

Q2 2021



## Highlights

- PARADIGME timelines revised following review of patient recruitment rate and expected impact of continuing COVID-19 pandemic caused by the spread of the more infectious SARS-CoV-2 delta variant
  - o Preliminary three-month data readout now expected during H1'2022
  - 94 of a targeted 120 patients have been enrolled into PARADIGME as of 26 August 2021 (83 patients enrolled as of 25 May 2021)
- Successful Private Placement and oversubscribed Repair Offering completed in February and April, respectively, raised approximately NOK 422 million (USD 49.7 million) in gross proceeds
  - o Extends the company's cash runway into H2'2022
- Promising Phase 1b data reported from the Phase 1 Archer-1 study evaluating Betalutin® in combination with rituximab in 2L follicular lymphoma (FL)
  - The combination showed a very good safety profile comparable to that of single agent Betalutin®, and early signs of efficacy, with all seven patients responding to treatment and six patients still in remission
  - On 3 August 2021, the Company announced that the findings from Archer-1 will be important to inform the future development strategy for Betalutin® in 2L FL and that it will invest no further funds in Archer-1.
- Betalutin® was found to be well tolerated, with a good safety profile consistent with all previous studies, in the LYMRIT 37-05 Phase 1 trial in Relapsed/Refractory Diffuse Large B-cell Lymphoma (DLBCL)
  - Clinical activity of Betalutin® was seen in the six evaluable patients receiving the highest dosing regimen
  - Next steps for development of Betalutin® in DLBCL are under consideration
- The Company has committed to hosting an R&D Day in Q4'2021 to discuss the positioning and next steps for Betalutin® development and commercialisation, as well as further pipeline opportunities
- Malene Brondberg was appointed interim Chief Executive Officer in July
  - Ms Brondberg replaces Peter Braun, who left Nordic Nanovector for personal reasons. Ms Brondberg will continue in her role as CFO. The Board has initiated a search for a new CEO
- Board changes
  - o Hilde Hermansen Steineger, PhD, decided not to stand for re-election at the AGM on 28 April 2021
  - o Solveig Hellebust, PhD, was appointed Non-executive Director at the AGM

Malene Brondberg, interim CEO of Nordic Nanovector, said: "Nordic Nanovector continues to make important progress towards completing patient enrolment into the pivotal PARADIGME trial despite ongoing disruption from the COVID-19 pandemic. This disruption has reduced the acceleration in recruitment that we anticipated as a result of the amendments we made to the trial protocol and the multiple recruitment initiatives we have implemented. We now expect to report the preliminary readout from PARADIGME in H1'2022 and are focused on delivering this crucial milestone. The Company remains convinced that Betalutin® is uniquely positioned to meet the need for a chemo-free, effective yet tolerable treatment for NHL patients, coupled with its convenient administration schedule, with potential quality of life advantages for elderly and frail patients.

## Key figures Nordic Nanovector Group

Amounts in MNOK	Second	Quarter	First Half Year		Full Year
(except earnings/loss per share)	2021	2020	2021	2020	2020
Total revenues	0.0	0.0	0.0	0.0	0.0
Total operating expenses	103.9	113.4	205.1	239.3	434.2
Operating profit (loss)	-103.9	-113.4	-205.1	-239.3	-434.2
Net financial items	2.0	-11.0	1.8	21.5	18.0
Total comprehensive income (loss) for the period	-101.8	-125.6	-204.0	-217.2	-417.6
Basic and diluted earnings (loss) per share	-1.05	-1.88	-2.23	-3.3	-5.99
Number of employees	39	44	39	44	36
Net change in bank deposits, cash and equivalents	-47.8	-138.0	156.1	-224.6	-176.8
Cash and equivalents at beginning of period	497.9	384.3	294.0	470.8	470.8
Cash and equivalents at end of period	450.1	246.2	450.1	246.2	294.0

## Operational review

#### Introduction

Nordic Nanovector is committed to develop and deliver the therapeutic potential of Betalutin® and other innovative CD37-targeted immunotherapies to patients to address major unmet medical needs.

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

There is a clear need for new treatment options in NHL as it has been reported that 40-60% of patients treated with an RTX-containing regimen either become refractory to anti-CD20 based therapy or develop resistance within five years.

The company is advancing Betalutin® in PARADIGME, a global pivotal Phase 2b trial in 3<sup>rd</sup>-line follicular lymphoma (FL) patients, refractory to RTX/anti-CD20 based treatments, as a first-to-market NHL indication based on compelling clinical data from earlier clinical 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 in Europe for relapsed/refractory (R/R) marginal zone lymphoma (MZL).

Beyond Betalutin®, the company intends to leverage its R&D expertise and proprietary technologies to evaluate opportunities with other CD37-targeting immunotherapies across NHL and other 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**

During 2021, Nordic Nanovector has seen an improvement in the enrolment rate into PARADIGME compared to previous years as a result of a range of actions taken during 2020, including trial protocol amendments to increase the size of the eligible patient population and multiple initiatives to improve the execution of the trial.

As of 26 August 2021, 94 of a targeted 120 patients have been enrolled into PARADIGME, compared with 83 patients enrolled as of 25 May 2021. The end of the recruitment phase is coming into sight.

However, while the actions mentioned have positively impacted recruitment, the ongoing COVID pandemic situation, exacerbated by the spread of the more infectious SARS-CoV-2 delta variant, continues to affect the company's ability to screen, enrol and treat new patients. This is because the physical condition of the patient population targeted for this study means they are at the greatest risk from COVID-19.

This situation is made more difficult in Europe as ESMO-EHA guidelines\* on the management of cancer patients during the pandemic state that 'watch and wait' strategies should be followed wherever possible.

As a result, the rate of patient recruitment has been slower than anticipated.

In August, the company, having reviewed the recent rate of patient recruitment in discussion with its clinical advisors and considering the continuing impact from the COVID pandemic, announced that it now anticipates the preliminary three-month data readout from PARADIGME during the first half of 2022.

Nordic Nanovector continues to prioritise and commit all necessary resources to the completion of PARADIGME. As part of this prioritisation, the company has decided to close clinical sites at which enrolment has been particularly challenging and refocus resources on other initiatives; the trial remains open for enrolment at 85 sites.

As the completion of recruitment and the preliminary data readout draw closer, the company is preparing for success and completing further activities, such as qualification of its manufacturing process in the CMC (Chemistry, Manufacturing and Controls) space, to support a regulatory filing. The company is also initiating the preparatory

activities for the confirmatory Phase 3 trial, the start of which is required upon submission, and for commercialisation. In addition, the company continues to execute its partnering strategy to enable the full potential of Betalutin® in NHL to be realised.

#### Betalutin® profile could be attractive to majority of elderly or frail R/R FL patients

Nordic Nanovector continues to develop its market knowledge as a basis for designing a commercialisation strategy for Betalutin®. The company is convinced that Betalutin® has an attractive profile for treating NHL based on extensive market research conducted over several years and the positive results from earlier clinical studies.

If PARADIGME delivers positive results, the company believes that Betalutin® will have a unique therapeutic profile allowing it to address the unmet needs of the approximately 70% of 3L FL patients who are elderly and/or frail. This is particularly the case for the many elderly patients whose disease is refractory to anti-CD20 immunotherapy and who have gone through multiple prior lines of treatment.

Many of these patients have significant co-morbidities that often prevent the use of chemotherapy, targeted or cell therapies, which are effective treatments yet associated with a high side-effect burden. In addition, most of these patients have developed resistance or have become refractory to anti-CD20 based regimens.

Physicians caring for these patients are looking for treatment options that deliver durable responses with a gentler tolerability profile, that preserves the patients' quality of life while maintaining remission. They also favour treatments that are easier to administer and do not require frequent visits to a clinic.

The company believes the safety and efficacy data generated to date from a single administration of Betalutin® would uniquely position this product to address these unmet needs and make it an attractive option for the difficult-to-treat patient population included in PARADIGME.

Given the unmet medical need in this targeted first-to-market indication and its Orphan Drug designation in the US and Europe, the company believes positive results from PARADIGME could allow a rapid path to approval for Betalutin®.

## Betalutin® pipeline update

Given its strategic focus on PARADIGME, the company decided in 2020 to pause the Phase 1 Archer-1 trial investigating Betalutin® in combination with rituximab in 2L FL and the Phase 1 LYMRIT 37-05 trial of Betalutin® in R/R diffuse large B-cell lymphoma (DLBCL) once the ongoing cohorts had been completed.

During Q2'2021, the company reported encouraging early results from both studies, which supported the attractive safety profile of Betalutin® in fragile and highly pre-treated NHL patients, and also showed promising efficacy.

Nordic Nanovector considers the findings from these trials to be important to inform the future development strategy for Betalutin® as a potential treatment for difficult-to-treat NHL sub-types and confirmed it would be investing no further funds in these trials.

The company intends to discuss future and wider development opportunities for Betalutin® and other CD37-targeting immunotherapies at its R&D Day, which is planned to take place in Q4'2021.

### Positive Archer-1 data

Preliminary results from the Archer-1 Phase 1b trial show clinical activity with all seven out of seven patients achieving a response, including five complete responses and two partial responses. Six patients are still in remission.

Across this patient group, Betalutin® with RTX showed a very good safety profile, comparable to that of single agent Betalutin®, with no dose limiting toxicities observed.

The primary objective of the study was to evaluate the safety and tolerability of Betalutin® in combination with RTX, with the secondary objective to evaluate the preliminary anti-tumour activity of combination treatment.

st Haematological malignancies: Indolent B-NHL in the second phase of the COVID-19 pandemic (ESMO-EHA)

#### Betalutin® in DLBCL

Initial results from the LYMRIT 37-05 Phase 1 showed that Betalutin® was well tolerated, with a good safety profile consistent with all previous studies.

A single, reversible dose-limiting toxicity (DLT) was seen in the last cohort investigating the highest dosing regimen (20 MBq/kg Betalutin® and 100 mg/m² lilotomab), which following review by the Independent Review Committee (IRC) resulted in three additional patients being enrolled. No further DLTs were seen.

Clinical activity of Betalutin® was seen in the six evaluable patients receiving the highest dosing regimen including one complete response and one partial response. The IRC commented that the safety and anti-tumour activity of the highest dosing regimen could be considered for investigation in combination with other therapies used in R/R DLBCL which the company is now evaluating, with an emphasis on combination partners that would not compromise the current safety profile of Betalutin®.

#### Betalutin® in Marginal Zone Lymphoma

Nordic Nanovector is also currently evaluating how to validate the possible role of Betalutin® as a single-agent treatment for relapsed marginal zone lymphoma (MZL), a rarer type of indolent NHL. Betalutin® treatment produced very promising clinical responses in nine MZL patients in the Phase 1/2a LYMRIT 37-01 trial.

Betalutin® was granted Fast-track designation in the US and Orphan Drug designation in the European Union during H1′2020 for MZL, reflecting the clear need for new therapeutic options for MZL patients who no longer respond to anti-CD20 immunotherapy.

#### Private Placement and Repair Offering extend cash runway into H2'2022

In February and April, respectively, the company successfully completed a Private Placement and oversubscribed Repair Offering, raising a total of approximately NOK 422 million (equivalent to approximately USD 49.7 million) in gross proceeds. The Private Placement and Repair Offering were completed at a subscription price of NOK 22.75 per share, which was determined through an accelerated book-building process in the Private Placement.

Nordic Nanovector intends to use the net proceeds raised for the following purposes:

- Conduct pharmacokinetics (PK) studies and execute CMC activities required for regulatory filing of Betalutin<sup>®</sup>
- Initiate the preparatory activities for the confirmatory Phase 3 trial and preparation for U.S. market launch
- General corporate purposes

The proceeds from the Private Placement and the Repair Offering extend Nordic Nanovector's cash runway into H2'2022.

## **Management/Board Changes**

In July, the Company announced that Ms. Malene Brondberg had been appointed interim Chief Executive Officer.

Ms. Brondberg, who was formerly the company's Chief Financial Officer, replaces Peter Braun who decided to leave Nordic Nanovector for personal reasons. Ms. Brondberg will continue in her role as CFO. The Board has initiated a search for a new CEO.

The Chairman and other board members continue to support the management team as and when needed.

In other notable changes, Mrs Hilde Hermansen Steineger, PhD, who has served as a Non-executive Director on the Board of Nordic Nanovector since November 2014, decided not to stand for re-election at the company's Annual General Meeting (AGM) in April due to increased workload and other priorities. Mrs Solveig Hellebust, PhD, was appointed as a Non-executive Director at the AGM.

## Financial review

The interim consolidated financial statements for Nordic Nanovector Group as of 30 June 2021 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 2020 unless stated otherwise)

Revenues in the second quarter of 2021 amounted to NOK 0.0 million (NOK 0.0 million). Revenues for the first half of 2021 amounted to NOK 0.0 million (NOK 0.0 million).

Total operating expenses for the quarter came to NOK 103.9 million (NOK 113.4 million). Payroll and related expenses increased to NOK 20.9 million (NOK 20.2 million). Other expenses amounted to NOK 78.4 million during the quarter (NOK 89.5 million). Total operating expenses for the first half of 2021 decreased to NOK 205.1 million (NOK 239.3 million). The decrease is due to careful management of financial resources, which are now focused on completing PARADIGME and the allied clinical and manufacturing development activities needed to support the filing of a Biologics License Application (BLA) for Betalutin®, pending positive results from PARADIGME.

Research and development (preclinical, clinical, medical affairs, regulatory and CMC activities) expenses accounted for 84 % of total operating expenses year to date 2021 (82 %).

Operating loss for the quarter was NOK 103.9million (loss of NOK 113.4 million). Operating loss for the first half of 2021 was NOK 205.1 million (NOK 239.3 million).

Net financial items for the second quarter came to NOK 2.0 million (negative NOK 11.0 million). Net financial items for the first half amounted to NOK 1.8 million (negative 21.5 million), mainly driven by increased value in NOK of cash deposited in foreign currency.

Nordic Nanovector's comprehensive loss for the quarter amounted to NOK 101.8 million (loss of NOK 125.6 million), due to the reasons stated above. Comprehensive loss for the first half was NOK 204 (NOK 217.2 million).

#### **Financial position**

Total assets on 30 June 2021 amounted to NOK 494.8 million, up from NOK 314.6 million at year-end 2020. The increase was driven by the private placement and repair offering in February and April 2021 respectively.

Total shareholders' equity on 30 June 2021 was NOK 374.4 million (NOK 178.7 million at year-end 2020), corresponding to an equity ratio of 75.7% (56.8 % at year-end 2020).

Total liabilities on 30 June 2021 were NOK 120.4 million, down from NOK 135.9 million from year-end 2020, driven by a decrease in account payables.

#### **Cash flow**

Net cash flow from operating activities in the second quarter and first half of 2021 was negative NOK 102.7 million (negative NOK 123.2 million), and negative NOK 236.3 million (negative 239.2 million), respectively, mainly reflecting changes described above and fluctuations in working capital.

Net cash flow from investing activities in the second quarter and first half of 2021 was NOK 0.0 million (NOK 0.0 million) and negative NOK 0.1 (NOK 0.0 million), respectively.

Net cash flow from financing activities for the second quarter of 2021 was NOK 53.1 million (negative NOK 3.5 million).

Net cash flow from financing activities for the first half 2021 was NOK 391.0 million (negative NOK 7.0 million), driven by the private placement and repair issue completed in February and April of 2021

Exchange rate fluctuations in the second quarter and first half 2021 were NOK 1.9 million (negative NOK 11.3) and 1.5 million (NOK 21.7 million), respectively.

Cash and cash equivalents amounted to NOK 450.1 million at the end of June 2021, compared to NOK 294.0 million at the end of December 2020 for reasons explained above.

## Outlook

Nordic Nanovector's current focus is to complete patient enrolment into PARADIGME and is targeting the readout of preliminary three-month top line data during H1'2022.

The company's current cash position will support its operations into H2'2022 and will enable further preparatory work on the potential Betalutin® BLA filing and planning for commercialisation to be undertaken.

The company believes that, if positive, the PARADIGME trial data could represent a significant value inflection point for the company and its shareholders, confirming Betalutin® as a highly promising new targeted radioimmunotherapy that can address the unmet needs of R/R FL patients.

The company intends to discuss the development plan and opportunities for expanding the market for Betalutin® into other NHL indications, together with other potential areas for pipeline expansion based on CD37-targeting immunotherapies, at its R&D Day, which is planned to take place in Q4′2021.

## **Responsibility statement**

The Board of Directors and the CEO of Nordic Nanovector ASA have today considered and approved the condensed financial statements as of 30 June 2021 and for the six-month period ended 30 June 2021. 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 30 June 2021 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, 26 August 2021	
The Board of Directors Nordic Nanovector ASA	
Jan H. Egberts Chairman	Jean-Pierre Bizzari Board Member
 Rainer Boehm	 Joanna Horobin
Board Member	Board Member
	<del></del>
Per Samuelsson Board Member	Karin Meyer Board Member
Solveig Hellebust	Malene Brondberg
Board Member	Interim CEO & CFO

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

Amounts in NOK 1 000	Noto	Note Second Qua		First Ha	alf Year	Full Year	
Amounts in NOK 1 000	Note	2021	2020	2021	2020	2020	
Revenues		0	0		0	0	
Total revenues		0	0		0	0	
Payroll and related expenses	4, 5	20 927	20 201	43 381	39 982	78 301	
Depreciation		4 549	3 723	5 298	7 437	14 895	
Other operating expenses	4, 6	78 398	89 452	156 382	191 834	340 965	
Total operating expenses		103 874	113 376	205 061	239 253	434 161	
Operating profit (loss)		-103 874	-113 376	-205 061	-239 253	-434 161	
Net finance income (expenses)	9	1 969	-10 960	1 766	21 469	18 000	
Loss before income tax		-101 905	-124 336	-203 295	-217 784	-416 161	
Income tax		-197	-291	-413	-585	-914	
Loss for the period		-102 102	-124 627	-203 708	-218 369	-417 075	
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 subsequent periods  Re-measurement gains (losses) on defined benefit plans		257 0	-959 0	-266 0	1 131	-912	
Total comprehensive income (loss) for the period		-101 845	-125 586	-203 974	-217 238	-417 564	
Loss for the period attributable to owners of the company		-102 102	-124 627	-203 708	-218 369	-417 075	
Total comprehensive income (loss) for the period attributable to owners of the company		-101 845	-125 586	-203 974	-217 238	-417 564	
Earnings (loss) per share Basic and diluted earnings (loss) per share in NOK	8	-1.05	-1.88	-2.23	-3.30	-5.99	

## Interim condensed consolidated statement of financial position Nordic Nanovector Group

Amounts in NOK 1 000	Note	30.06.2021	31.12.2020
ASSETS			
Non-current assets			
Property, plant and equipment		1 082	1 394
Right-of-use-assets		10 797	4 290
Total non-current assets		11 879	5 684
Current assets			
Receivables			
Other current receivables	4	32 845	14 951
Total receivables		32 845	14 951
Cash and cash equivalents		450 089	293 975
Total current assets		482 934	308 926
TOTAL ASSETS		494 813	314 610
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	7	19 616	15 878
Share premium	7	510 588	118 371
Other paid in capital	5, 6	65 307	61 565
Retained earnings		-221 120	-17 146
Total shareholders' equity		374 391	178 668
LIABILITIES			
Non-current liabilities			
Lease liability		1 197	2 356
Net employee defined benefit liabilities		4 384	5 025
Total non-current liabilities		5 581	7 381
Current liabilities			
Accounts payable		33 801	65 862
Tax payable		843	803
Other current liabilities		80 197	61 896
Total current liabilities		114 841	128 561
Total liabilities		120 422	135 942
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		494 813	314 610

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

For the period ended 30.06.2021								
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 1 January 2020		13 229	335 336	69 025	-28 806	329	-1 105	388 008
Loss for the period Other comprehensive income (loss) for the year, net of income tax					-417 075	423	-912	-417 075 -489
Total comprehensive income for the period		0	0	0	-417 075	423	-912	-417 564
Recognition of share-based payments	5, 6			-7 460				-7 460
Issue of ordinary shares	5, 6	2 646	228 856					231 502
Issue of ordinary shares under share options and RSUs	5, 6, 7	4						4
Share issue costs			-15 821					-15 821
Reclassification of accumulated losses			-430 000		430 000			0
Balance at 31 December 2020		15 878	118 371	61 565	-15 881	752	-2 017	178 668
Loss for the period					-203 708			-203 708
Other comprehensive income (loss) for the year, net of income tax						-266	0	-266
Total comprehensive income for the period		0	0	0	-203 708	-266	0	-203 974
Recognition of share-based payments	5, 6			3 742				3 742
Issue of ordinary shares	5, 6	3 715	418 920					422 635
Issue of ordinary shares under share options and RSUs		22	910					932
Share issue costs			-27 613					-27 613
Balance at 30 June 2021		19 616	510 588	65 307	-219 589	486	-2 017	374 391

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 1 January 2020		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 June 2020		13 232	135 336	60 035	-47 175	1 461	-1 105	161 784

## Interim condensed consolidated statement of cash flow Nordic Nanovector Group

Amounts in NOK 1 000	Note	Second Quarter		First Ha	alf Year	Full Year
Amounts in NOK 1 000	Note	2021	2020	2021	2020	2020
Cash flow from operating activities						
Loss for the period before income tax		-101 905	-124 336	-203 295	-217 784	-416 161
Adjustments for:						
Interests paid		208	138	243	313	471
Interest received		-28	-42	-34	-203	-1 590
Share option and PSU expenses employees	5	1 376	-1 295	3 025	-9 414	-8 484
Restricted share units (RSUs) expenses board	6	424	143	717	424	1 024
Taxes paid		-8	0	-432	-433	-1 068
Depreciation		4 549	3 723	5 298	7 437	14 895
Currency (gains) losses not related to operating activities		-1 887	11 269	-1 487	-21 656	-18 490
Changes in working capital and non-cash adjustments		-5 471	-12 802	-40 289	2 076	31 197
Net cash flow from operating activities		-102 742	-123 202	-236 254	-239 240	-398 206
Cash flow from investing activities						
Investments in property, plant and equipment and intangible assets		-65	-54	-123	-165	-185
Interests received		28	42	34	203	1 590
Net cash flow from investing activities		-37	-12	-89	38	1 405
Cash flows from financing activities						
Net proceeds from equity issue	7	57 491	4	395 955	4	215 684
Payment of principle portion of lease liabilities		-4 202	-3 400	-4 742	-6 726	-13 751
Interests paid		-208	-138	-243	-313	-471
Net cash flow from financing activities		53 081	-3 534	390 970	-7 035	201 462
Effects of exchange rate changes on cash and cash equivalents		1 887	-11 269	1 487	21 656	18 490
Net change in bank deposits, cash and equivalents		-47 811	-138 017	156 114	-224 581	-176 849
Cash and equivalents at beginning of period		497 900	384 260	293 975	470 824	470 824
Cash and equivalents at end of period		450 089	246 243	450 089	246 243	293 975

# Notes to the condensed interim financial statements for the Second Quarter and First Half Year report 2021

### 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 2021 report are non-audited figures.

These financial statements were approved for issue by the board of directors on 26 August 2021.

## 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 2020. 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 1 January 2021, 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 31 December 2020.

## 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 NOV 1 000	Second	Quarter	First Half Year		
Amounts in NOK 1 000	2021	2020	2021	2020	
Payroll and related expenses	137	98	399	305	
Other operating expenses	1 209	1 840	2 403	3 570	

Grant's receivable presented as other current receivables in the statement of financial position:

Amounts in NOK 1 000	30.06.2021	31.12.2020
Grant's receivable	7 551	5 750

- 1) R&D projects have been approved for SkatteFUNN grants for the period 2017 through 2021. For the financial period ended 30 June 2021, the company has recognised NOK 2.4 million compared to NOK 2.4 million for the same period in 2020. The amount was recognised partly as a reduction of payroll and related expenses and partly as a reduction of other operating expenses.
- 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 30 June 2021, the company recognised NOK 0.4 million partly as a reduction of payroll and related expenses and other operating expenses, compared to NOK 1.5 million for the same period in 2020.

## Note 5. Employee share incentive programmes

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

The board of directors of Nordic Nanovector ASA decided on 26 March 2021 to grant 1 070 000 PSUs to current and newly hired employees.

## **Overview of outstanding PSUs**

	Year to date 2021				
	Number of PSUs	Weighted average exercise price, NOK			
Balance at 01.01.2021	774 750	0.2			
Granted during the period	1 070 000	0.2			
Exercised during the period	-35 524	0.2			
Forfeited	-421 726	0.2			
Balance at 30.06.2021	1 387 500	0.2			
Hereof vested PSUs	8 544	0.2			

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 2020.

### **Share options**

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

## **Overview of outstanding options**

	Year to date 2021				
	Number of options	Weighted average exercise price, NOK			
Balance at 01.01.2021	1 351 967	40.74			
Granted during the year	0	0			
Exercised during the year	-65 900	15.61			
Forfeited	-21 088	45.58			
Balance at 30.06.2021	1 264 979	41.97			
Hereof vested options	1 264 979	41.97			

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 2020.

## Note 6. Restricted Stock Units (RSUs)

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

At the annual general meeting (AGM), 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 AGM in 2021 to the AGM in 2022, in the form of RSUs.

The RSUs are non-transferable and each RSU give 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 minimum 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 25.68.

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:

Nome	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	

A total of 40 625 RSUs have thus been allocated following the AGM. The RSUs will vest on 28 April 2022. For further information about the RSU Program see section 6.3.2 to the Company's financial statements for 2020, included in the Company's annual report for 2020 on page 95.

#### **Exercise of restricted stock units**

The two US-based board members of Nordic Nanovector ASA, Joanna Horobin and Jean-Pierre Bizzari resolved to settle a total number of 22 860 RSUs that were issued to them in June 2020 after they had elected to receive all or part of their remuneration for the period from the AGM in 2020 to the AGM in 2021 in RSUs. In addition, Hilde Steineger, who did not stand for re-election as board member at the annual general meeting in 2021, resolved to settle a total number of 29 106 RSUs previously issued as remuneration under the RSU-program. Each RSU gives the right to subscribe for one share in the Company at a subscription price of NOK 0.20.

## **Overview of outstanding RSUs**

	Year to date 202	
	Number of RSUs	
Balance at 01.01.2021	85 233	
Granted during the year	40 625	
Exercised during the year	51 966	
Forfeited	0	
Balance at 30.06.2021	73 892	
Hereof vested RSUs	33 267	

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 2020.

## Note 7. Share capital and shareholder information

The share capital as at 30 June 2021 is NOK 19 615 676 (31 December 2020: NOK 15 878 122), being 98 078 380 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:	Note	30.06.2021	31.12.2020
Ordinary shares at beginning of the period		79 390 612	66 143 363
Issue of ordinary shares 1)		18 577 402	13 228 670
Issue of ordinary shares under options <sup>2)</sup>	5	58 400	0
Issue of ordinary shares under RSUs 3)	6	51 966	18 579
Ordinary shares at end of the period		98 078 380	79 390 612

<sup>&</sup>lt;sup>1</sup> In February 2021 the company raised approximately NOK 361 million in gross proceeds through a private placement of 15 878 122 new shares. The private placement was completed at a subscription price of NOK 22.75 per share, which was determined through an accelerated bookbuilding process. In April 2021 the company raised NOK 61 million in gross proceeds through a repair offering, which increased the company's share capital by NOK 539 856 through the issuance of 2 699 280 new shares.

 $<sup>^{\</sup>rm 2}$  In June current and former employees exercised 58 400 share options.

<sup>&</sup>lt;sup>3</sup> In June 2021 two US-based board members resolved to settled 22 860 RSUs. In addition, one former board member resolved to settle a total number of 29 106 RSUs previously issued as remuneration under the RSU-program. To fulfil the Company's obligations under the RSU agreements, the board of directors of the company solved to issue 51 966 new shares at a subscription price of NOK 0.20.

## Nordic Nanovector ASA had 12 084 shareholders as of 30 June 2021

	Shareholders	Number of shares	Percentage of total shares
1	Folketrygdfondet	7 788 697	7.94%
2	HealthCap VI L.P.	6 834 095	6.97%
3	OM Holding AS	3 762 692	3.84%
4	Fjarde AP-Fonden	3 062 432	3.12%
5	Nordnet Livsforsikring AS	1 719 072	1.75%
6	Sundt AS	1 640 433	1.67%
7	Ro Invest AS	1 000 000	1.02%
8	Urbanium Gruppen AS	918 000	0.94%
9	Linux Solutions Norge	845 071	0.86%
10	Nordnet Bank AB	835 757	0.85%
11	Verdipapirfondet Nordea Kapital	834 968	0.85%
12	USB Switzerland AG	819 907	0.84%
13	Birk Venture AS	800 000	0.82%
14	Verdipapirfondet Nordea Avkastning	703 480	0.72%
15	Must Invest AS	700 000	0.71%
16	Sciencons AS	650 000	0.66%
17	Myna AS	632 976	0.65%
18	Radiumhospitalets Forskningsstiftelse	624 972	0.64%
19	Boddco AS	600 454	0.61%
20	Inven2 AS	541 247	0.55%
	Total shares for top 20 shareholders	35 314 253	36.01%
	Total shares for other 12 064 shareholders	62 764 127	63.99%
	Total shares (12 084 shareholders)	98 078 380	100.00%

The shares of Nordic Nanovector ASA have been traded on the Oslo Stock Exchange since 23 March 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 Year 2021	First Half Year 2020
Loss for the period	-203 708 000	-218 369 000
Average number of outstanding shares during the year	91 486 707	66 143 466
Earnings (loss) per share - basic and diluted	-2.23	-3.30

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 NOK 1 000	2021	2020	2021	2020	2020
Finance income	249	243	617	1 249	1 610
Finance expenses	286	244	345	540	860
Net currency gains (losses) on cash and cash equivalents	1 887	-11 269	1 487	21 656	18 490
Net other currency gains (losses) related to operating items	119	310	7	-896	-1 239
Net finance income	1 969	-10 960	1 766	21 469	18 000

Finance expenses include interest expenses on lease liabilities.

## Note 10. Subsequent events

On 3 august 2021, the company announced, having reviewed the recent rate of patient recruitment in discussion with its clinical advisors and in light of the continuing impact from the COVID pandemic, that the company now anticipates the preliminary three-month data readout from PARADIGME during the first half of 2022.

In addition, the company confirmed it will invest no further funds in its Archer-1 Phase 1b trial investigating Betalutin® in combination with rituximab in 2nd-line FL. The findings from this study, announced on 25 May 2021, will be important to inform the future development strategy for Betalutin® in 2L FL.

## **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

KOL: 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 DoctormAb: 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)

**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

US: United States

## Financial calendar

Q3 2021 results: 18 November 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).

## **Investor contact**

Contact person: Malene Brondberg, CFO

Phone: (+ 44) 7561 431 762

E-mail: ir@nordicnanovector.com

Web: <u>www.nordicnanovector.com/investors-and-media</u>

## **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.

This information is subject to the disclosure requirements pursuant to Section 5-12 the Norwegian Securities Trading Act

Notes

#### **Head office**

**Nordic Nanovector ASA** 

Kjelsåsveien 168 B 0884 Oslo Norway

Phone: (+47) 22 18 33 01

E-mail: mail@nordicnanovector.com

### Subsidiary

**Nordic Nanovector GmbH** 

Grafenauweg 8 6300 Zug Switzerland

Phone: (+47) 22 18 33 01

E-mail: mail@nordicnanovector.com

### **Nordic Nanovector Denmark**

branch of Nordic Nanovector ASA, Norway Th. Bergs Gade 12 9900 Frederikshavn Denmark

Phone: (+47) 22 18 33 01

E-mail: mail@nordicnanovector.com

## Subsidiary

**Nordic Nanovector Ltd** 

1 Brassey Road Old Potts Way Shrewsbury SY3 7FA United Kingdom

Phone: (+47) 22 18 33 01

E-mail: mail@nordicnanovector.com

www.nordicnanovector.com



#### **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 antibody-radionuclide-conjugate 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 26 billion by 2028. Nordic Nanovector retains global marketing rights to Betalutin® and intends to actively participate in the commercialisation of Betalutin® in the US and other major markets.