

# Third Quarter Report 2016 Nordic Nanovector ASA





### Q3'16 Highlights

- Lymrit 37-01 clinical study with Betalutin® in FL on track
  - Completed recruitment of the first cohorts of Arm 3 and Arm 4 investigating Betalutin® treatment with two different pre-dosing regimens

#### Events after Q3'16

- Safety Review Committee for Lymrit 37-01 trial recommended:
  - o Progress Arm 4 at 20 MBq/kg Betalutin® with 100mg/m² lilotomab
  - Change treatment regimen in Arm 1/Phase 2 to match that used in Arm 4, pending confirmation of safety from Arm 4 and approval of protocol amendment
  - o Discontinue Arm 3
- Latest available results from Lymrit 37-01 to be presented at the 58<sup>th</sup> American Society of Hematology Annual Meeting on December 3<sup>rd</sup>
  - o Safety, efficacy and duration of response data from all evaluable NHL patients to be reported
- Further progress on pipeline
  - o Entered into R&D collaborations with LegoChem Biosciences and Heidelberg Pharma to explore potential of ADCs with non-radionuclide payloads for the treatment of leukaemias
- New members join Executive Management Team and Board of Directors
  - o Dr Lisa Rojkjaer, MD, joins as Chief Medical Officer
  - o Dr Joanna Horobin, MD, elected as Non-executive Director

#### **Key figures**

Amounts in MNOK	Third Quar	ter	Year to da	ite	Full Year
(except earnings/loss per share)	2016	2015	2016	2015	2015
Total revenue	0.1	0.1	0.2	0.3	0.4
Total operating expenses	50.4	63.0	151.3	150.1	183.5
Operating profit (loss)	-50.3	-62.9	-151.1	-149.8	-183.1
Net financial items	-10.6	2.4	-24.9	7.9	10.4
Total comprehensive income (loss) for the period	-61.3	-60.7	-176.5	-142.1	-173.1
Basic and diluted earnings (loss) per share	-1.37	-1.36	-3.95	-3.63	-4.28
Number of employees	29	29	29	29	26
Net change in bank deposits, cash and equivalents	-58.3	-47.7	-183.3	432.5	406.3
Cash and equivalents at beginning of period	618.4	817.1	743.4	337.0	337.0
Cash and equivalents at end of period	560.1	769.5	560.1	769.5	743.4

The ongoing Lymrit 37-01 clinical trial for Nordic Nanovector's lead product candidate, Betalutin®, has reached a new important milestone with the SRC recommendation to test a higher dosing regimen. The new dosing regimen has the potential to provide both an even better efficacy and an improved safety for treatment of 3<sup>rd</sup> line FL with Betalutin®. Patient recruitment into the Phase 1/2 study is on track to enable the decision on the optimal dosing regimen for the pivotal Phase 2 PARADIGME trial in the first quarter of 2017. Updated results from the Phase 1/2 trial will be presented at the ASH annual meeting on 3<sup>rd</sup> December.

As part of its strategy to broaden and diversify its pipeline, the company continues to leverage its expertise in the field of antibody conjugates and has initiated additional R&D activities, supported by complementary technologies from expert partners. The collaboration agreements with LegoChem and Heidelberg Pharma are in line with the execution of this strategy and follow similar collaborations in the ARC area in the second quarter.

#### Operational review

#### Phase 1/2 trial (Lymrit 37-01) enters final stage

Significant progress continued to be made in the Lymrit 37-01 trial during the year. The study has now entered its final stage: two remaining active arms (Arm1 /Phase 2 and Arm 4) aim to investigate the safety and efficacy of a new higher dosing regimen of 20 MBq/kg Betalutin® following pre-dosing with 100 mg/m² lilotomab. The company believes that the results from these arms, combined with results from the trial overall, will enable the selection of the final dosing regimen for pivotal Phase 2 PARADIGME trial by the end of the first quarter 2017.

Lymrit 37-01 is a Phase 1/2 open label, single injection ascending dose study with four different treatment arms to investigate various Betalutin® doses and pre-dosing regimens in patients with relapsed/refractory non-Hodgkin lymphoma (NHL), predominantly follicular lymphoma (FL) (see chart below).

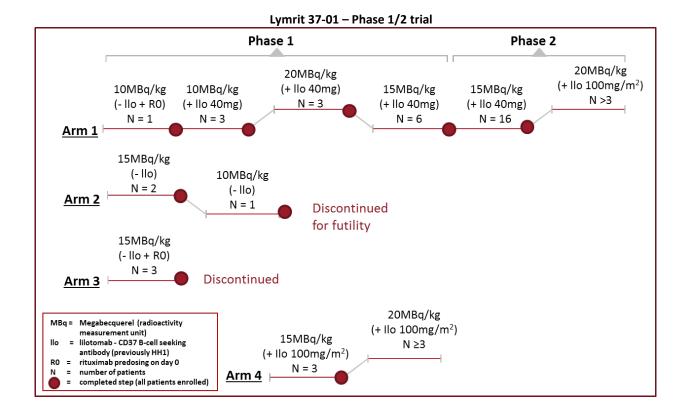
In October, the Safety Review Committee (SRC) reviewed the results of the interim analysis based on 15 patients with relapsed/refractory FL treated with 15 MBq/kg Betalutin® and pre-dosed with 40 mg lilotomab. In November, the SRC conducted a follow-up review of the available safety and dosimetry data from the first cohorts of three patients each enrolled in Arms 3 and 4 to determine which arm should continue, if dose escalation is warranted and to what extent. Patients in Arm 3 were pre-dosed with standard rituximab immunotherapy prior to receiving 15 MBq/kg Betalutin®; patients in Arm 4 received 100 mg/m² lilotomab prior to 15 MBq/kg Betalutin®.

As a result of these reviews, the SRC recommended escalating the Betalutin® dose in Arm 4 from 15 MBq/kg to 20 MBq/kg following pre-dosing with 100 mg/m² lilotomab. The SRC also concluded that Arm 3 should be discontinued due to a less favourable clinical profile.

An important reason for the SRC to recommend advancing Arm 4 is that the generated safety data demonstrate that pre-dosing with 100 mg/m² lilotomab prior to Betalutin® reduces bone marrow toxicity as a result of lower absorbed radiation to this tissue. In addition, available dosimetry data from Arm 4 showed that higher pre-dosing does not prevent therapeutically relevant amounts of Betalutin® being absorbed into the tumours. Dose escalation to the new higher regimen therefore allows the company to test a higher and potentially more efficacious dose of Betalutin® following increased pre-dosing with lilotomab.

The SRC has agreed that the company can change the treatment regimen used in Arm 1/Phase 2 to match that used in Arm 4. The dose of Betalutin® specified in Phase 2 will be increased from 15 MBq/kg to 20 MBq/kg pending review of the safety data from the first three patients treated in Arm 4 with 20 MBq/kg.

Escalation to the new higher dosing regimen in Arm 1/Phase 2 will require the approval of a protocol amendment by the European regulators. The planned amendment will allow for additional patients to be enrolled into Arm 1/Phase 2, which is expected to contribute to building a more robust safety database, particularly with data from patients receiving the new higher dosing regimen.



A dosimetry study, designed to provide additional information about absorbed radiation collected in the 37-01 study, has been approved in Germany by the German Radiation Agency (BfS). The study is expected to run in parallel with PARADIGME and to be initiated in 2017.

#### Updated clinical results with Betalutin® in follicular lymphoma

The most recent clinical results from the ongoing Lymrit 37-01 study from 21 evaluable patients (at the time) were presented in April at the American Association of Cancer Research (AACR) Annual Meeting. Updated safety and efficacy results (including duration of response) from all evaluable patients in the trial will be presented in a poster at the 58<sup>th</sup> American Society of Hematology (ASH) Annual Meeting, on 3<sup>rd</sup>- 6<sup>th</sup> December in San Diego, CA (abstract 1780).

The previous results, presented at AACR, from 21 patients confirmed the favourable safety profile of Betalutin® and its promising efficacy as a single agent in NHL patients who have failed several prior treatments regimens. Key conclusions from AACR were:

- Betalutin® is well tolerated, with a predictable and manageable safety profile. Most adverse events are haematological in nature, all transient and reversible.
- Betalutin® delivers a highly favourable response rate (best response) in this heavily treated patient population (ORR 63.2% and CR 31.6%).
- Clinical responses observed were sustained, with DoR exceeding 12 months in most responders in the 15 MBq/kg group who have been followed up for at least 12 months.

These results – from patients receiving three different doses of Betalutin® (10 MBq/kg, 15MBq/kg, 20 MBq/kg) with (n=19) or without (n=2) pre-dosing with 40mg lilotomab – are very encouraging, and demonstrate the potential of Betalutin® to provide a strong clinical profile as a single agent therapy, and therefore, a relevant and highly competitive new option for FL patients.

#### Investigating Betalutin® in a second NHL indication

Nordic Nanovector aims to maximise the commercial potential of Betalutin® by conducting clinical studies in other types of haematological malignancies, and is preparing to initiate the first clinical study in a second NHL indication, diffuse large B-cell lymphoma (DLBCL).

DLBCL and FL are the two most common forms of NHL accounting for approximately 60 percent of cases. At first, the company plans to investigate Betalutin® in relapsed DLBCL patients ineligible for stem cell transplant. This represents the most prevalent relapsed DLBCL patient population and the one with the greatest unmet medical need with a market value estimated at over USD 4.5 billion by 2024.

The clinical study (called "Lymrit 37-05") is a Phase 1 open label, single injection, ascending dose study that aims to investigate various Betalutin® doses and lilotomab pre-dosing regimens in up to 24 patients in the US and Europe. The objective of the study, like Lymrit 37-01, is to identify the optimal dose regimen to take into Phase 2.

Prof. Timothy Illidge at The Christie NHS Foundation Trust in Manchester, UK, and Co-Chair of Nordic Nanovector's Scientific Advisory Board, is the Principal Investigator for the trial. The first of up to 11 sites at which the trial will take place, have been activated. The first patient is expected to be enrolled and dosed by the end of 2016 and the first read out is expected in the first half 2018.

#### Pipeline development - research and development update

While Nordic Nanovector's main focus is on its clinical development programmes, the company (with its academic partners) is undertaking further research to better characterise the mechanism of action, dosimetry and biodistribution of Betalutin®. Nordic Nanovector is also conducting its own R&D to investigate the potential of Betalutin® in combination with rituximab, and with its chimeric anti-CD37 antibody (NNV003) in various types of NHL.

Studies are advancing and, in October, three presentations in these areas were made at the European Association of Nuclear Medicine (EANM) conference, as follows:

- An analysis showing that pre-dosing with unlabeled anti-CD37 antibody (lilotomab) has the effect of reducing the absorbed dose in red bone marrow and hence reducing toxicity of Betalutin® in NHL patients;
- An investigation of the mechanism of action of Betalutin® demonstrated that the uptake of Betalutin® into tumour cells was more efficient than the uptake of Lu177-labeled rituximab and cetuximab in different NHL cell lines; and
- An investigation in preclinical lymphoma and leukaemia models confirming the therapeutic potential of the unlabeled and <sup>177</sup>Lu-labelled chimeric anti-CD37 antibodies and the rationale for further studies with these candidates.

Furthermore, a poster to be presented at the ASH annual meeting in December, will describe the synergistic therapeutic effect of combining Betalutin® and rituximab in a preclinical model of NHL (abstract 4189). These studies build on previously presented data showing that the treatment with Betalutin® increased binding of rituximab to NHL cells and uptake of rituximab in NHL tumours. The combination treatment resulted in 90-100 % survival for 150 days after treatment, while each treatment alone gave 10-40 % survival.

Nordic Nanovector's broader strategy is to expand its pipeline of targeted therapies, by leveraging its expertise alongside partners' complementary technologies to create opportunities for innovative pipeline products with other radionuclide and non-radionuclide payloads as tumour-killing agents.

Earlier in 2016, the company initiated collaborations with AREVA Med and Paul Scherrer Institute to develop ARCs targeting leukaemias. During the third quarter of 2016, Nordic Nanovector entered further research collaborations with LegoChem Biosciences and Heidelberg Pharma to explore the potential of antibody-drug conjugates (ADCs) including tumour-targeting antibodies conjugated to anti-cancer compounds that are not radionuclides. These agreements are focused on developing ARCs and ADCs for treating types of leukaemia, which are orphan diseases with a significant unmet medical need, representing a growing market estimated to be worth over USD 5 billion by 2020.

#### **Senior Management and Board strengthened**

The company is pleased to welcome Dr Lisa Rojkjaer, MD, who joined as Chief Medical Officer (CMO) and as a member of the Executive Management Team on November 15<sup>th</sup>. Dr Rojkjaer is a board-certified haematologist with more than 15 years of global and regional clinical development and medical affairs expertise in the biotech and pharma industry, where she developed an extensive experience in the development of both biologics and small molecules in haematology and immunology. She joins Nordic Nanovector from Novartis Pharmaceuticals where she held the position of Global Clinical Program Head, Oncology Global Development. She has also held the roles of CMO at Molecular Partners (Switzerland), Vice President, Head of Clinical Development at Morphosys AG (Germany), and Head of Global Medical Affairs, Biopharmaceuticals and Director of Clinical Development, Hematology in the US for Novo Nordisk. Dr Rojkjaer will lead all clinical development activities at Nordic Nanovector and support the company's efforts to identify opportunities to expand its pipeline.

At the company's Extraordinary General Meeting (EGM) in October, Dr Joanna Horobin, MD, was elected to Board as Non-executive Director. Dr Horobin replaces Dr Renee P Tannenbaum who stepped down from the Board of Directors for personal reasons. Dr Horobin has comprehensive experience within the biopharmaceutical industry focusing on the development and regulatory strategy as well as the execution of clinical trial programmes for novel cancer therapies. In addition, she has played significant leadership roles in the approvals and launches of several successful products including Taxotere® (docetaxel) in breast cancer and Campto/ Camptosar® (CPT11) for colorectal cancer.

#### Financial review

The interim consolidated financial statements for Nordic Nanovector Group<sup>1</sup> as of September 30<sup>th</sup> 2016 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 2015 unless stated otherwise)

Revenues in the third quarter of 2016 amounted to NOK 0.078 million (NOK 0.076 million), primarily consisting of sales of incubator services and sublease of office and laboratory facilities. Revenues for the first nine months of 2016 were NOK 0.235 million (NOK 0.294 million).

Total operating expenses for the quarter came to NOK 50.4 million (NOK 63.0 million). Payroll and related expenses rose to NOK 16.7 million (NOK 15.7 million) mainly due to an increase in social security accruals related to granted options. Other expenses declined to NOK 33.4 million during the quarter (NOK 47.1 million) mainly as a result of a high level of clinical trial activity related to the ramp up of PARADIGME during the third quarter of 2015. Total operating expenses for the first nine months of 2016 was NOK 151.3 million (NOK 150.1 million), in line with the same period last year.

Research and development (preclinical, clinical, regulatory and CMC activities) expenses accounted for 73% of total operating expenses in the third quarter of 2016 (81 %) and 71 % in the first nine months of 2016 (73 %).

Operating loss for the quarter was NOK 50.3 million (loss of NOK 63.0 million), for the reasons stated above. Operating loss for the first nine months of 2016 was NOK 151.1 million (loss of NOK 149.8 million).

Net financial items came to negative NOK 10.6 million (NOK 2.4 million) mainly due to currency fluctuations on bank accounts in foreign currencies and reduced interest income in the third quarter of 2016.

Nordic Nanovector's comprehensive loss for the quarter amounted to NOK 61.3 million (loss of NOK 60.7 million), due to the reasons stated above. Comprehensive loss for the first nine months was NOK 176.5 million (NOK 142.1 million).

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

#### **Financial position**

Total assets at September 30<sup>th</sup> 2016 amounted to NOK 582.5 million, down from NOK 760.4 million at December 31<sup>st</sup> 2015. The decline was primarily due to a lower cash holding following higher operational activities and currency fluctuations on bank deposits in foreign currencies.

Total liabilities were NOK 41.1 million at the end of the third quarter, down from NOK 47.6 million from year end 2015 primarily following payments of accounts payable.

Total shareholders' equity at September 30<sup>th</sup> 2016 was NOK 541.4 million (NOK 712.7 million at year end 2015), corresponding to an equity ratio of 92.9 % (93.7 % at year end 2015).

#### Cash flow

Net cash flow from operating activities in the third quarter and first nine months of 2016 was negative NOK 46.5 million (negative NOK 46.9 million) and negative NOK 155.1 million (negative NOK 112.7 million) respectively, reflecting the impact of higher research and development activities.

Net cash flow from investing activities in the third quarter and first nine months of 2016 was negative NOK 0.2 million (negative NOK 0.6 million) and negative NOK 0.3 million (negative NOK 1.3 million) respectively, primarily related to investments in infrastructure, lab equipment and IT hardware and software.

Net cash flow from financing activities for the third quarter and first nine months of 2016 was NOK 0.1 million (negative NOK 0.2 million) and NOK 0.6 million (NOK 546.4 million) respectively, related to exercise of options during the second and third quarters of 2016.

Exchange rate fluctuations in the third quarter and first nine months of 2016 had a negative impact on cash and cash equivalents of NOK 11.7 million and NOK 28.4 million respectively.

Cash and cash equivalents amounted to NOK 560.1 million at the end of September 2016, compared to NOK 618.4 million at the end of June 2016 and NOK 743.4 million at the end of December 2015.

#### Strategy and outlook

Nordic Nanovector is committed to develop, manufacture 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. The strategic roadmap to realise this aspiration is:

- Primary focus of financial and other resources directed to the clinical development of Betalutin® to achieve first regulatory filings in NHL in 1H 2019, and in parallel to run additional trials in 2<sup>nd</sup> line FL and DLBCL;
- Establish a development and commercialisation plan for Betalutin® with the intent to deliver a differentiated Target Product Profile that meets the requirements of both regulatory and reimbursement agencies, while achieving a strong and competitive market position;
- Leverage the company's proprietary technology and expertise to target challenging haematological cancers
  where the unmet medical need is high, such as NHL, chronic lymphocytic leukaemia and other B cell
  malignancies and multiple myeloma, through focused investments in discovery research and strategic
  collaborations;
- Continue to reinforce the company's organisation by attracting key talents with strong technical and international experience while maintaining flexibility and efficiency.

The competitive landscape for Betalutin® is promising. Strong results and good progress in the Phase 1/2 study, including the opportunity to test a higher Betalutin® dosing regimen, in addition to encouraging findings from the research and development pipeline bode well for Nordic Nanovector's operations going forward. Management will continue to focus its efforts on the efficient execution of its plans and to meet anticipated clinical milestones. Current cash resources are expected to be sufficient to reach the first regulatory submission for Betalutin® in FL in the first half of 2019.

Oslo, 22 November 2016

The Board of Directors
Nordic Nanovector ASA

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

Amounts in NOK 1000	Note	Third qua	rter	Year to d	late	Full year
Alliounts in NOR 1000	Note	2016	2015	2016	2015	2015
December		70	76	225	204	407
Revenues		78	76	235	294	437
Total revenues		78	76	235	294	437
Payroll and related expenses	4, 5, 6	16 703	15 666	40 185	36 699	52 360
Depreciation		299	269	831	696	994
Other operating expenses	4	33 409	47 092	110 271	112 737	130 178
Total operating expenses		50 411	63 027	151 287	150 132	183 532
Operating profit (loss)		-50 333	-62 951	-151 052	-149 838	-183 095
Finance income and finance						
expenses Finance income		1 108	3 422	3 541	9 322	12 214
Finance expenses		11 748	1 019	28 432	1 399	1 796
Net financial items		-10 640	2 403	-24 891	7 923	10 418
Loss before income tax		-60 973	-60 548	-175 943	-141 915	-172 677
Loss before income tax		-60 973	-60 548	-1/5 943	-141 915	-1/26//
Income tax		-158	-44	-225	-64	-398
Loss for the period		-61 131	-60 592	-176 168	-141 979	-173 075
Other comprehensive income (loss), net of income tax to be reclassified to profit and loss in subsequent periods						
Translation effects		-125	-79	-296	-99	-37
Total comprehensive income (loss) for the period		-61 256	-60 671	-176 464	-142 078	-173 112
Loss for the period attributable to owners of the Company		-61 131	-60 592	-176 168	-141 979	-173 075
Total comprehensive income (loss) for the period attributable to owners of the Company		-61 256	-60 671	-176 464	-142 078	-173 112
Earnings (loss) per share Basic and diluted earnings (loss) per share in NOK	9	-1.37	-1.36	-3.95	-3.63	-4.28

The interim financial information has not been subject to audit.

# Interim condensed consolidated statement of financial position

Amounts in NOK 1000	Note	30.09.2016	31.12.2015
ASSETS			
Non-current assets			
Property, plant and equipment		2 403	2 807
Total property, plant and equipment		2 403	2 807
Receivables			
Other non-current receivables		0	0
Total non-current receivables		0	0
Current assets			
Receivables			
Other current receivables	4	20 010	14 193
Total receivables		20 010	14 193
Cash and cash equivalents		560 077	743 367
Total current assets		580 087	757 560
TOTAL ASSETS		582 490	760 367
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	7	8 920	8 904
Share premium	7	969 756	969 175
Other paid in capital	5,6	17 448	12 973
Accumulated losses		-454 777	-278 314
Total shareholders' equity		541 347	712 738
Liabilities			
Current liabilities			
Accounts payable		13 040	20 156
Tax payable		161	404
Other current liabilities	10	27 942	27 069
Total current liabilities		41 143	47 629
Total liabilities		41 143	47 629
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		582 490	760 367

The interim financial information has not been subject to audit.

# Interim condensed consolidated statement of changes in equity

For the period ended 30 September							
Amounts in NOK 1000	Note	Share capital	Share premium	Equity-settled share-based payments	Accumulated losses	Translation effects	Total equity
Balance at 1 January 2015		5 310	426 339	3 763	-105 037	-164	330 211
Loss for the year					-173 075	0	-173 075
Other comprehensive income (loss) for the year net of income tax					0	-37	-37
Total comprehensive income for the year		0	0	0	-173 075	-37	-173 212
Recognition of share- based payments	5	0	0	9 210	0	0	9 210
Issue of ordinary shares	7	3 594	571 406	0	0	0	575 000
Share issue costs	7	0	-28 571	0	0	0	-28 571
Balance at 31 December 2015		8 904	969 175	12 973	-278 113	-201	712 738
Consider the period Other comprehensive					-176 168	0	-176 168
income (loss) for the year, net of income tax						-296	-296
Total comprehensive							
income for the year		0	0	0	-176 168	-296	-176 464
Recognition of share-							
based payments	5,6	0	0	4 475	0	0	4 475
Issue of ordinary shares	5,7	16	581				598
Balance at 30 September 2016		8 920	969 756	17 448	-454 281	-496	541 347

		Share	Share	Equity-settled share-based	Accumulated	Translation	Total
Amounts in NOK 1000	Note	capital	premium	payments	losses	effects	equity
Balance at 1 January 2015		5 310	426 339	3 763	-105 037	-164	330 211
Loss for the period					-141 979	0	-141 979
Other comprehensive income (loss) for the year net of income tax					0	-99	-99
Total comprehensive							
income for the year		0	0	0	-141 979	-99	-142 078
Recognition of share- based payments	5	0	0	8 109	0	0	8 109
basea payments		O	· ·	0 103	O	O	0 103
Issue of ordinary shares	7	3 594	571 406	0	0	0	575 000
Share issue costs	7	0	-28 571	0	0	0	-28 571
Balance at 30 September 2015		8 904	969 175	11 871	-247 016	-263	742 671

The interim financial information has not been subject to audit.

# Interim condensed consolidated statement of cash flow

Amounts in NOK 1000	Note	Third q	uarter	Year to	o date	Full Year
		2016	2015	2016	2015	2015
Cash flow from operating activities						
Loss for the period before income tax		-60 973	-60 548	-175 943	-141 915	-172 677
Adjustments for:						
Interest received		-38	-45	-116	-782	-12 365
Share option expense employees	5	1 245	2 971	4 106	8 109	9 210
Restricted share units expenses	6	251	0	369	0	0
Taxes paid		-132	0	-199	-51	-69
Depreciation		299	269	831	696	994
Currency (gains) losses not related to operating activities		11 748	0	28 432	0	0
Changes in working capital and non-cash adjustments		1 082	10 465	-12 625	21 225	24 690
Net cash flow from operating activities		-46 518	-46 888	-155 145	-112 718	-150 217
Cash flow from investing activities						
Investments in property plant and equipment and intangible assets		-195	-631	-427	-2 047	-2 228
Interests received		38	45	116	782	12 365
Net cash flow from investing activities		-157	-586	-311	-1 265	10 137
Cash flows from financing activities						
Net proceeds from equity issue	7	85	-205	598	546 429	546 429
Net cash flow from financing activities		85	-205	598	546 429	546 429
Effects of exchange rate changes on cash and cash equivalents		-11 748	0	-28 432	0	0
Net change in bank deposits, cash and equivalents		-58 338	-47 679	-183 290	432 446	406 349
Cash and equivalents at beginning of period		618 415	817 143	743 367	337 018	337 018
Cash and equivalents at end of period		560 077	769 464	560 077	769 464	743 367

The interim financial information has not been subject to audit.

# Nordic Nanovector ASA – Notes to the condensed interim financial statements for the third quarter of 2016

#### Note 1. General information

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 third quarter report are non-audited figures.

These financial statements were approved for issue by the Board of Directors on 22 November 2016.

#### 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 2015. 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 2015, and Norwegian disclose requirements listed in the Norwegian Accounting Act as of 31 December 2015. The 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 2015.

#### Note 4. Government grants

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

	Third quarter		Year to date September	
Amounts in NOK 1000	2016	2015	2016	2015
Payroll and related expenses	1 145	145	1 713	1 944
Other operating expenses	2 175	1 474	5 754	2 973

- 1) In 2016, the company received a new grant of up to NOK 15 million grant 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 2018. The purpose of the grant is to support research and development of novel targeted therapeutics for leukemia and NHL. The company will investigate further the potential of chHH1 in a preclinical programme with the intention, if successful, of taking it forward into clinical studies. The grant will be distributed to the company over the course of three years, with the first payment scheduled for in 2016. For the financial period ended 30 September 2016, the company has recognised NOK 3.3 million classified partly as a reduction of payroll and related expenses and partly as a reduction of other operating expenses.
- 2) The company has been awarded a grant from The Research Council programme for user-managed innovation arena (BIA) of NOK 10.5 million in total for the period 2012 through 1H 2016. For the financial period ended 30 September 2016, the company has recognised NOK 0.1 million (as of 30 September, 2015: NOK 1.4 million) classified partly as a reduction of payroll and related expenses and partly as a reduction of other operating expenses.
- 3) The Research Council Eurostars has 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 30 September 2016, the company has recognised NOK 1.0 million (30 September, 2015: NOK 1.2 million) partly as a reduction of payroll and related expenses and partly as a reduction of other operating expenses.
- 4) R&D projects have been approved for SkatteFUNN grants for the period 2012 through 2017. For the financial period ended 30 September 2016, the company has recognised NOK 3.0 million compared to NOK 2.3 million for the same period in 2015. The amount was recognised partly as a reduction of payroll and related expenses and partly as a reduction of other operating expenses.

#### Note 5. Employee share option programme

The company has a share option scheme for all employees of the group. Each share option gives the right to acquire one ordinary share of the company on exercise. The company may settle options in cash.

Amounts in NOK	Year to date September 2016				
Amounts in NOR	Number of	Weighted average			
	options	exercise price			
Balance at 1 January	2 171 576	26.77			
Granted during the year	525 000	14.39			
Exercised during the year	- 81 333	7.35			
Forfeited	- 123 542	29.24			
Balance at period end	2 491 701	24.67			

As of 30 September 2016 there are no outstanding options granted in 2011 to 2012. The remaining 78 333 options were exercised on 20 April 2016. The options granted in 2014, 2015 and 2016 vest in accordance with the following vesting schedule: (i) 25% of the options vest 12 months after the date of grant and (ii) 1/36 of the remaining options vest each month thereafter. It is a condition for vesting that the option holder is an employee of the group at the time of vesting. Vested options may be exercised in a period of 15 Norwegian business days from the day following the day of the company's release of its annual or quarterly results, unless the Board of Directors resolves otherwise. The options expire seven years from grant date.

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

At the general meeting, the company resolved to issue 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 2016 to the annual general meeting in 2017, in the form of RSUs pursuant to the respective restricted share units agreements ("RSU Agreement") entered into between the company and the relevant board members.

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 Agreement.

The board members who elect to receive RSUs, must elect to either (i) receive 100% of the compensation in RSUs, (ii) receive 1/3 of the compensation in cash and 2/3 in RSUs, or (iii) receive 2/3 of the compensation in cash and 1/3 in RSUs. The election made by each board member has been set out in the table below. The number of RSUs to be granted to the members of the Board of Directors is calculated as the NOK amount of the RSU opted portion of total compensation to the board member, divided by the market price for the Nordic Nanovector share. The market price is calculated as volume weighted average share price the 10 trading days prior to the grant date, i.e. NOK 22.68.

Pursuant to the RSU programme, the board members and primary insiders of the company received the following number of RSUs:

Name	Remuneration for the period 2016-2017	Allocation between cash and RSUs	Number of RSUs for the period 2016- 2017	Total number of RSUs	Total number of shares
Ludvik Sandnes	NOK 490,000 [1]	100% RSU	21,604	21,604	125,000
Per Samuelsson	NOK 300,000 [2]	[3]	0	0	0
Hilde Hermansen Steineger	NOK 300,000 [4]	2/3 RSU	8,818	8,818	750
Gisela Schwab	NOK 240,000	2/3 RSU	7,054	7,054	0
Renee P. Tannenbaum	NOK 240,000	1/3 RSU	3,527	3,527	0
Jean-Pierre Bizzari	NOK 240,000	1/3 RSU	3,527	3,527	0
Total			44,530	44,530	125,750

<sup>[1]</sup> NOK 450 000 as chairman of the Board, NOK 20 000 as a member of the audit committee and NOK 20 000 as a member of the compensation committee

A total of 44 530 RSUs have thus been granted as of 30 September 2016. The RSUs will vest on 19 May 2017.

<sup>[2]</sup> NOK 240 000 as board member, NOK 40 000 as chairman of the compensation committee and NOK 20 000 as a member of the audit committee

<sup>[3]</sup> Per Samuelsson is not allowed to hold equity in the company due to his affiliation with HealthCap, and will only receive cash.

<sup>[4]</sup> NOK 240 000 as board member, NOK 40 000 as chairman of the audit committee and NOK 20 000 as a member of the compensation committee.

#### Note 7. Share capital and shareholder information

Share capital as at 30 September 2016 is NOK 8 920 075 (31 December 2015: NOK 8 903 808), being 44 600 374 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:	Year to date Q3 2016	2015
Ordinary shares at 1 January	44 519 041	26 550 291
Issue of ordinary shares <sup>1)</sup>	0	17 968 750
Issue of ordinary shares under share options <sup>2)</sup>	81 333	0
Ordinary shares	44 600 374	44 519 041

1) Nordic Nanovector undertook its Initial Public Offering (IPO) in March 2015, in conjunction with the listing of its shares on the Oslo Stock Exchange (OSE). The IPO was upsized from NOK 400 million to NOK 500 million on the basis of strong investor demand, and oversubscribed at the issue price of NOK 32. As a result, Nordic Nanovector raised NOK 500 million in gross proceeds from the sale of 15,625 000 shares at the issue price, from domestic and international institutional investors (Europe and US) and retail investors in Norway.

No stabilisation activities were undertaken in connection with Nordic Nanovector's initial public offering in March. The stabilisation manager exercised 22 April 2015 the option to purchase from the company 2,343,750 new shares in the company, equalling 15% of the aggregate number of new shares allocated in the public offering, at a price per share of NOK 32, which is equal to the offer price. The 2,343,750 shares were delivered to HealthCap VI L.P. from whom the same number of shares were borrowed in connection with the over-allotment and stabilisation activities in the offering.

After the issuance of the shares in connection with the exercise of the over-allotment option, the company had 44 519 041 shares in issue and received NOK 75 million in additional proceeds from the offering. Total gross proceeds from the offering increased to NOK 575 million.

2) The Annual General Meeting held 19 May 2016 granted an authorisation to increase the share capital limited to 10% of the share capital, to be used in connection with the share based incentive programmes for the group's employees. Of the authorised 4 459 737 shares, 2 491 701 shares are granted (ref. note 5). The authorisation is valid until the next Annual General Meeting, but no longer than 30 June 2017.

The Annual General Meeting held 19 May 2016 granted an authorisation to increase the share capital limited to 10% of the share capital, to be used for general corporate purposes, including but not limited to financing and acquisitions of other companies, including issuance of consideration shares in connection with the above mentioned transactions. The authorisation is valid until the next Annual General Meeting, but no longer than 30 June 2017.

The Annual General Meeting held 19 May 2016 granted an authorisation to increase the share capital limited to NOK 20,000 at par value. The authorisation may only be used to issue shares to members of the Company's board of directors against contributions in NOK. Of the authorised 100 000 shares, 44,530 shares are granted (ref. note 6). The authorisation is valid until 19 May 2018.

Participants in Nordic Nanovector ASA's first share option programme from 2011/2012 have on 20 April 2016 exercised a total number of 30,000 options at a strike price of NOK 6.25, and 48 333 options at a strike price of NOK 6.75. Each option gives the right to receive one share in the Company. The Board of Directors of the Company has approved the exercise of the options and resolved to increase the company's share capital by NOK 15 666.6 through the issuance of 78 333 new shares, each at a nominal or par value of NOK 0.20.

A participant in Nordic Nanovector ASA's second share option programme has on 30 August 2016 exercised a total number of 3 000 options at a strike price of NOK 28 per share. Each option gives the right to receive one share in the Company. The Board of Directors of the Company has approved the exercise of the options and resolved to increase the Company's share capital by NOK 600 through the issuance of 3 000 new shares, each at a nominal or par value of NOK 0.20.

#### Nordic Nanovector ASA had 3 583 shareholders as at 30 September 2016.

	Shareholders	Number of shares	Percentage of total shares
1	HealthCap VI L.P.	5 445 833	12.21 %
2	Folketrygdfondet	3 948 736	8.85 %
3	OM Holding AS	1 175 000	2.63 %
4	Sciencons AS (Roy Hartvig Larsen)	1 000 000	2.24 %
5	Linux Solutions Norge AS	890 306	2.00 %
6	Nordnet Livsforsikring AS	830 694	1.86 %
7	Radiumhospitalets Forskningsstiftelse	803 518	1.80 %
8	Must Invest AS	789 142	1.77 %
9	Inven2 AS	613 401	1.38 %
10	Roy Hartvig Larsen	601 777	1.35 %
11	Ro Invest AS	600 000	1.35 %
12	Boddco AS	550 000	1.23 %
13	Invesco Perp EUR	533 568	1.20 %
14	Birk Venture AS	500 000	1.12 %
15	VPF Nordea Kapital	480 310	1.08 %
16	Skandinaviska Enskilda Banken AB	475 000	1.07 %
17	Netfonds Livsforsikring AS	422 910	0.95 %
18	KLP Aksje Norge Index	359 871	0.81 %
19	Verdipapirfondet KLP Aksjenorge	310 265	0.70 %
20	Verdipapirfondet DNB SMB	305 060	0.68 %
	Total shares for top 20 shareholders	20 635 391	46.27 %
	Total shares for other 3 563 shareholders	23 964 983	53.73 %
	Total shares (3 583 shareholders)	44 600 374	100.00 %

The shares of Nordic Nanovector ASA have been traded on the Oslo Stock Exchange since 23 March 2015, and the shareholder base has increased from 535 shareholders as of 31 December 2014 to 3 583 shareholders as of 30 September 2016.

#### Note 8. Information about subsidiaries

The interim consolidated financial statements of the Group include:		% Equity	% Equity interest	
Name	Country of incorporation	Q3 2016	2015	
Nordic Nanovector GmbH	Switzerland	100	100	
Nordic Nanovector Ltd	United Kingdom	100	100	

Nordic Nanovector is a public limited company incorporated and domiciled in Norway. The company is the parent company in the group's operations are carried out by the company and its wholly owned subsidiaries Nordic Nanovector GmbH and Nordic Nanovector Ltd. Nordic Nanovector GmbH is incorporated in Zug, Switzerland, with its registered address at *Dammstrasse 19, Zug, Switzerland*. Nordic Nanovector Ltd is incorporated in London, England, with its registered address at *Paternoster House, 65 St. Paul's Churchyard, London EC4M 8A, United Kingdom*.

#### Note 9. 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:

	Year to date September 2016	Year to date September 2015
Loss for the period (in NOK)	-176 168 000	-141 979 000
Average number of outstanding shares during the year	44 563 129	39 064 652
Earnings (loss) per share - basic and diluted	-3.95	-3.63

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 10. Other current liabilities

Amounts in NOK 1000	30.09.2016	31.12.2015
Unpaid duties and charges	1 655	4 390
Unpaid vacation pay	1 895	1 877
Other accrued costs	24 392	20 802
Other current liabilities	27 942	27 069

Other accrued costs for period ended 30 September 2016 are mainly related to development cost of the lead product candidate Betalutin®.

#### Note 11. Subsequent events

#### Issuance of restricted stock unites (RSUs) to the new board member, Joanna Horobin:

Joanna Horobin has resolved to receive her full board remuneration, as determined by the company's annual general meeting in 2016, in the form of RSUs and the board of directors has resolved to issue 2,678 RSUs to Joanna Horobin. The number of RSUs is calculated on the basis of a board remuneration of NOK 144,000 divided by the market price of the company's shares calculated as the average share price for the 10 trading days prior to the EGM being NOK 53.77 per share. Joanna Horobin does not hold any other shares in the company.

#### Allotment of share options to the new CMO, Lisa Rojkjaer

The Board of Directors of Nordic Nanovector ASA has resolved to grant 340,000 options to Lisa Rojkjaer to subscribe for shares in the Company. Lisa Rojkjaer has been employed as the Company's new CMO. Each option, when exercised, will give the right to acquire one share in the Company. The options are granted without consideration. Pursuant to the vesting schedule, 25% of the options will vest 12 months after the day of grant as long as the option holder is still employed. Thereafter, 1/36 of the remaining options will vest each month (as long as the option holder is still employed), with the first 1/36 vesting 13 months after the day of grant. The exercise price of the options is NOK 66.74. The exercise price is equal to the volume weighted average trading price of the shares of the Company on Oslo Børs the last five trading days prior to the date of the grant. Options that have not been exercised will lapse 7 years after the date of grant.

#### **Additional information**

#### Glossary of terms

- 1L, 2L, 3L: first, second and third line of treatment
- ADC: Antibody-Drug Conjugate
- ARC: Antibody-Radionuclide Conjugate
- (A)SCT: (Autologous) stem cell transplant
- ASH: American Society of Hematology Annual
- **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 specialised 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
- CR: Complete response
- DLBCL: Diffuse Large B-Cell Lymphoma
- FL: Follicular Lymphoma
- FDA: Food and Drug Administration
- IFRS: International Financial Reporting Standard
- IND: Investigational New Drug
- IPO: Initial Public Offering
- KOL: Key opinion leader
- LCM: Lifecycle management
- **Lilotomab:** Betalutin® consists of the radionuclide lutetium-177 conjugated to the B-cell seeking anti-CD37 antibody lilotomab (formerly referred to as HH1).
- Lu-177: Radionuclide lutetium-177
- mAb: Monoclonal antibody
- MBq: Megabecquerel (radioactivity measurement unit)
- M.D: Medical doctor
- nASCT: Not eligible for autologous stem cell transplant
- NNV003: chimeric anti-CD37 antibody developed by Nordic Nanovector
- NHL: non-Hodgkin Lymphoma
- OSE: Oslo Stock Exchange
- ORR: Overall response rate (the CR and PR, jointly)
- PARADIGME: Name of Nordic Nanovector's pivotal Phase 2 study
- PFS: Progression free survival
- PR: Partial response
- QoL: Quality of life
- R: Rituximab
- RIT: Radioimmunotherapy
- SAB: Scientific Advisory Board
- SD: Stable disease
- SRC: Safety Review Committee
- **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.

#### Financial calendar

Q4 2016 results: 28 February 2017

Q1 2017 results: 24 May 2017

Q2 2017 results: 23 August 2017

Q3 2017 results: 22 November 2017

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

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#### Forward-looking statements

This report may contain certain forward-looking statements and forecasts based on uncertainty, 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", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realised. Factors that could cause these differences include, but are not limited to, implementation of Nordic Nanovector's strategy and its ability to further grow, risks associated with the development and/or approval of Nordic Nanovector's products candidates, ongoing clinical trials and expected trial results, the ability to commercialise Betalutin®, technology changes and new products in Nordic Nanovector's potential market and industry, 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 a biotech company focusing on the development and commercialisation of novel targeted therapeutics in haematology and oncology. The Company's lead clinical-stage product opportunity is Betalutin®, the first in a new class of Antibody-Radionuclide-Conjugates (ARCs), designed to improve upon and complement current options for the treatment of non-Hodgkin Lymphoma (NHL). NHL is an indication with substantial unmet medical need and orphan drug opportunities, representing a growing market forecast to be worth over USD 12 billion by 2018.

Betalutin® comprises a tumour-seeking anti-CD37 antibody, lilotomab (previously referred to as HH1), conjugated to a low intensity radionuclide (lutetium-177). Preliminary data from an ongoing Phase 1/2 study, in a difficult-to-treat NHL patient population, has been encouraging, highlighting an attractive efficacy and safety profile for Betalutin®. The Company aims to rapidly develop Betalutin® for the treatment of major types of NHL with first regulatory submission in follicular lymphoma (FL) anticipated 1H 2019.

Nordic Nanovector intends to retain marketing rights and to actively participate in the commercialisation of Betalutin® in core markets, while exploring potential distribution agreements in selected geographies. The Company is committed to developing its ARC pipeline to treat multiple selected cancer indications.