

# Fourth Quarter and Full Year 2018 Report Nordic Nanovector ASA

# Q4'18 Highlights

- Updated results from Phase 1/2 LYMRIT 37-01 demonstrating that single-administration Betalutin® is
  effective and well-tolerated in relapsed/refractory indolent non-Hodgkin's lymphoma (R/R iNHL) patients
  reported at ASH (December)
- Pivotal Phase 2b PARADIGME trial progressing with 69 (of 80-85) sites in 23 countries open for enrolment, as of February 26<sup>th</sup>, 2019, including the first site in the US
- Promising Innovative Medicine (PIM) designation (October) in the UK granted for the treatment of advanced R/R FL, adding to US Fast Track designation (granted in June)
- First patient dosed in Phase 1b Archer-1 trial of Betalutin® in combination with rituximab in second-line (2L) FL patients (November)
- Promising results from an R&D collaboration to develop a CD37-targeted alpha therapy published at ASH

# Events after Q4'18

- Approximately NOK 222 million (USD 26m) (gross) raised in an oversubscribed private placement which
  provides funds to support manufacturing and other activities in preparation for the commercialisation of
  Betalutin®
- Jan H. Egberts, M.D. elected new Chairman, succeeding Ludvik Sandnes who stepped down from the board of directors
- Dr Mark Wright appointed as Head of Manufacturing to lead production of Betalutin® for clinical trials and future commercialisation, and of CD37-targeting candidates emerging from the company's pipeline

Eduardo Bravo, CEO, commented: "We believe we have made solid progress during 2018 advancing the key clinical development programmes for Betalutin® as a single agent and in combination with rituximab in non-Hodgkin's lymphoma patients. The latest results from the LYMRIT 37-01 trial, presented at ASH in December, continue to highlight strong clinical profiles of two dosing regimens that we are now testing in the pivotal PARADIGME trial. Furthermore, the recent financing enables us to expand our preparatory activities for the future commercialisation of our exciting lead asset, pending completion of PARADIGME and successful regulatory review. Our clear priority for the coming year is on recruiting patients into PARADIGME to ensure we can achieve our goal of data read-out in the first half of 2020."

# **Key figures Nordic Nanovector Group**

Amounts in MNOK	Fourth	Quarter	Full year		
(except earnings/loss per share)	2018	2017	2018	2017	
Total revenues	0.0	0.05	0.0	0.3	
Total operating expenses	96.3	102.0	340.0	316.8	
Operating profit (loss)	-96.3	-101.9	-340.0	-316.5	
Net financial items	7.8	16.0	3.0	23.1	
Total comprehensive income (loss) for the period	-87.7	-87.6	-336.8	-295.6	
Basic and diluted earnings (loss) per share	-1.80	-1.75	-6.88	-5.99	
Number of employees	38	36	38	36	
Net change in bank deposits, cash and equivalents	-59.6	-47.2	-316.5	-261.6	
Cash and equivalents at beginning of period	499.7	803.7	756.6	1 018.2	
Cash and equivalents at end of period	440.1	756.6	440.1	756.6	

# Operational review

#### Introduction

Nordic Nanovector is developing its lead candidate Betalutin® (177Lu-satetraxetan-lilotomab) as a new, targeted treatment for patients with non-Hodgkin's lymphoma (NHL). Betalutin® targets the CD37 receptor on the surface of B cell malignancies and represents an alternative tumour target to CD20 on which the current standard-of-care NHL therapies (e.g. rituximab/RTX) are based. Betalutin® could therefore offer a new treatment mechanism for patients who progress on RTX-based regimens.

The company's priority is to develop Betalutin® as a single-administration treatment for advanced recurrent follicular lymphoma (FL). Following the encouraging efficacy and favourable safety profile demonstrated in the LYMRIT 37-01 Phase 1/2 study, two Betalutin® dosing regimens are being compared in a pivotal, global, randomised Phase 2b trial (PARADIGME) to identify the best regimen and support market authorisation applications. Initial efficacy and safety data read-outs are expected in the first half of 2020.

Based on the promising safety and efficacy data from the LYMRIT 37-01 trial, Betalutin® has been granted Fast Track designation (June 2018) in the US and PIM designation in the UK (October 2018) for the treatment of patients with R/R FL, adding to Orphan Drug designation for FL in the USA and Europe received in 2014.

Betalutin® in combination with RTX is also being investigated in second-line (2L) FL in the Phase 1b Archer-1 trial, and a Phase 1 study of single-agent Betalutin® in patients with R/R diffuse large B-cell lymphoma (DLBCL) (LYMRIT 37-05) is ongoing.

In addition, the company is beginning to see encouraging results from R&D collaborations with third parties that leverage its anti-CD37 targeting approach for NHL and other types of haematological malignancies.

#### Updated results presented at ASH continue to highlight strong clinical profile of Betalutin®

Updated results from the LYMRIT 37-01 Phase 1/2 clinical study of Betalutin® in patients with R/R iNHL were presented in a poster at the 60<sup>th</sup> American Society of Hematology (ASH) Annual Meeting & Exposition in December 2018. The published dataset (as of November 2<sup>nd</sup>, 2018) included 74 evaluable patients; all patients received Betalutin® as a once-only administration and had six or more months of follow-up.

The conclusions from the study results are that a single administration of Betalutin® is well-tolerated and demonstrates encouraging anti-tumour activity in recurrent iNHL, especially in FL patients, the primary NHL population for which Betalutin® is being developed.

# Key results are:

Patients	Number of patients (n)	Overall Response Rate (ORR)	Complete Responses (CR)
All iNHL patients	74	61%	28%
FL patients	57	65%	28%
3L FL patients (≥2 prior therapies)	37	70%	32%
FL patients in Arm 1 (40 mg lilotomab followed by 15 MBq/kg Betalutin®)	25	64%	32%
FL patients in Arm 4 (100 mg/m² lilotomab followed by 20 MBq/kg Betalutin®)	16	69%	25%
RTX refractory FL, ≥2 prior therapies	21	62%	19%

The median duration of response (mDoR) was 9.0 months for all patients and 20.7 months for those with a CR. Twenty-five patients (34%) have remained free of disease progression for 12 months or more. These data are still maturing as follow-up for duration of response is on-going.

Betalutin® therapy was well tolerated with no unexpected safety findings. The most common adverse events were transient Grade 3/4 neutropenia and thrombocytopenia and were predictable and manageable.

Separately, biodistribution (dosimetry) data generated during LYMRIT 37-01, some of which was recently presented at the European Association of Nuclear Medicine annual congress (October), have proved sufficient to advance the clinical development of Betalutin®. Dosimetry data will continue to be collected in the PARADIGME study, and the company has therefore discontinued the LYMRIT 37-02 dosimetry study, which was planning to enroll 8-12 patients.

#### **PARADIGME** update

As mentioned above, PARADIGME is a pivotal, global, randomised Phase 2b trial comparing two Betalutin® dosing regimens, identified in the LYMRIT 37-01 trial, in relapsed, rituximab/anti-CD20 refractory FL patients who have received ≥2 prior therapies.

The dosing regimens identified are:

- 15 MBq/kg Betalutin® with a pre-dose of 40 mg lilotomab, and
- 20 MBq/kg Betalutin® with a pre-dose of 100 mg/m² lilotomab

The primary endpoint for the trial is overall response rate (ORR) and secondary endpoints include duration of response (DoR), progression-free survival (PFS), overall survival (OS), safety and quality of life. The trial aims to enrol 130 patients at 80–85 sites in 20 countries. The first patient was dosed in June 2018 and an initial data readout is targeted for the first half of 2020.

As of February 26<sup>th</sup>, 2019, PARADIGME is open for patient enrolment at 69 (of 80–85) sites in 23 countries, including the USA, where activation of the first site, in Long Beach, CA, was announced in October 2018.

The company also announced in October 2018 that Betalutin® therapy has been granted Promising Innovative Medicine (PIM) designation by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) for the treatment of patients with advanced R/R FL. The designation was granted based on data from the Phase 1/2 LYMRIT 37-01 trial.

Both the PIM and Fast Track designations (by the US Food & Drug Administration in June) acknowledge the high unmet medical need of the target patient population as well as the potential of Betalutin® to offer therapeutic benefits to FL patients. These designations are very encouraging, as they provide opportunities for enhanced dialogue with health authorities and the potential to bring Betalutin® to patients quicker.

#### First patient dosed in Archer-1: evaluating Betalutin® in combination with rituximab in 2L FL

Rituximab (RTX) is a CD20-targeting antibody and the most widely used therapy administered to patients with newly-diagnosed or relapsed FL as a single agent or in combination with chemotherapy. It has been reported that approximately 40-60% of NHL patients treated with an RTX-containing regimen are either refractory to therapy or develop resistance within five years\*, thus alternative treatment modalities are needed. The five-year overall survival rate for RTX-refractory FL patients is 58% compared to approximately 90% for all FL patients. Therefore, relapsed FL is considered to be a serious and life-threatening disease. In addition, developing novel "chemo-free" regimens for patients as an alternative to chemotherapy is desirable.

The company believes that CD37, the molecule targeted by Betalutin®, could represent an important alternative target for new therapies for FL patients. Furthermore, the combination of anti-CD37 and anti-CD20 modalities could represent a novel dual immunotherapy approach for the treatment of these patients.

The rationale for a combination trial of Betalutin® and RTX was provided by preclinical data published in the *European Journal of Haematology* in July 2018 (Repetto-Llamazares, A.H.V. *et al.*). These data demonstrate that treatment with the combination of Betalutin® and RTX significantly prolonged overall survival in a murine model of NHL compared to treatment with either agent alone, possibly by reverting downregulation of CD20 and resistance to RTX.

In November 2018, the company reported that the first patient had been dosed in the Archer-1 trial. Archer-1 is a Phase 1b open-label, single-arm, multi-centre dose-escalation trial to assess the safety and preliminary activity of Betalutin® plus RTX in 20–25 patients with relapsed/refractory 2L FL. The trial is underway in Norway.

- Starting doses of Betalutin® and lilotomab are 10 MBq/kg and 40 mg/m², respectively, with the option to increase the Betalutin® dose to 15 MBq/kg
- Patients will receive Betalutin® followed by four weekly doses of RTX. Responding patients will go on to receive up to two years of maintenance RTX therapy
- The primary endpoint is safety, and secondary endpoints include ORR, DoR, PFS and OS

Data from Archer-1 is expected during the second half of 2020.

\*Reference: 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.

#### Phase 1 study with Betalutin® in DLBCL advances to next dosing level

A Phase 1 study evaluating Betalutin® in patients with R/R diffuse large B-cell lymphoma (DLBCL) (LYMRIT 37-05) is ongoing. DLBCL is an aggressive form of NHL and accounts for up to 43 percent of all cases, making it the most common type of NHL.

During the first half of 2018, the Safety Review Committee for the trial reviewed the data from the first two cohorts of patients and recommended proceeding with Betalutin® dose escalation to 15 MBq/kg, with a lilotomab pre-dose of 100 mg/m<sup>2</sup>.

Patients in these first two dosing cohorts received 10 MBq/kg Betalutin® following 60 mg/m² and 100 mg/m² lilotomab, respectively. Both dosing regimens were found to be well tolerated with no unexpected safety issues.

The company aims to finalise enrolment into the two, final dose-escalation cohorts in the first half of 2019, with the first data readout in the second half of 2019. A single dosing regimen is expected to be selected for further expansion into Phase 2 based on the findings from this study.

#### Encouraging preclinical results emerging from collaborative R&D project

In December, a poster reporting initial results from a research collaboration to develop a novel CD37-targeting alpha therapy for B-cell malignancies was presented at ASH.

The collaboration with Orano Med (formerly known as AREVA Med) is underway to develop and investigate a next-generation targeted alpha therapy comprising Nordic Nanovector's chimeric anti-CD37 antibody (NNV003) with lead-212 (212Pb), for the treatment of B-cell malignancies.

The preclinical studies investigated the dose-dependent efficacy and tolerability of <sup>212</sup>Pb-NNV003 in human cell and mouse models of chronic lymphocytic leukaemia (CLL) and Burkitt's lymphoma (a type of NHL). In the studies, <sup>212</sup>Pb-NNV003 was found to be well tolerated and led to a 90–100% survival rate in mouse models of CLL and NHL.

There is a strong scientific rationale for combining CD37-targeting approaches with other cytotoxic payloads, including radionuclides and toxins. CD37 is an important target for B-cell malignancies as it is selectively expressed on the surface of B-cell malignancies. Alpha-emitting radionuclides have demonstrated good potential for targeted cancer therapies because their high energy is limited to a very short distance (50–100  $\mu$ m, a few cell widths) resulting in localised cytotoxicity while sparing surrounding healthy tissues. The development of  $^{212}$ Pb-conjugated CD37-targeted alpha therapy therefore offers the potential to treat leukaemias and lymphomas where there is no substantial tumour mass and tumour cells are near healthy tissues.

Other research collaborations and projects investigating the potential of Nordic Nanovector's CD37-targeting approach with radionuclide and cytotoxic payloads are ongoing.

#### **Management and Board changes**

In June, Nordic Nanovector appointed Eduardo Bravo as its Chief Executive Officer. Mr Bravo brings more than 25 years' experience in the biopharmaceutical industry and a strong track record in leading and growing international biotech and pharmaceutical organisations. Most recently, he served as CEO of biopharmaceutical company TiGenix from 2012 until June 2018, prior to its acquisition by Takeda Pharmaceutical Co. Ltd announced in January 2018 for €520 million. At TiGenix, Mr Bravo led the development of the company through several successful financing rounds, as well as its NASDAQ IPO, and secured European marketing approval of its lead asset. He has also held several senior management positions at Sanofi-Aventis and SmithKline Beecham. Mr Bravo took up the CEO position at Nordic Nanovector on July 2<sup>nd</sup>.

The company made several other appointments to the senior management team during 2018 adding significant international experience and expertise to key functions. In February, Malene Brondberg joined as Vice President, Investor Relations and Corporate Communications; in June, Maureen Deehan, PhD, joined as Head of Corporate Development and Strategy; and in January 2019, the company appointed Dr Mark Wright as Head of Manufacturing.

At Board level, Rainer Boehm, MD, was elected as a Non-executive Director at the company's Annual General Meeting in May. Mr Boehm is an oncology expert with nearly 30 years' product development, commercial and corporate development experience working at Novartis, at which he oversaw the commercial launches of various oncology brands in the US and globally including Femara®, Zometa®, Glivec®, among others.

In January 2019, Jan H. Egberts, M.D. was nominated Chairman-elect, succeeding Ludvik Sandnes, who stepped down from the role and the Board. Dr Egberts was formally elected Chairman of the Board of Directors at an extraordinary general meeting held on February 18<sup>th</sup>, 2019. Dr Egberts brings over 25 years of experience in the pharmaceutical and medical devices sector, gained through business development and general management positions of increasing responsibility in the USA at Merck & Co. and Johnson & Johnson. He was also the CEO of Octoplus, a publicly listed company acquired by Dr Reddy's Laboratories. Dr Egberts is currently the Managing Partner of Veritas Investments, a family investment firm focused on investments in healthcare companies in the USA and Europe. He also serves as the Chairman of Photocure ASA (OSE; PHO) and on the board of Pharming (AEX; PHARM) as well as a number of privately held companies and foundations.

#### Financial review

The interim consolidated financial statements for Nordic Nanovector Group<sup>1</sup> as of December 31<sup>st</sup>, 2018 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 2017 unless stated otherwise)

Revenues in the fourth quarter of 2018 amounted to NOK 0.0 million (NOK 0.05 million), the Company has terminated an agreement for sales of incubator services and sublease of office and laboratory facilities. Revenues for the fiscal year 2018 were NOK 0.0 million (NOK 0.3 million).

Total operating expenses for the quarter came to NOK 96.3 million (NOK 102.0 million). Payroll and related expenses were NOK 23.1 million (NOK 24.2 million). Costs from an increased number of employees were partly offset by reduced non-cash costs related to granted options. Other expenses amounted to NOK 72.6 million during the quarter (NOK 77.2 million). Lower spending in the quarter compared to Q4 2017 due to the decision in 2018 to put Humalutin® project on hold. Total operating expenses for the fiscal year 2018 increased to NOK 340.0 million (NOK 316.8 million), primarily reflecting higher operational activities.

Research and development (preclinical, clinical, medical affairs, regulatory and CMC activities) expenses accounted for 76.0 % of total operating expenses in the fourth quarter of 2018 (69.5 %) and 73.9 % in the fiscal year 2018 (70.8 %).

Operating loss for the quarter was NOK 96.3 million (loss of NOK 101.9 million), for the reasons stated above. Operating loss for the fiscal year 2018 was NOK 340.0 million (loss of NOK 316.5 million).

Net financial items for the quarter came to NOK 7.8 million (NOK 16.0 million), mainly reflecting the effect of currency fluctuations on bank deposits and interest income. Net financial items for the fiscal year 2018 amounted to NOK 3.0 million (NOK 23.1 million), driven by currency fluctuations on bank deposits as well as interest income.

Nordic Nanovector's comprehensive loss for the quarter amounted to NOK 87.7 million (loss of NOK 87.6 million), due to the reasons stated above. Comprehensive loss for the fiscal year 2018 was NOK 336.8 million (NOK 295.6 million).

#### **Financial position**

Total assets at December 31<sup>th</sup>, 2018, amounted to NOK 473.6 million, down from NOK 780.5 million at December 31<sup>st</sup>, 2017. The decline was primarily due to a lower cash holding following operational activities.

Total shareholders' equity at December 31<sup>st</sup>, 2018, was NOK 363.2 million (NOK 679.6 million at year end 2017), corresponding to an equity ratio of 76.7% (87% at year-end 2017).

Total liabilities at the end of the fourth quarter were NOK 110.4 million, up from NOK 100.9 million from year-end 2017, driven by increase of accounts payable and cost accruals.

#### Cash flow

Net cash flow from operating activities in the fourth quarter was negative NOK 77.6 million (negative NOK 66.7 million), mainly reflecting the impact of higher research and development activities and fluctuations in the working capital.

Net cash flow from operating activities in the fiscal year 2018 was negative NOK 326.6 million (negative NOK 249.4 million) due to higher operational activities.

Net cash flow from investing activities in the fourth quarter and fiscal year 2018 was NOK 4.3 million (NOK 5.2 million) and NOK 2.4 million (NOK 3.3 million) respectively, primarily related to received interest on bank deposits.

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

Net cash flow from financing activities for the fourth quarter of 2018 was NOK 6.4 (NOK 0 million). Net cash flow from financing activities for the fiscal year 2018 amounted to NOK 8.6 million (negative NOK 32.6 million), respectively caused by exercise of share options.

Exchange rate fluctuations in the fourth quarter had a positive impact on cash and cash equivalents of NOK 7.4 million (NOK 14.3 million). The corresponding figure for the fiscal year 2018 was a negative impact of NOK 0.9 million (positive NOK 17.1 million).

Cash and cash equivalents amounted to NOK 440.1 million at the end of December 2018, compared to NOK 499.7 million at the end of September 2018 and NOK 756.6 million at the end of December 2017.

#### New funds raised

The Company announced on January 25<sup>th</sup>, 2019 that it has raised approximately NOK 222 million (USD 26 million) in gross proceeds through a private placement of 4 943 094 new shares. The private placement was completed at a subscription price of NOK 45 per share, which was determined through an accelerated book-building process. The private placement, which was oversubscribed, attracted strong interest from both existing shareholders and new institutional investors, Norwegian as well as international.

Nordic Nanovector intends to use the net proceeds of the private placement for the following purposes:

- Manufacturing development activities (including process validation studies) for Betalutin®
- A scale-up of the Company's clinical and commercial activities in preparation for a commercial launch of Betalutin®
- General corporate purposes

The Company's Board of Directors resolved to carry out a repair offering of up to 777 777 new shares, to raise gross proceeds of approximately NOK 35 million (USD 4 million). This was approved by the Company's extraordinary general meeting February 18<sup>th</sup>, 2019.

#### **Risks and uncertainties**

Nordic Nanovector is currently in a development phase involving activities which entail exposure to various risks. Nordic Nanovector's strategy is to continuously identify and manage risks. There are no significant changes in the risk factors which are described in the annual Report for 2017 and published on the Company's website: www.nordicnanovector.com

## Outlook

Nordic Nanovector aspires to become a leader in the field of targeted therapies for haematological cancers by developing, manufacturing and commercialising innovative therapies to address major unmet medical needs and advance cancer care.

Betalutin®, the company's most advanced product candidate, has a highly differentiated, competitive, clinical profile for R/R FL, based on the promising results from the LYMRIT 37-01 Phase 1/2 clinical study. The company's pivotal Phase 2b PARADIGME trial with a once-only administration of Betalutin® in 3L R/R FL is underway with the initial clinical data read-out targeted for 1H 2020 and subsequent filing in 2020 for marketing approval.

Nordic Nanovector intends to maximize the value of Betalutin® and other CD37-targeting opportunities across other stages of FL, NHL and other haematological cancer indications.

The company is confident that Betalutin® could become an attractive and convenient therapeutic option, which, based on detailed market research, has the potential to be commercially successful.

Current cash resources are expected to be sufficient to reach data read-out from PARADIGME in the first half of 2020.

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

Amounts in NOV 1 000	Note Fourth C		Quarter	Full	Year
Amounts in NOK 1 000	Note	2018	2017	2018	2017
					000
Revenues		0	50	0	302
Total revenues		0	50	0	302
Payroll and related expenses	4, 5, 6	23 113	24 239	79 208	80 609
Depreciation		606	543	2 252	1 483
Other operating expenses	4, 6	72 598	77 187	258 553	234 732
Total operating expenses		96 317	101 969	340 013	316 824
Operating profit (loss)		-96 317	-101 919	-340 013	-316 522
Net finance income (expense)	9	7 828	16 047	3 041	23 089
Loss before income tax		-88 489	-85 872	-336 972	-293 433
Income tax		-256	-64	-800	-381
Loss for the period		-88 745	-85 936	-337 772	-293 814
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 subsequent periods  Re-measurement gains (losses) on defined benefit plans		404 633	146 -1 839	369 633	-1 839
Total comprehensive income (loss) for the period		-87 708	-87 629	-336 770	-295 567
Loss for the period attributable to owners of the company		-88 745	-85 936	-337 772	-293 814
Total comprehensive income (loss) for the period attributable to owners of the company		-87 708	-87 629	-336 770	-295 567
Earnings (loss) per share Basic and diluted earnings (loss) per share in NOK	8	-1.80	-1.75	-6.88	-5.99

# Interim condensed consolidated statement of financial position Nordic Nanovector Group

Amounts in NOK 1 000	Note	December 31 <sup>st</sup> , 2018	December 31st, 2017
ASSETS			
Non-current assets			
Property, plant and equipment		4 082	4 174
Total property, plant and equipment		4 082	4 174
Current assets			
Receivables			
Other current receivables	4	29 435	19 726
Total receivables		29 435	19 726
Cash and cash equivalents		440 069	756 571
Total current assets		469 504	776 297
TOTAL ASSETS		473 586	780 471
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	7	9 886	9 809
Share premium	7	593 399	1 434 896
Other paid in capital	5, 6	56 320	44 551
Accumulated losses		-296 412	-809 642
Total shareholders' equity		363 193	679 614
Liabilities			
Non-current liabilities			
Net employee defined benefit liabilities		3 371	3 619
Total non-current liabilities		3 371	3 619
Current liabilities			
		24.040	29 317
Accounts payable		34 040	29 317
Tax payable Other current liabilities			
		72 178	67 454
Total liabilities		107 022	97 238
Total liabilities  TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		110 393 473 586	100 857 780 471

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

For the period ended December 31st, 2	2018							
Amounts in NOK 1 000	Note	Share capital	Share premium	Equity-settled share-based payments	Accumulated losses	Translation effects	Remeasure- ment gains (losses)	Total equity
Balance at January 1 <sup>st</sup> , 2017		9 795	1 433 743	19 826	-513 623	-452	0	949 289
Loss for the year					-293 814			-293 814
Other comprehensive income (loss) for the year net of income tax						86	-1 839	-1 753
Total comprehensive income for the year		0	0	0	-293 814	86	-1 839	-295 567
Recognition of share-based payments	5, 6			24 725				24 725
Issue of ordinary shares	7	0	0					0
Issue of ordinary shares under share options	5, 7	14	1 613					1 627
Share issue costs	7		-460					-460
Balance at December 31 <sup>st</sup> , 2017		9 809	1 434 896	44 551	- 807 437	-366	-1 839	679 614
Loss for the period					-337 772			-337 772
Other comprehensive income (loss) for the year, net of income tax						369	633	1 002
Total comprehensive income for the period		0	0	0	-337 772	369	633	-336 770
Recognition of share-based payments	5, 6			11 769				11 769
Issue of ordinary shares under share options and RSUs	5, 6, 7	77	8 599					8 676
Share issue costs			-96					-96
Reclassification of accumulated losses			-850 000		850 000			
Balance at December 31 <sup>st</sup> , 2018		9 886	593 399	56 320	-295 209	3	-1 206	363 193

# Interim condensed consolidated statement of cash flow Nordic Nanovector Group

Amounts in NOK 1 000	Note	Fourth Quarter		Full '	Year
		2018	2017	2018	2017
Cash flow from operating activities					
Loss for the period before income tax		-88 489	-85 872	-336 972	-293 433
Adjustments for:					
Interest received		-4 368	-5 735	-4 570	-5 846
Share option and PSU expenses employees	5	3 837	5 673	10 271	23 428
Restricted share units (RSUs) expenses	6	407	350	1 498	1 297
Taxes paid		-121	-9	-487	-291
Depreciation		606	543	2 252	1 483
Currency (gains) losses not related to operating activities		-7 357	-14 306	866	-17 086
Changes in working capital and non-cash adjustments		17 863	32 687	515	41 018
Net cash flow from operating activities		-77 622	-66 669	-326 627	-249 430
Cook flow from investing activities					
Cash flow from investing activities					
Investments in property, plant and equipment and intangible assets		-56	-536	-2 159	-2 513
Interests received		4 368	5 735	4 570	5 846
Net cash flow from investing activities		4 312	5 199	2 411	3 333
Cook flows from financing activities					
Cash flows from financing activities  Net proceeds from equity issue	7	6 372	0	8 580	-32 635
	,				
Net cash flow from financing activities		6 372	0	8 580	-32 635
Effects of exchange rate changes on cash and cash equivalents		7 357	14 306	-866	17 086
Net change in bank deposits, cash and equivalents		-59 581	-47 164	-316 502	-261 646
Cash and equivalents at beginning of period		499 650	803 735	756 571	1 018 217
Cash and equivalents at end of period		440 069	756 571	440 069	756 571

# Notes to the condensed interim financial statements for the fourth quarter 2018

#### 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 fourth quarter 2018 report are non-audited figures.

These financial statements were approved for issue by the board of directors on February 26<sup>th</sup>, 2019.

#### 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 2017. 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>, 2018, and Norwegian disclose requirements listed in the Norwegian Accounting Act. The interim consolidated condensed 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.

#### Standards issued but not yet effective

IFRS 16 Leases is effective for annual periods beginning on or after January 1st, 2019, with early application permitted. The Group adopted the new standard on the required effective date using the modified retrospective method. The new standard has on implementation impacted the accounting of the lease agreements for office facilities and office machines in Oslo, which according to the new standard is classified as a "right to use asset" with a corresponding liability in the statement of financial position. The "right to use asset" is depreciated over estimated time of use (leasing term). The implementation of IFRS 16 increases the value of total assets by NOK 6.6 million and associated liability by the same amount, split into short-term and long-term debt of NOK 1.5 and NOK 5.1 million, respectively. If IFRS 16 was implemented as per December 31st, 2018 the equity ratio would have changed from the reported 76.7% to 75.6%.

#### 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>, 2017.

## 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	Fourth (	Quarter	Year to date		
Amounts in NOR 1 000	2018 2017		2018	2017	
Payroll and related expenses	482	-179	2 502	2 532	
Other operating expenses	4 211	4 148	9 308	11 691	

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

Amounts in NOK 1 000	December 31 <sup>th</sup> , 2018	December 31 <sup>st</sup> , 2017
Grants receivable	7 827	9 350

- 1) In 2016, the company received a new grant 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 is from 2016 to August 2019. The purpose of the grant is to support research and development of novel targeted therapeutics for leukaemia and NHL. The grant will be distributed to the company over the course of three years and eight months. For the financial period ended December 31<sup>th</sup>, 2018, the company has recognised NOK 3.5 million (as of December 31<sup>st</sup>, 2017: NOK 5.0 million) classified partly as a reduction of payroll and related expenses, and partly as a reduction of other operating expenses.
- 2) R&D projects have been approved for SkatteFUNN grants for the period 2017 through 2020. For the financial period ended December 31<sup>st</sup>, 2018, the company has recognised NOK 7.5 million compared to NOK 7.4 million for the same period in 2017. The amount was recognised partly as a reduction of payroll and related expenses and partly as a reduction of other operating expenses.
- 3) 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 December 31st, 2018, the company recognised NOK 0.7 million (December 31st, 2017: NOK 0.7 million) as a reduction of payroll and related expenses, and partly as a reduction of other operating expenses.
- 4) The Research Council Eurostars awarded a grant supporting a collaboration research agreement with Affibody AB for the period 2014 through 2017 of NOK 4 million in total. For the financial period ended December 31st, 2017, the company recognised NOK 1.0 million partly as a reduction of payroll and related expenses, and partly as a reduction of other operating expenses. The company has decided to discontinue the Affilutin project considering the current challenging market landscape in multiple myeloma, and concentrated efforts and resources on other leading discovery projects

# Note 5. Employee share incentive programme

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

The Board of Directors of Nordic Nanovector ASA has on January 29<sup>th</sup>, 2018 decided to grant 216 550 PSUs to current and newly hired employees. In April and July 2018, an additional 285 000 PSUs was granted to newly hired employees, of which 250 000 was granted the new CEO.

## **Overview of outstanding PSUs**

Amounts in NOK	Full Year 2018
	Number of PSUs
Balance at January 1st, 2018	0
Granted during the year	501 550
Exercised during the year	0
Forfeited	-40 300
Balance at December 31st, 2018	461 250
Hereof vested PSUs	0

For further information about the PSU programme see note 13 to the company's annual accounts included in the company's annual report for 2017 and note 10 in this report.

#### **Share options**

# **Overview of outstanding options**

	Year to date 2018			
Amounts in NOK	Number of options	Weighted average exercise price		
Balance at January 1st, 2018	3 482 843	42.20		
Granted during the year	0	0		
Exercised during the year	-380 508	22.80		
Forfeited	-443 161	53.46		
Balance at December 31st, 2018	2 659 174	43.09		
Hereof vested options	2 153 144	37.47		

For further information about the share option programme see note 13 to the company's annual accounts included in the company's annual report for 2017.

# Note 6. Restricted Stock Units (RSUs)

At the annual general meeting held on May 30<sup>th</sup>, 2018, 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 2018 to the annual general meeting in 2019, in the form of RSUs.

A total of 29 412 RSUs have thus been allocated following the annual general meeting held on May  $30^{th}$ , 2018. The RSUs will vest on May  $30^{th}$ , 2019.

In July 2018, three of the board members of Nordic Nanovector ASA, Gisela Schwab, Joanna Horobin and Jean-Pierre Bizzari, resolved to settle a total number of 6 035 RSUs that were issued to them in June 2017.

#### **Overview of outstanding RSUs**

Amounts in NOK	Full year 2018
Amounts in NOR	Number of RSUs
Balance at January 1st, 2018	45 014
Granted during the year	29 412
Exercised during the year	-6 035
Forfeited	0
Balance at December 31st, 2018	68 391
Hereof vested RSUs	38 979

For further information about the RSU programme see note 12 to the company's annual accounts included in the company's annual report for 2017.

# Note 7. Share capital and shareholder information

The share capital as at December 31<sup>st</sup>, 2018 is NOK 9 886 189 (December 31<sup>st</sup>, 2017: NOK 9 808 880), being 49 430 945 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	December 31st, 2018	December 31st, 2017
Ordinary shares at beginning of the period		49 044 402	48 974 618
Issue of ordinary shares under share options	5	380 508	56 525
Issue of ordinary shares under RSUs	6	6 035	13 259
Ordinary shares at end of the period		49 430 945	49 044 402

The annual general meeting held on May 30<sup>th</sup>, 2018 (the "AGM") approved the company's share-based incentive programme and authorised the board of directors to grant up to 600 000 PSUs to the company's employees. The AGM further resolved to issue up to 600 000 to free-standing warrants to employees that were awarded PSUs.

# Nordic Nanovector ASA had 8 276 shareholders as at December 31st, 2018

	Shareholders	Number of shares	Percentage of total shares
1	HealthCap VI L.P.	5 445 833	11.02 %
2	Folketrygdfondet	2 896 506	5.86 %
3	OM Holding AS	2 411 883	4.88 %
4	Nordnet Livsforsikring AS	1 423 259	2.88 %
5	State Street Bank and Trust Comp	1 128 867	2.28 %
6	Linux Solutions Norge AS	845 071	1.71 %
7	Sciencons AS (Roy Hartvig Larsen)	720 000	1.46 %
8	Radiumhospitalets Forskningsstiftelse	689 518	1.39 %
9	Must Invest AS	625 000	1.26 %
10	Inven2 AS	541 247	1.09 %
11	VPF Nordea Avkastning	508 251	1.03 %
12	Roy Hartvig Larsen	454 801	0.92 %
13	Ro Invest AS	450 000	0.91 %
14	Birk Venture AS	425 000	0.86 %
15	JP Morgan Securities PLC	419 712	0.85 %
16	VPF Nordea Kapital	367 807	0.85 %
17	KLP Aksje Norge	300 000	0.61 %
18	Statoil Pensjon	277 701	0.57 %
19	Nordnet Bank AB	264 683	0.54 %
20	Citibank, N.A	247 636	0.50 %
	Total shares for top 20 shareholders	20 442 775	41.36 %
	Total shares for other 8 256 shareholders	28 988 170	58.64 %
	Total shares (8 276 shareholders)	49 430 945	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	Full Year 2018	Full Year 2017
Loss for the period	-337 772 000	- 293 814 000
Average number of outstanding shares during the year	49 114 764	49 030 654
Earnings (loss) per share - basic and diluted	-6.88	-5.99

Share options 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	Fourth Quarter		Full year	
Amounts in NOR 1 000	2018	2017	2018	2017
Finance income	1 074	1 303	4 584	5 899
Finance expenses	1	9	2	10
Net currency gains (losses) on cash and cash equivalents	7 357	14 306	-866	17 086
Net other currency gains (losses) related to operating items	-602	447	-675	114
Net finance income (expense)	7 828	16 047	3 041	23 089

#### Note 10. Subsequent events

#### **Private placement**

On January 25<sup>th</sup>, 2019 the company raised NOK 222.4 million in gross proceeds through a private placement of 4 943 094 new shares. The Private Placement was completed at a subscription price of NOK 45 per share, which was determined through an accelerated book-building process. Following registration of the new share capital pertaining to the Private Placement in the Norwegian Register of Business Enterprises, which took place on January 30<sup>th</sup>, 2019, the company have an issued share capital of NOK 10 874 807.80, divided into 54 374 039 shares, each with a par value of NOK 0.20.

#### **Allocation of PSUs**

The Board of Directors of Nordic Nanovector ASA has on January 31<sup>st</sup>, 2019 decided to grant 259 000 Performance Share Units ("PSUs") to employees in accordance with the authorisation granted at the Annual General Meeting held on May 30<sup>th</sup>, 2018. The PSUs are granted without consideration. The PSUs are non-transferable and will vest three years after the date of grant subject to satisfaction of the applicable vesting conditions. Each vested PSUs will give the holder the right to acquire one share in the Company at an exercise price corresponding to the par value of the shares being NOK 0.20.

Of the 259 000 allocated PSUs, 205 000 PSUs have been granted to members of the company's executive management, 28 000 PSUs have been granted to new employees and 26 000 PSUs have been granted to other current employees. The total number of outstanding options and PSUs are as of February 26<sup>th</sup>, 2019, 2 659 174 and 720 250 respectively. Subject to all vesting conditions being fulfilled exercise of the options and PSUs would create a 5.9 % dilution of the outstanding shares on a fully diluted basis.

#### **Extraordinary general meeting**

The extraordinary general meeting February 18<sup>th</sup>, 2019 approved the authorisation to the Board of Directors to increase the share capital in connection with the repair offering as announced on January 25<sup>th</sup>, 2019, and the election of Dr Jan H. Egberts as new chairman of the board of directors.

## Additional information

## Glossary of terms

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

(A)SCT: (Autologous) stem cell transplant

ADC: Antibody-Drug-Conjugate AHCP: Allied Healthcare Professional AML: Acute Myeloid Leukemia

ARC: Antibody-Radionuclide-Conjugate

ARCHER-1: Name of Nordic Nanovector's combination study;

Betalutin® and rituximab

ASH: American Society of Hematology

Authorized User: Physician authorized to prescribe and administer

a radiopharmaceutical drug

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

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

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)

FDG PET/CT: Positron emission tomography with 2-deoxy-2-[fluorine-18] fluoro- D-glucose integrated with computed tomography

FL: Follicular Lymphoma

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

**HCP:** Healthcare Professional

HH1: Lilotomab

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

iNHL: Indolent non-Hodgkin Lymphoma

KI: Kinase Inhibitor KOL: Key Opinion Leader LCM: Life-cycle management

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

Medicare: US government reimbursement programme for insured

elderly

MedOnc: Medical oncologist MoA: Mechanism of Action MSL: Medical science liaison

nASCT: Not eligible for autologous stem cell transplant

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 study

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

RadOnc: Radiation oncologist

R-Benda/R-B/RB: Rituximab, bendamustine

R-Chemo: Combination treatment consisting of rituximab plus one (i.e., bendamustine, fludarabine) or more (i.e., CHOP, CVP)

chemotherapy agents

R-CHOP: Rituximab, hydroxydaunorubicin (doxorubicin), oncovin (vincristine), prednisolone

**RIT:** Radioimmunotherapy

R-CVP: Rituximab, cyclophosphamide, vincristine, prednisone

R-Squared: Combination treatment consisting of rituximab plus

SAB: Scientific Advisory Board

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

TKI: Tyrosine Kinase Inhibitor TPP: Target Product Profile

US: United States

#### **Financial calendar**

Q4 2018 results: February 27<sup>th</sup>, 2019

Annual General meeting: April 25<sup>th</sup>, 2019

Q1 2019 results: May 23<sup>rd</sup>, 2019

Half-yearly results: August 22<sup>nd</sup>, 2019

Q3 2019 results: November 21<sup>st</sup>, 2019

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

In accordance with its new corporate disclosure policies, the company has introduced 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.

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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 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 29 billion by 2026. Nordic Nanovector intends to retain marketing rights and to actively participate in the commercialisation of Betalutin® in core markets. Further information can be found at www.nordicnanovector.com.