restricted stock units (RSUs) to the board of directors

At the AGM in 2020, the shareholders approved the issuance of restricted stock units ("RSUs") to board members who elect to receive all or parts of their remuneration, for the period from the annual general meeting in 2020 to the annual general meeting in 2020, in the form of RSUs.

The RSUs are non-transferable and each RSU gives the right and obligation to acquire one share in the company at a price of NOK 0.20 per share (corresponding to the nominal value of the shares) subject to satisfaction of the applicable vesting conditions stated in the RSU agreements.

The board members may elect to either (i) receive 100% of the compensation in RSUs, (ii) receive 1/3 of the compensation in cash and 2/3 in RSUs, or (iii) receive 2/3 of the compensation in cash and 1/3 in RSUs. The election made by each board member has been set out in the table below. The number of RSUs to be granted to the members of the board of directors is calculated as the NOK amount of the RSU opted portion of total compensation to the board member, divided by the market price for the Nordic Nanovector share. The market price is calculated as volume weighted average share price 10 trading days prior to the date of the AGM, i.e. NOK 19.83.

Pursuant to the RSU program, the board members have made the following election and hold the following number of RSUs and shares following such election:

Name	Remuneration for the	Allocation between	Number of RSUs for	Total number of	
Name	period 2020-2021	cash and RSUs	the period 2020-2021	RSUs out standing	
Jan H. Egberts	NOK 520 000 <sup>1</sup>	1/3 RSUs	8 740	16 607	
Per Samuelsson	NOK 360 000 <sup>2</sup>	100% Cash <sup>3</sup>	0	0	
Hilde H. Steineger	NOK 340 000 <sup>4</sup>	3/3 RSUs	17 146	29 106	
Karin Meyer	NOK 320 000 <sup>5</sup>	1/3 RSUs	5 379	5 379	
Joanna Horobin	NOK 340 000 <sup>6</sup>	2/3 RSUs	11 430	11 430	
Jean-Pierre Bizzari	NOK 340 000 <sup>7</sup>	2/3 RSUs	11 430	11 430	
Rainer Boehm	NOK 320 000 <sup>8</sup>	1/3 RSUs	5 379	11 281	

- 1. NOK 500 000 as chairman of the board and NOK 20 000 as a member of the audit committee.
  2. NOK 300 000 as board member, NOK 40 000 as chair of the compensation committee and NOK 20 000 as a member of the audit committee.
- 3. Per Samuelsson is not allowed to hold equity in the company due to his affiliation with HealthCap and will only receive cash. 4. NOK 300 000 as board member, NOK 40 000 as chair of the audit committee.
- 5. NOK 300 000 as board member and NOK 20 000 as member of the compensation committee.
- 6. NOK 300 000 as board member, NOK 20 000 as member of the clinical committee and NOK 20 000 as member of the compensation committee.

  7. NOK 300 000 as board member and NOK 40 000 as chair of the clinical committee.
- 8. NOK 300 000 as board member and NOK 20 000 as member of the clinical committee

A total of 59 504 RSUs have thus been allocated following the AGM. The RSUs will vest on 10 June 2021.

## **Overview of outstanding RSUs**

	Year to date 2020
	Number of RSUs
Balance at 01.01.2020	44 308
Granted during the year	59 504
Exercised during the year	18 579
Forfeited	0
Balance at 30.06.2020	85 233
Hereof vested RSUs	25 729

For further information about the RSU programme see note 6.3.2 to the company's annual accounts included in the company's annual report for 2019.

# Note 7. Share capital and shareholder information

The share capital as at June 30<sup>th</sup>, 2020 is NOK 13 232 388 (December 31<sup>st</sup>, 2019: NOK 13 228 673), being 66 161 942 ordinary shares at a nominal value of NOK 0.20. All shares carry equal voting rights.

The change in the number of shares during the period was as follows:		30.06.2020	31.12.2019
Ordinary shares at beginning of the period		66 143 363	49 430 945
Issue of ordinary shares		0	16 036 037
Issue of ordinary shares under share options	5	0	630 420
Issue of ordinary shares under RSUs	6	18 579	45 961
Ordinary shares at end of the period		66 161 942	66 143 363

# Nordic Nanovector ASA had 10 762 shareholders as at June 30<sup>th</sup>, 2020

	Shareholders	Number of shares	Percentage of total shares
1	HealthCap VI L.P.	6 165 378	9.32 %
2	Folketrygdfondet	3 663 715	5.54 %
3	OM Holding AS	2 565 352	3,88 %
4	Nordnet Livsforsikring AS	1 319 432	1.99 %
5	Linux Solutions Norge AS	845 071	1.28 %
6	Ro Invest AS	800 000	1.21 %
7	VPF Nordea Kapital	778 910	1.18 %
8	Sciencons AS (Roy Hartvig Larsen)	733 000	1.11 %
9	Must Invest AS	700 000	1.06 %
10	Radiumhospitalets Forskningsstiftelse	684 972	1.04 %
11	VPF Nordea Avkastning	656 251	0.99 %
12	Birk Venture AS	650 000	0.98 %
13	Inven2 AS	541 247	0.82 %
14	Equinor Pensjon	480 874	0.73 %
15	Roy Hartvig Larsen	454 801	0.69 %
16	USB Switzerland AG	438 258	0.66 %
17	Verdipapirfondet KLP Aksjenorge	419 533	0.63 %
18	Lucellum AS	405 000	0.61 %
19	Interactive Brokers LLC	401 421	0.61 %
20	Nordnet Bank AB	399 592	0.60 %
	Total shares for top 20 shareholders	23 102 807	34.9 %
	Total shares for other 10 742 shareholders	43 059 135	65.1 %
	Total shares (10 762 shareholders)	66 161 942	100.00 %

The shares of Nordic Nanovector ASA have been traded on the Oslo Stock Exchange since March 23<sup>rd</sup>, 2015.

# Note 8. Earnings per share

The calculation of basic and diluted earnings per share attributable to the ordinary shareholders of the parent is based on the following data:

Amounts in NOK	First Half 2020	First Half2019
Loss for the period	-218 369 000	-201 854 000
Average number of outstanding shares during the year	66 143 466	53 813 373
Earnings (loss) per share - basic and diluted	-3.30	-3.75

Share options and PSUs issued have a potential dilutive effect on earnings per share. No dilutive effect has been recognised as potential ordinary shares only shall be treated as dilutive if their conversion to ordinary shares would decrease earnings per share or increase loss per share from continuing operations. As the company is currently loss-making an increase in the average number of shares would have anti-dilutive effects.

# Note 9. Net finance income (expense)

Net finance income (expense) is mainly driven by interests on bank deposits and the currency gain (loss) on cash and cash equivalents in foreign currency.

Amounts in NOK 1 000	Second Quarter		First Half Year		Full Year
Amounts in NOR 1 000	2020	2019	2020	2019	2019
Finance income	243	1 353	1 249	2 797	5 635
Finance expenses	244	306	540	454	1 018
Net currency gains (losses) on cash and cash equivalents	-11 269	76	21 656	-2 984	1 907
Net other currency gains (losses) related to operating items	310	-255	-896	116	1 169
Net finance income	-10 960	868	21 469	-525	7 693

Finance expenses year to date June 2020 include interest expenses on lease liabilities of NOK 0.3 million (NOK 0.3 million), as an effect of IFRS 16.

## **Additional information**

#### Glossary of terms

1L, 2L, 3L: First, second and third line of treatment

ADC: Antibody-Drug-Conjugate

ARC: Antibody-Radionuclide-Conjugate

ARCHER-1: Name of Nordic Nanovector's combination study; Betalutin® and rituximab

**ASH:** American Society of Hematology

**B-cell:** A type of lymphocyte (white blood cell) in the humoral immunity of the body's adaptive immune system. Can be distinguished from other lymphocytes by the presence of a protein on the B-cell's outer surface known as a B cell receptor (BCR). This specialized receptor protein allows a B-cell to bind to a specific antigen.

**CD20:** B-lymphocyte antigen CD20 is an activated-glycosylated phosphoprotein expressed in the surface of all B-cells beginning at the pro-B phase and progressively increasing in concentration until maturity

**CD37:** B-lymphocyte antigen CD-37 is a protein, a member of the transmembrane 4 superfamily, also known as the tetraspanin superfamily of cell surface antigens

chHH1: Chimeric version of the HH1 antibody

**CLL:** Chronic Lymphocytic Leukemia

CR: Complete Response

**DLBCL:** Diffuse Large B-Cell Lymphoma

**DoR:** Duration of Response

EANM: European Association of Nuclear Medicine

EMA: European Medicines Agency
EMEA: Europe, Middle East, and Africa
FDA: Food and Drug Administration (US)

FL: Follicular Lymphoma

**GMP:** Good Manufacturing Practice **Haem-Oncs:** Haematologist-oncologist

HH1: Lilotomab

**Humalutin®:** Chimeric anti-CD37 ARC **IND:** Investigational New Drug

iNHL: Indolent non-Hodgkin Lymphoma

KI: Kinase InhibitorKOL: Key Opinion Leader

Lilotomab (IIo): Betalutin® consists of the radionuclide lutetium-177 conjugated to the B-cell seeking anti-CD37 antibody lilotomab

Lu-177: Radionuclide lutetium-177

M.D: Medical Doctor

mAb: Monoclonal antibody

MBq: Megabecquerel (radioactivity measurement unit)

MCL: Mantle Cell Lymphoma
MSL: Medical science liaison
MZL: Marginal zone lymphoma
NDA: New Drug Application
NHL: Non-Hodgkin's Lymphoma

NNV003: Chimeric anti-CD37 antibody developed by Nordic Nanovector

**ODD:** Orphan Drug Designation

ORR: Overall Response Rate (CR plus PR)

OS: Overall Survival

PARADIGME: name of Nordic Nanovector's pivotal Phase 2b trial

**PD:** Progressive Disease **PFS:** Progression Free Survival

Pi3K: Phosphoinositide 3-kinase; class of Pi3K inhibitors include idelalisib, copanlisib, duvelisib

**PR:** Partial Response **QoL:** Quality of Life

R/R: Relapsed/refractory

R: Rituximab

**RIT:** Radioimmunotherapy

RTX: Rituximab

**SAB:** Scientific Advisory Board **SCT:** Stem cell transplant

SD: Stable Disease

SPECT/CT: Single photon emission computed tomography (SPECT) integrated with computed tomography (CT)

TAT11: 11th International Symposium on Targeted-Alpha-Therapy

**T-cell:** A type of lymphocyte (white blood cell) that plays a central role in cell-mediated immunity. Can be distinguished from other lymphocytes by the presence of a T-cell receptor (TCR) on the cell surface. They are called T-cells because they mature in the thymus

TRP11: Targeted Radiopharmaceuticals Summit

**US**: United States

#### **Financial calendar**

Q3 2020 results: 19 November 2020

Q4 and FY 2020 results: February 2021

The dates are subject to change. The time and location of the presentations will be announced in due course.

In accordance with its corporate disclosure policies, the company has a two-week quiet period ahead of its full year and quarterly results announcements. During the quiet periods, the company will not participate in meetings, seminars or engage with external individuals or groups (including analysts, investors, media).

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#### **Forward-looking statements**

This report contains certain forward-looking statements. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Nordic Nanovector's business, financial condition and results of operations. The terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "targets", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. These forward-looking statements are not historic facts. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in the forward-looking statements. Factors that could cause these differences include, but are not limited to, risks associated with implementation of Nordic Nanovector's strategy, risks and uncertainties associated with the development and/or approval of Nordic Nanovector's product candidates, ongoing and future clinical trials and expected trial results, the ability to commercialise Betalutin", technology changes and new products in Nordic Nanovector's potential market and industry, Nordic Nanovector's freedom to operate (competitors patents) in respect of the products it develops, the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions, and legislative, regulatory and political factors. No assurance can be given that such expectations will prove to have been correct. Nordic Nanovector disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Notes

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#### **About Nordic Nanovector**

Nordic Nanovector is committed to develop and deliver innovative therapies to patients to address major unmet medical needs and advance cancer care. The company aspires to become a leader in the development of targeted therapies for haematological cancers.

Nordic Nanovector's lead clinical-stage candidate is Betalutin®, a novel CD37-targeting radioimmunotherapy designed to advance the treatment of non-Hodgkin's lymphoma (NHL). NHL is an indication with substantial unmet medical need, representing a growing market forecast to be worth nearly USD 29 billion by 2026. Nordic Nanovector intends to retain marketing rights and to actively participate in the commercialisation of Betalutin® in core markets.