

# Genmab Announces Financial Results for the First Quarter of 2016

May 10, 2016; Copenhagen, Denmark; Interim Report for the First Quarter of 2016

- Net Sales of DARZALEX<sup>®</sup> (daratumumab) by Janssen for the first quarter of 2016 were USD 101.9 million, resulting in royalty income of DKK 83 million
- Announced positive interim result in Phase III Castor study of daratumumab in relapsed or refractory multiple myeloma
- Announced studies of daratumumab in combination with atezolizumab in a solid tumor and multiple myeloma
- Achieved USD 5 million milestone for progress in the Phase II study of daratumumab in non-Hodgkin's lymphoma (NHL) under collaboration with Janssen
- Announced updated development plans for ofatumumab in autoimmune indications
- U.S. Food and Drug Administration (FDA) Approval of Arzerra<sup>®</sup> (ofatumumab) as extended treatment for recurrent or progressive chronic lymphocytic leukemia (CLL)
- U.S. and EU regulatory submissions for of atumumab in combination with fludarabine and cyclophosphamide for relapsed CLL

"The first quarter of 2016 saw continued rapid progress in the development of daratumumab with Janssen: We reported positive interim data in the Phase III Castor study of daratumumab in combination with bortezomib and dexamethasone, achieved the second milestone in the Phase II NHL study, and announced the first study to combine daratumumab with Roche's anti-PDL1 antibody atezolizumab, in a solid tumor and multiple myeloma. We also started off the year with a number of achievements under our Arzerra collaboration with Novartis. Arzerra was approved in the U.S. as extended treatment for recurrent or progressive CLL and regulatory submissions for ofatumumab in combination with fludarabine and cyclophosamide in relapsed CLL were submitted in the U.S. and Europe. Furthermore, we announced that development of the subcutaneous formulation of ofatumumab in autoimmune indications will be focused on relapsing multiple sclerosis, with large Phase III studies run by Novartis expected to start later this year," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

## **Financial Performance First Quarter**

- Revenue was DKK 170 million in the first quarter of 2016 compared to DKK 107 million in the first quarter of 2015. The increase of DKK 63 million, or 59%, was mainly driven by higher royalty and milestone revenue under our daratumumab collaboration with Janssen.
- Operating expenses were DKK 154 million in the first quarter of 2016 compared to DKK 110 million in the first quarter of 2015. The increase of DKK 44 million, or 40%, was due to the additional investment in our pipeline of products, including the advancement of tisotumab vedotin, HuMax-AXL-ADC, HexaBody-DR5/DR5, DuoBody-CD3xCD20, and our other pre-clinical programs.
- Operating income was DKK 16 million in the first quarter of 2016 compared to DKK 173 million in the first quarter of 2015. The decrease of DKK 157 million was driven by the one-time reversal of the ofatumumab funding liability of DKK 176 million in 2015 combined with increased operating expenses, which were partly offset by higher revenue.
- On March 31, 2016, Genmab had a cash position of DKK 3,491 million, similar to the cash position of DKK 3,493 million at December 31, 2015.

# **Business Progress First Quarter to Present**

## Daratumumab

 March: Announced that the Phase III Castor study (MMY3004) of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma met the primary endpoint of improving progression free survival (PFS) in a planned interim analysis (p<0.0001). Janssen will engage in a dialogue with</li>

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the health authorities about the potential for these data to serve as the basis for a regulatory submission.

- March: Announced that daratumumab will be investigated in Phase Ib clinical studies in combination with atezolizumab, an anti-PD-L1 antibody, in a solid tumor and multiple myeloma. The studies will be conducted under a collaboration agreement between Janssen Biotech, Inc. (Janssen) and Genentech, a member of the Roche Group.
- March: Achieved the second milestone in the ongoing Phase II study of daratumumab in NHL, triggering a USD 5 million payment from Janssen.

## Ofatumumab

- March: Announced that supplemental regulatory applications for the use of Arzerra in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL were submitted in the U.S. and EU by Novartis.
- March: Announced an update on development plans for ofatumumab in autoimmune indications focusing on relapsing multiple sclerosis following the transfer of the rights to ofatumumab in this disease area from GlaxoSmithKline (GSK) to Novartis at the end of 2015. Phase III studies of the subcutaneous formulation of ofatumumab in relapsing multiple sclerosis are expected to be initiated by Novartis during the second half of 2016. The Phase III study of the subcutaneous formulation of ofatumumab in pemphigus vulgaris, which was started by GSK, will be discontinued.
- January: The U.S. FDA approved a supplemental Biologics License Application (sBLA) for the use of Arzerra for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL.

## **Subsequent Events**

- April: Reported additional data from the Phase III Castor study of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma. The study met the primary endpoint of improving PFS; Hazard Ratio (HR) = 0.39, p<0.0001. The median PFS for patients treated with daratumumab has not been reached, compared to median PFS of 7.2 months for patients who did not receive daratumumab. Data from this study was accepted for oral presentation in a Plenary Session at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting.
- April: Announced that MorphoSys filed a complaint at the U.S. District Court of Delaware against Genmab and Genmab's collaboration partner Janssen, for patent infringement under U.S. patent no. 8,263,746 based on activities relating to the manufacture, use and sale of DARZALEX in the United States. Genmab and Janssen disagree with the allegations made by MorphoSys in its complaint for patent infringement related to CD38 antibodies and intend to vigorously contest those allegations.
- April: The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the granting of a conditional marketing authorization for DARZALEX intended for the treatment of relapsed and refractory multiple myeloma. The recommendation is for the use of DARZALEX as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor (PI) and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

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#### Outlook

Genmab is maintaining its 2016 improved financial guidance published on April 20, 2016. The improvement announced in April is driven by the anticipation of increased royalty income related to the sales of DARZALEX. This resulted in a DKK 100 million increase in our outlook for revenue, operating income and cash position.

#### **Conference Call**

Genmab will hold a conference call in English to discuss the results for the first quarter of 2016 today, Tuesday, May 10, at 6.00 pm CEST, 5.00 pm BST or noon EDT. The dial in numbers are:

+1 212 444 0412 (US participants) and ask for the Genmab conference call +44 20 3427 1917 (international participants) and ask for the Genmab conference call

A live and archived webcast of the call and relevant slides will be available at www.genmab.com.

#### **Contact:**

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This interim report contains forward looking statements. The words "believe", "expect", "anticipate", "intend" and "plan" and similar expressions identify forward looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with product discovery and development, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products obsolete, and other factors. For a further discussion of these risks, please refer to the section "Risk Management" in Genmab's annual report, which is available on <u>www.genmab.com</u> and the "Significant Risks and Uncertainties" section in this interim report. Genmab does not undertake any obligation to update or revise forward looking statements in this interim report nor to confirm such statements in relation to actual results, unless required by law.

Genmab A/S and its subsidiaries own the following trademarks: Genmab®; the Y-shaped Genmab logo®; Genmab in combination with the Y-shaped Genmab logo™; the DuoBody logo®; the HexaBody logo™; HuMax®; HuMax-CD20®; DuoBody®; HexaBody® and UniBody®. Arzerra® is a trademark of Novartis AG or its affiliates. DARZALEX® is a trademark of Janssen Biotech, Inc.

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# **CONSOLIDATED KEY FIGURES**

	1st quarter of 2016 DKK'000	1st quarter of 2015 DKK'000	Full Year 2015 DKK'000
Income Statement	470 474	400 770	4 400 044
Revenue	170,171	106,778	1,133,041
Research and development expenses	(127,116)	(85,532)	(487,656)
General and administrative expenses	(26,716)	(24,524)	(91,224)
Operating expenses	(153,832)	(110,056)	(578,880)
Other income	-	176,218	176,218
Operating result	16,339	172,940	730,379
Net financial items	(27,850)	44,364	27,148
Netresult	(11,525)	217,290	763,513
Balance Sheet			
Cash position*	3,490,522	2,945,134	3,493,229
Non-current assets	228,101	142,614	234,659
Assets	3,911,133	3,175,247	3,902,548
Shareholders' equity	3,521,253	2,588,148	3,486,720
Share capital	59,678	58,134	59,531
Investments in intangible and tangible assets	4,104	19,740	135,389
Cash Flow Statement	(0.000)	(==)	
Cash flow from operating activities	(8,636)	(55,399)	311,449
Cash flow from investing activities	(244,817)	(328,311)	(480,883)
Cash flow from financing activities	38,384	317,122	643,092
Cash and cash equivalents	634,914	328,538	873,986
Cash position increase/(decrease)	(2,707)	284,619	832,714
Financial Ratios			
Basic net result per share	(0.19)	3.80	13.05
Diluted net result per share	(0.19)	3.64	12.56
	(00)		
Period-end share market price	907.50	523.00	917.50
Price / book value	15.38	11.75	15.67
Shareholders' equity per share	59.00	44.52	58.57
Equity ratio	90%	82%	89%
Average number of employees (FTE**)	186	175	180
Number of employees at the end of the period	189	175	186
	100		

\* Cash, cash equivalents, bank overdraft and marketable securities.

\*\* Full-time equivalent

The figures and financial ratios have been prepared on a consolidated basis. The financial ratios have been calculated in accordance with the recommendations of the Association of Danish Financial Analysts (2015) and key figures in accordance with IFRS.

## **ABOUT GENMAB**

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated antibody therapeutics for the treatment of cancer. Founded in 1999, the company has two approved antibodies, Arzerra®

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(ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications and DARZALEX® (daratumumab) for the treatment of heavily pretreated or double refractory multiple myeloma. Daratumumab is in clinical development for additional multiple myeloma indications and for non-Hodgkin's lymphoma. Genmab also has a broad clinical and pre-clinical product pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody® platform for generation of bispecific antibodies, and the HexaBody® platform which creates effector function enhanced antibodies. The company intends to leverage these technologies to create opportunities for full or co-ownership of future products. Genmab has alliances with top tier pharmaceutical and biotechnology companies. For more information visit www.genmab.com.

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# OUTLOOK

MDKK	Revised Guidance	Original Guidance
Revenue	925 – 975	825 – 875
Operating expenses	(775) – (825)	(775) – (825)
Operating income	125 – 175	25 – 75
Cash position at end of year*	3,400 – 3,500	3,300 – 3,400
*Cash, cash equivalents, and marketable securities		

Genmab is maintaining its 2016 revised financial guidance published on April 20, 2016.

We expect our 2016 revenue to be in the range of DKK 925 – 975 million, an increase of DKK 100 million compared to the previous guidance. Our projected revenue for 2016 consists primarily of daratumumab milestones of DKK 400 million and DARZALEX royalties of DKK 300 – 350 million (previously DKK 200 – 250 million) that are based on an estimated USD 400 – 450 million of DARZALEX sales in 2016 (previously USD 250 – 300 million). The remainder of the revenue mainly consists of Arzerra royalties, DuoBody milestones, and non-cash amortization of deferred revenue.

We anticipate that our 2016 operating expenses will remain in the range of DKK 775 – 825 million. The increased expense level from previous years is driven by the additional investment in our pipeline of products, including the advancement of tisotumab vedotin as well as HuMax-AXL-ADC, HexaBody-DR5/DR5, DuoBody-CD3xCD20, and our other pre-clinical programs.

We expect the operating income for 2016 to be approximately DKK 125 - 175 million, an improvement of DKK 100 million, compared to the previous guidance of DKK 25 - 75 million.

We are projecting a cash position at the end of 2016 of DKK 3,400 – 3,500 million, an improvement of DKK 100 million, compared to the previous guidance of DKK 3,300 – 3,400 million.

## **Outlook: Risks and Assumptions**

In addition to factors already mentioned, the estimates above are subject to change due to numerous reasons, including but not limited to the achievement of certain milestones associated with our collaboration agreements; the timing and variation of development activities (including activities carried out by our collaboration partners) and related income and costs; Arzerra and DARZALEX sales and corresponding royalties to Genmab; fluctuations in the value of our marketable securities; and currency exchange rates. The financial guidance does not include any potential proceeds from future warrant exercises and also assumes that no significant agreements are entered into during 2016 that could materially affect the results.

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# **2016 GOALS**

Priority	✓	Targeted Milestone	
MAXIMIZE DARATUMUMAB PROGRESS	¥	<ul> <li>Launch DARZALEX in US and other approved territories</li> <li>CHMP decision on monotherapy application</li> <li>Phase III multiple myeloma (MM) interim efficacy analysis in relapsed / refractory MM settings [Pollux and Castor trials]</li> <li>File for label in relapsed / refractory settings if results of interim analyses are favorable</li> <li>Start multiple clinical trials in MM and non-MM indications</li> <li>Report initial clinical data non-MM indications</li> </ul>	
OPTIMIZE OFATUMUMAB VALUE	√ √ 2017*	<ul> <li>Start Phase III subcutaneous autoimmune trials</li> <li>Regulatory decision for CLL maintenance</li> <li>File for label in relapsed CLL</li> <li>Phase III refractory follicular lymphoma (FL) interim efficacy data</li> </ul>	
STRENGTHEN DIFFERENTIATED PRODUCT PIPELINE		<ul> <li>Phase I/II tisotumab vedotin additional data</li> <li>IND for HuMax-AXL-ADC and start clinical trial</li> <li>Progress HexaBody-DR5/DR5 program</li> <li>Progress pre-clinical DuoBody &amp; HexaBody projects</li> </ul>	
BROADEN PARTNERSHIP PORTFOLIO WITH NEXT GENERATION TECHNOLOGIES	V	<ul> <li>Sign new / expanded DuoBody &amp; HexaBody collaborations</li> <li>Progress partnered programs</li> <li>New IND filings</li> </ul>	
DISCIPLINED FINANCIAL MANAGEMENT		Selectively invest to progress and broaden differentiated product pipeline	

\*Study continued at interim analysis. Full data expected 2017.

# **PRODUCT PIPELINE PROGRESS FIRST QUARTER OF 2016**

Our product pipeline includes nine antibodies in clinical development, including two marketed products, and over 25 in-house and partnered pre-clinical programs. The following chart illustrates the disease indications and most advanced development status for each of our pipeline products. For additional information, visit www.genmab.com/product-pipeline.

## **Product Pipeline**

Product	Disease	Most Advanced Development Status	
<b>Daratumumab</b> Target: CD38 Partner: Janssen	Multiple Myeloma (MM)	Marketed in certain indications; in Phase III development for others	
	Non-Hodgkin's Lymphoma (NHL)	Phase II study ongoing	
	Solid tumor	Phase I study announced	
Ofatumumab Target: CD20 Indication: Cancer	Chronic Lymphocytic Leukemia (CLL)	Marketed in certain indications; in Phase III development for others	
Partner: Novartis	Follicular Lymphoma (FL)	Phase III study ongoing	
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Product	Disease	Most Advanced Development Status
<b>Ofatumumab</b> Subcutaneous formulation Target: CD20 Indication: Autoimmune Partner: Novartis	Relapsing Multiple Sclerosis	Phase III studies announced
<b>Tisotumab vedotin</b> Target: Tissue factor (TF) Partner: Seattle Genetics	Solid cancers	Phase I/II studies ongoing
<b>Teprotumumab</b> Target: IGF-1R Partner: River Vision	Graves' orbitopathy (GO) Diabetic macular edema	Recruitment completed in Phase II Phase I ongoing
<b>AMG 714</b> Target: IL-15 Partner: Amgen	Celiac disease	Phase II studies announced
HuMax-TAC-ADC (ADCT-301) Target: CD25 Partner: ADC Therapeutics	Lymphoma Acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL)	Phase I study ongoing Phase I study ongoing
<b>HuMax-IL8</b> Target: IL-8 Partner: Cormorant	Metastatic solid tumors	Phase I study ongoing
<b>JNJ-61186372</b> Targets: EGFR, cMET Partner: Janssen	Non-small-cell lung cancer (NSCLC)	Phase I study announced
<b>JNJ-63709178</b> Targets: CD3, CD123 Partner: Janssen	Acute myeloid leukemia (AML)	Phase I study announced
>25 Active Pre-clinical Programs including HuMax-AXL-ADC	Partnered & propriety programs: HuMab, HuMab-ADC, DuoBody, DuoBody-ADC & HexaBody	Pre-clinical

Announced = study has been announced via a company announcement or clinicaltrials.gov but the first patient has not yet been dosed

Ongoing = first patient has been dosed in the study; study has started

## DARZALEX (daratumumab) – A First-in-Class Antibody

- First-in-class CD38 antibody in development to treat cancer
- Approved by FDA for heavily pretreated or double-refractory multiple myeloma
- CHMP adopted positive opinion recommending conditional marketing authorization
- Five Phase III studies ongoing in multiple myeloma
- First study in three different types of NHL ongoing & first study in a solid tumor announced
- Collaboration with Janssen
- Q1 2016 net sales of DARZALEX by Janssen were USD 101.9 million

DARZALEX injection for intravenous infusion is indicated in the U.S. for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a PI and an

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immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent. DARZALEX is the first monoclonal antibody (mAb) to receive FDA approval to treat multiple myeloma.

An MAA for daratumumab as a monotherapy for patients with relapsed or refractory multiple myeloma was submitted in Europe in September 2015. In April 2016 the CHMP of the EMA adopted a positive opinion recommending the granting of a conditional marketing authorization for DARZALEX, intended for the treatment of relapsed and refractory multiple myeloma.

Daratumumab is a human IgG1k mAb that binds with high affinity to the CD38 molecule, which is highly expressed on the surface of multiple myeloma cells. It induces rapid tumor cell death through multiple diverse mechanisms of action. It is marketed and developed under a collaboration agreement with Janssen Biotech, Inc. Five Phase III clinical studies with daratumumab in relapsed and front line settings are currently ongoing, and additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant diseases on which CD38 is expressed, such as smoldering myeloma, non-Hodgkin's lymphoma and in a solid tumor.

## Approved in Double-refractory Multiple Myeloma

In November 2015, DARZALEX (daratumumab) injection for intravenous infusion was approved by the U.S. FDA for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent. The approval was predominantly based on results from the pivotal Phase II MMY2002 (SIRIUS) study which showed that treatment with single-agent DARZALEX resulted in an overall response rate (ORR) of 29.2% in patients who had received a median of five prior lines of therapy, including a PI and an immunomodulatory agent. Stringent complete response (sCR) was reported in 2.8% of patients, very good partial response (VGPR) was reported in 9.4% of patients, and partial response (PR) was reported in 17% of patients.

For responders, the median duration of response was 7.4 months. At baseline, 97% of patients were refractory to their last line of therapy, 95% were refractory to both a PI and an immunomodulatory agent, and 77% were refractory to alkylating agents. Additional efficacy data from the Phase I/II GEN501 monotherapy study also supported this approval.

## Safety Information for DARZALEX

The warnings and precautions for DARZALEX include infusion reactions, interference with serological testing and interference with determination of complete response. The most frequently reported adverse reactions (incidence  $\geq$ 20%) were: fatigue, nausea, back pain, pyrexia, cough and upper respiratory tract infection.

In data from three pooled clinical studies including a total of 156 patients, 4% of patients discontinued treatment due to adverse reactions, none of which were considered drug-related. Infusion reactions were reported in approximately half of all patients treated with DARZALEX. Common (≥5%) symptoms of infusion reactions included nasal congestion, chills, cough, allergic rhinitis, throat irritation, dyspnea (shortness of breath) and nausea. Severe infusion reactions included bronchospasm, dyspnea, hypoxia and hypertension (<2% each).

Please consult the full U.S. Prescribing information for all the labeled safety information for DARZALEX.

For more development information on daratumumab, visit <u>www.genmab.com/product-pipeline/products-in-development/daratumumab</u>.

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## **Subsequent Events**

- April: Reported additional data from the Phase III Castor study of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma. The study met the primary endpoint of improving PFS; HR = 0.39, p<0.0001. The median PFS for patients treated with daratumumab has not been reached, compared to median PFS of 7.2 months for patients who did not receive daratumumab. Data from this study were accepted for oral presentation in a Plenary Session at the 2016 ASCO Annual Meeting.
- April: Announced that MorphoSys filed a complaint at the U.S. District Court of Delaware against Genmab and Genmab's collaboration partner Janssen, for patent infringement under U.S. patent no. 8,263,746 based on activities relating to the manufacture, use and sale of DARZALEX in the United States. Genmab and Janssen disagree with the allegations made by MorphoSys in its complaint for patent infringement related to CD38 antibodies and intend to vigorously contest those allegations.
- April: The CHMP of the EMA adopted a positive opinion recommending the granting of a conditional marketing authorization for DARZALEX in the European Union. The recommendation is for the use of DARZALEX as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

## **First Quarter Updates**

- March: Announced that the Phase III Castor study (MMY3004) of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma met the primary endpoint of improving PFS in a planned interim analysis (p<0.0001). Daratumumab showed a tolerable safety profile in the interim analysis. Based on the recommendation of the Independent Data Monitoring Committee (IDMC), the study will be stopped early. Janssen will engage in a dialogue with the health authorities about the potential for these data to serve as the basis for a regulatory submission.
- March: Announced that daratumumab will be investigated in Phase Ib clinical studies in combination with atezolizumab, an anti-PD-L1 antibody, in a solid tumor and multiple myeloma. The studies will be conducted under a clinical trial collaboration agreement between Janssen and Genentech, a member of the Roche Group.
- March: Achieved the second milestone in the ongoing Phase II study of daratumumab in NHL, triggering a USD 5 million payment from Janssen.

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# Expansive Daratumumab Development Program

Disease	isease Disease Therapy Patie		Patients*		Development Phase			
Disease	Stage	тпегару	Fallenis	I.	I/II	I	Ш	
	High Risk Smoldering	Mono	120	SMM	12001 (Cer	ntaurus)		
		Dara + VMP	700		MMY300	7 (Alcyone)		
	Front line (transplant	Dara + Revlimid + Dex	730		MMY30	08 (Maia)		
la**	& non-	Dara + VTD	1,080		MMY3006	(Cassiopei	a)	
Multiple Myeloma**	transplant)	Multi combo Study (6 arms)	190	MMY10	01 (Equul	eus)		
ž	ź	Dara + Revlimid + Dex	45	GE	EN503			
ltiple		Dara + Revlimid + Dex	570		MMY300	03 (Pollux)	$ \rightarrow $	
Mu	Relapsed or	Dara + Velcade + Dex	480		MMY300	04 (Castor)	$\rightarrow$	
	Refractory	Dara + Velcade + Dex, Japan	6	MMY10	05		-	
		Subcutaneous	128	MMY10	04			
		Dara + atezolizumab	130	Annour	ced			
NHL (DLBCL / /MCL / FL)	Relapsed or Refractory	Mono	210	LY	M2001 (Ca	arina)		
Solid Tumor	To be confirmed	Dara + atezolizumab	100	Announ	leed			

\*Approx. no. based on clinicaltrials.gov \*\*Maintenance integrated into some study protocols

Mono = monotherapy, Dara = daratumumab, VMP = bortezomib & melphalan & prednisone, Dex = dexamethasone, VTD = bortezomib, thalidomide & dexamethasone

# Arzerra (Ofatumumab) – Our First Marketed Product

- Human CD20 monoclonal antibody in development to treat cancer & autoimmune disease
- Arzerra launched in U.S. in combination with chlorambucil for first-line CLL and in Europe in combination with chlorambucil or bendamustine for first-line CLL
- Arzerra approved in U.S. for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL
- Arzerra marketed in all major markets for CLL refractory to fludarabine and alemtuzumab
- Phase III studies planned in relapsing multiple sclerosis
- Collaboration with Novartis
- Q1 2016 net sales of Arzerra by Novartis were USD 11.6 million

Arzerra (ofatumumab) is a human monoclonal antibody which targets an epitope on the CD20 molecule encompassing parts of the small and large extracellular loops. It is marketed and developed under a collaboration agreement with Novartis Pharma AG. Arzerra is approved in the U.S. in combination with chlorambucil and in Europe in combination with chlorambucil or bendamustine for first-line CLL. Arzerra is approved in the U.S. for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL. Arzerra is also approved to treat CLL in patients who are refractory to fludarabine and alemtuzumab in all major markets.

# **Approved in First-line CLL**

In April 2014, the U.S. FDA approved the use of Arzerra in combination with chlorambucil for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate. In July 2014, EU authorization was granted for the use of Arzerra in combination with

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chlorambucil or bendamustine for the treatment of patients with CLL who have not received prior therapy and who are not eligible for fludarabine-based therapy.

The approvals were based on results from a Phase III study (COMPLEMENT 1) evaluating the combination of Arzerra and chlorambucil (N=221) versus chlorambucil alone (N=226) which demonstrated statistically significant improvement in median progression free survival (PFS) in patients randomized to Arzerra and chlorambucil compared to patients randomized to chlorambucil alone (22.4 months versus 13.1 months, respectively) (HR=0.57 [95% CI, 0.45, 0.72] p<0.001).

The EU approval was also based on results from a supportive Phase II study evaluating Arzerra in combination with bendamustine in 44 patients with previously untreated CLL for whom fludarabine-based treatment was considered inappropriate. Results of this study demonstrated that Arzerra in combination with bendamustine provided an overall response rate (ORR) of 95% (95% CI, 85, 99) and a complete response rate (CR) of 43%.

## Approved in Refractory CLL

Arzerra is marketed to treat CLL in patients who are refractory to fludarabine and alemtuzumab in all major markets. The approval was based on interim results from a pivotal study of 154 patients; 59 patients with CLL refractory to fludarabine and alemtuzumab comprised the efficacy population. The ORR was 42% (all partial responses; no complete responses) and median duration of response was 6.5 months.

## Approved as Extended Treatment for Recurrent or Progressive CLL

In January 2016, the U.S. FDA approved the use of Arzerra for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL. This approval was based on data from the Phase III study PROLONG (OMB114517), evaluating of atumumab maintenance therapy versus no further treatment (observation) in patients with relapsed CLL who responded to induction treatment at relapse (N=474). Results from the study showed that patients who received of atumumab maintenance treatment lived 14.2 months longer without their disease worsening than patients who received no further treatment. Median PFS as assessed by the investigators was 29.4 months for the of atumumab treatment arm and 15.2 months for the observation arm (Hazard Ratio 0.50; p<0.0001). Novartis submitted a regulatory filing to the EMA for of atumumab as maintenance therapy in relapsed CLL in July 2015.

## Safety Information for Arzerra

The overall safety profile of Arzerra in CLL (previously untreated and relapsed or refractory) is based on data from more than 3,500 patients treated alone or in combination with other therapies in clinical trials.

The most common side effects for Arzerra include adverse events associated with infusion reactions, cytopenias (neutropenia, anemia, thrombocytopenia), and infections (lower respiratory tract infection, including pneumonia, upper respiratory tract infection, sepsis, including neutropenic sepsis and septic shock, herpes virus infection, urinary tract infection).

Please consult the full European Summary of Product Characteristics and full <u>US Prescribing information</u>, including Boxed Warning, for all the labeled safety information for Arzerra.

For additional development information on ofatumumab, visit <u>http://www.genmab.com/product-pipeline/products-in-development/ofatumumab</u>.

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# **First Quarter Updates**

- March: Announced that supplemental regulatory applications for the use of Arzerra in combination with fludarabine and cyclophosphamide for the treatment of patients with relapsed CLL were submitted in the U.S. and EU by Novartis.
- March: Announced an update on development plans for ofatumumab in autoimmune indications focusing on relapsing multiple sclerosis following the transfer of the rights to ofatumumab in this disease area from GSK to Novartis at the end of 2015. Phase III studies of the subcutaneous formulation of ofatumumab in relapsing multiple sclerosis are expected to be initiated by Novartis during the second half of 2016. The Phase III study of the subcutaneous formulation of ofatumumab in pemphigus vulgaris, which was started by GSK, will be discontinued. The decision to discontinue the trial was not related to any safety or tolerability concerns.
- February: Following a planned interim analysis, an IDMC recommended continuing the Phase III study of ofatumumab in combination with bendamustine compared to bendamustine monotherapy in patients with indolent non-Hodgkin's lymphoma (iNHL) who did not respond to a rituximab-containing regimen during or within 6 months of the last treatment with rituximab. Results from the study are expected to read out in 2017, however timelines are subject to change.
- January: The U.S. FDA approved an sBLA for the use of Arzerra for extended treatment of
  patients who are in complete or partial response after at least two lines of therapy for recurrent or
  progressive CLL.

## **Tisotumab vedotin – A Next Generation Therapeutic**

- Antibody-drug conjugate (ADC, antibody coupled to a cell-killing agent) in development to treat solid tumors
- Two clinical studies in solid tumors ongoing
- License and collaboration agreement with Seattle Genetics

Tisotumab vedotin, formerly called HuMax-TF-ADC, is an ADC targeted to Tissue Factor (TF), a protein involved in tumor signaling and angiogenesis. Based on its high expression on many solid tumors and its rapid internalization, TF is a suitable target for an ADC approach. Tisotumab vedotin is in Phase I/II development for solid tumors. Genmab has a license and collaboration agreement for tisotumab vedotin with Seattle Genetics under which Seattle Genetics has the right to exercise a co-development option at the end of Phase I clinical development. Genmab is working with Ventana Medical Systems to develop a companion diagnostic.

For more development information on tisotumab vedotin visit <u>www.genmab.com/product-pipeline/products-in-development/humax-tf-adc</u>.

## Teprotumumab

- In clinical development by River Vision
- In Phase I and Phase II clinical studies for diseases of the eye

Teprotumumab is a fully human antibody that targets the Insulin-like Growth Factor-1 Receptor (IGF-1R), which is a well validated target. Teprotumumab was created by Genmab under our collaboration with Roche. Clinical development of teprotumumab is being conducted by River Vision Development Corporation, who licensed the product from Roche. Teprotumumab is in Phase II development for Graves' orbitopathy and in Phase I for diabetic macular edema. Teprotumumab has been granted Fast Track designation and Orphan Drug designation for Graves' orbitopathy by the U.S. FDA.

For more information on teprotumumab, visit <u>http://www.genmab.com/product-pipeline/products-in-development/teprotumumab</u>.

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## AMG 714

- In clinical development by Celimmune
- Phase II clinical studies for celiac disease announced

AMG 714 is a human monoclonal antibody that binds to Interleukin-15 (IL-15), a cytokine molecule appearing early in the cascade of events that ultimately leads to inflammatory disease. AMG 714 was created under a collaboration with Amgen. Amgen has sub-licensed AMG 714 to a private company, Celimmune, LLC. Celimmune is developing AMG 714 for the treatment celiac disease.

For more development information on AMG 714, visit <u>http://www.genmab.com/product-pipeline/products-in-development/AMG\_714</u>.

#### First Quarter Updates

 March: Two Phase II studies of AMG 714 to treat celiac disease run by Celimmune have been announced.

## HuMax-TAC-ADC

- ADC in development under a collaboration and license agreement with ADC Therapeutics
- Phase I clinical studies for lymphomas and leukemias ongoing

HuMax-TAC-ADC, also known as ADCT-301, is an ADC that combines Genmab's HuMax-TAC antibody and ADC Therapeutics' PBD-based warhead and linker technology. HuMax-TAC-ADC targets CD25, which is expressed on a variety of hematological tumors and shows limited expression on normal tissues, which makes it an attractive target for antibody-payload approaches. HuMax-TAC-ADC is in development under a Collaboration and License Agreement between Genmab and ADC Therapeutics, under which Genmab owns 25% of the product rights. Phase I studies of HuMax-TAC-ADC to treat lymphomas and leukemias are ongoing.

For more development information on HuMax-TAC-ADC, visit <u>http://www.genmab.com/product-pipeline/products-in-development/humax-tac-adc</u>.

## **First Quarter Updates**

• February: The first patient was dosed in the Phase I study of ADCT-301 in relapsed or refractory AML or relapsed or refractory ALL.

## HuMax-IL8

- Fully human antibody in development under a collaboration with Cormorant Pharmaceuticals
- Phase Ib clinical study for metastatic solid tumors ongoing

HuMax-IL8 is a high affinity fully human antibody directed towards IL-8. IL-8 has recently been shown to be involved in several aspects of tumor development, including tumor spread (metastasis), cancer stem cell renewal and tumor immunosuppression. HuMax-IL8 has been shown to inhibit these processes and to inhibit tumor growth in pre-clinical tumor models. HuMax-IL8 is in development for the treatment of solid tumors under an agreement with Cormorant Pharmaceuticals.

For more development information on HuMax-IL8, visit <u>http://www.genmab.com/product-pipeline/products-in-development/humax-il8</u>.

## JNJ-61186372

- DuoBody product targeting EGFR and cMet
- Phase I study announced in NSCLC
- First DuoBody product to enter clinical development

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• Developed by Janssen under the DuoBody technology collaboration

JNJ-61186372 is a bispecific antibody that targets EGFR and cMet, two validated cancer targets. JNJ-61186372 was created under a collaboration between Genmab and Janssen using Genmab's DuoBody technology. The two antibodies used to create JNJ-61186372 were both created by Genmab. Janssen is investigating JNJ-61186372 in a Phase I clinical study to treat NSCLC, which is the first bispecific antibody created with the DuoBody technology to enter clinical development.

For more development information on JNJ-61186372, visit <u>http://www.genmab.com/product-pipeline/products-in-development/JNJ-61186372</u>.

## JNJ-63709178

- DuoBody product targeting CD3 and CD123
- Phase I study announced in AML
- Second DuoBody product to enter clinical development
- Developed by Janssen under the DuoBody technology collaboration

JNJ-63709178 is a bispecific antibody that targets CD3, which is expressed on T-cells and CD123, which is overexpressed in various hematologic malignancies. JNJ-63709178 can redirect T-cells, resulting in T-cell mediated killing of CD123+ AML cells. JNJ-63709178 was created by Janssen using Genmab's DuoBody technology under the companies' collaboration. A Phase I clinical study of JNJ-63709178 to treat AML has been announced.

For more development information on JNJ-63709178, visit <u>http://www.genmab.com/product-pipeline/products-in-development/JNJ-63709178</u>.

## First Quarter Updates

 March: A Phase I clinical study of JNJ-63709178 to treat AML has been announced via clinicaltrials.gov.

# **Pre-clinical Programs**

- Broad pre-clinical pipeline of over 25 programs including HuMax-AXL-ADC, HexaBody-DR5/DR5, and DuoBody-CD3xCD20
- Pre-clinical pipeline includes both partnered products and in-house programs based on our proprietary technologies and in-licensed ADC technologies
- Multiple new INDs expected to be submitted over coming years

Genmab has over 25 active in-house and partnered pre-clinical programs. Our pre-clinical pipeline includes naked antibodies, immune effector function enhanced antibodies developed with our HexaBody technology, bispecific antibodies created with our DuoBody platform, and ADCs including HuMax-AXL-ADC. A majority of Genmab's own pre-clinical programs are based on our proprietary DuoBody and HexaBody technologies, with the remainder being ADC programs. A number of the pre-clinical programs are carried out under cooperation with our collaboration partners. These include: DuoBody programs with Novartis, Janssen, BioNTech, Aduro Biotech Europe, and Novo Nordisk; and antibodies for disorders of the central nervous system with H. Lundbeck A/S.

For more development information on our pre-clinical pipeline, visit <u>www.genmab.com/product-pipeline/products-in-development/pre-clinical</u>.

#### **First Quarter Updates**

• February: A EUR 1.5 million milestone was achieved for selection of a candidate for potential clinical development in one of the programs under the collaboration with Lundbeck.

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# **TECHNOLOGY PROGRESS FIRST QUARTER 2016**

## DuoBody Platform – Innovative Technology for Bispecific Antibody Therapeutics

- Bispecific antibody technology platform
- Potential in cancer, autoimmune, infectious and central nervous system diseases
- Commercial collaborations with Janssen, Novartis, Aduro Biotech Europe, BioNTech, and Novo Nordisk, plus multiple research collaborations

The DuoBody platform is Genmab's innovative platform for the discovery and development of bispecific antibodies. Bispecific antibodies bind to two different epitopes (or "docking" sites) either on the same, or on different targets (also known as dual-targeting). Dual-targeting may improve binding specificity and enhance therapeutic efficacy. Bispecific antibodies generated with the DuoBody platform can be used for the development of therapeutics for cancer, autoimmune, infectious and central nervous system diseases. DuoBody molecules are unique in combining the benefits of bispecificity with the strengths of conventional antibodies, which allows DuoBody molecules to be administered and dosed the same way as other antibody therapeutics. Genmab's DuoBody platform generates bispecific antibodies via a versatile and broadly applicable process which is easily performed at standard bench, as well as commercial manufacturing scale. Genmab uses the DuoBody platform to create our own bispecific antibody programs and the technology is also available for licensing. Genmab has numerous alliances for the DuoBody platform including collaborations with Janssen, Novartis, Novo Nordisk, Aduro Biotech Europe and BioNTech.

For more information on the DuoBody platform, visit www.genmab.com/duobody.

## HexaBody Technology – Creating Differentiated Therapeutics

- Enhanced potency antibody technology platform
- Broadly applicable technology builds on natural antibody biology
- Pre-clinical proof-of-concept achieved
- Research collaborations with Humabs BioMed and Agenus

The HexaBody technology is Genmab's proprietary technology that is designed to increase the potency of antibodies. The HexaBody platform strengthens the natural killing ability of antibodies while retaining regular structure and specificity. The technology allows for the creation of potent therapeutics by inducing antibody hexamer formation (clusters of six antibodies). The HexaBody platform builds on natural antibody biology and enhances direct or complement-mediated killing, allowing antibodies with limited or absent killing capacity to be transformed into potent, cytotoxic antibodies. The HexaBody technology creates opportunities to explore new product candidates, to repurpose drug candidates unsuccessful in previous clinical trials due to insufficient potency and may provide a useful strategy in product life cycle extension. The HexaBody technology is broadly applicable and can be combined with Genmab's DuoBody platform as well as other antibody technologies. The technology has the potential to enhance antibody therapeutics for a broad range of applications in cancer and infectious diseases. Genmab intends to use the HexaBody technology for our own antibody programs and the technology is also available for licensing. Genmab has entered HexaBody research collaborations with Humabs BioMed and Agenus.

For more information on the HexaBody technology, visit www.genmab.com/hexabody.

## SIGNIFICANT RISKS AND UNCERTAINTIES

As a biotech company, Genmab faces a number of risks and uncertainties. These are common for the industry and relate to operations, research and development, commercial and financial activities. For

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further information about risks and uncertainties which the Genmab group faces, refer to the 2015 annual report.

At the date of this interim report, there have been no significant changes to Genmab's overall risk profile since the publication of the 2015 annual report.

## **FINANCIAL REVIEW**

The interim report is prepared on a consolidated basis for the Genmab group. The financial statements are published in Danish Kroner (DKK).

#### Revenue

Genmab's revenue was DKK 170 million for the first quarter of 2016 compared to DKK 107 million for the corresponding period in 2015. The increase of DKK 63 million or 59% was mainly driven by higher royalty and milestone revenue under our daratumumab collaboration with Janssen.

MDKK	Q1 2016	Q1 2015
Royalties	100	22
Milestone payments	45	-
Deferred revenue	23	73
Reimbursement income	2	12
Total revenue	170	107

Recognition of revenue may vary from period to period as revenue comprises royalties, milestone payments and reimbursement of certain research and development costs in relation to development work under Genmab's collaboration agreements.

#### **Royalties**

Royalty income amounted to DKK 100 million in the first quarter of 2016 compared to DKK 22 million in the first quarter of 2015. The increase of DKK 78 million was driven by DARZALEX royalties which were partly offset by lower Arzerra royalties.

Net sales of DARZALEX by Janssen were USD 101.9 million for the first quarter of 2016, resulting in royalty income of DKK 83 million for the first quarter of 2016. The first sales of DARZALEX occurred following the U.S. FDA approval on November 16, 2015.

Novartis net sales of Arzerra were USD 11.6 million in the first quarter of 2016 compared to USD 16.8 million in the first quarter of 2015, a decrease of 31%. Sales were negatively impacted by increased competition, primarily from Imbruvica<sup>®</sup> (ibrutinib).

The total recognized royalties on net sales of Arzerra for the first quarter of 2016 were DKK 17 million compared to DKK 22 million in the corresponding period for 2015. The decrease in royalties of DKK 5 million, or 23%, is lower than the decrease in the underlying sales due to currency fluctuations between the USD and DKK.

#### **Milestone Payments**

In the first quarter of 2016, one milestone payment was achieved under the daratumumab collaboration with Janssen. In March, a milestone payment of DKK 34 million was triggered by progress in the ongoing Phase II study ("Carina" LYM2001). In addition, one pre-clinical development milestone of DKK 11 million was achieved under our collaboration with Lundbeck.

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No milestone payments were triggered in the first quarter of 2015.

#### **Deferred Revenue**

In the first quarter of 2016, deferred revenue amounted to DKK 23 million compared to DKK 73 million in the first quarter of 2015. The decrease of DKK 50 million, or 68%, was driven by the deferred revenue related to the ofatumumab collaboration, which was fully amortized at the end of 2015. Deferred revenue is related to our collaboration agreements and is recognized in the income statement on a straight line basis over planned development periods. As of March 31, 2016, DKK 260 million was included as deferred income in the balance sheet. Please refer to note 2.1 in the 2015 annual report for further details about the accounting treatment of deferred revenue.

#### **Reimbursement Income**

Reimbursement income amounted to DKK 2 million in the first quarter of 2016 compared to DKK 12 million in the first guarter of 2015. The decrease of DKK 10 million was due to lower reimbursement income under our daratumumab collaboration, as Janssen is executing all new clinical trials.

#### **Research and Development Costs**

Research and development costs amounted to DKK 127 million in the first guarter of 2016 compared to DKK 86 million in the first guarter of 2015. The increase of DKK 41 million or 48% was driven by the additional investment in our pipeline of products, including the advancement of tisotumab vedotin, HuMax-AXL-ADC, HexaBody-DR5/DR5, DuoBody-CD3xCD20, and our other pre-clinical programs. Research and development costs accounted for 83% of our total operating expenses in the first guarter of 2016 compared to 78% in the first guarter of 2015.

#### General and Administrative Expenses

General and administrative expenses were DKK 27 million in the first quarter of 2016, compared to DKK 25 million in the corresponding period for 2015. The increase of DKK 2 million, or 8%, was driven by higher general consultancy expenses. General and administrative expenses accounted for 17% of our total operating expenses in the first guarter of 2016 compared to 22% in the first guarter of 2015.

#### **Other Income**

In March 2015, the agreement to transfer the ofatumumab collaboration from GSK to Novartis became effective. As a result of the transfer, Genmab was not required to pay the existing deferred funding liability of DKK 176 million, which was reversed during the first guarter of 2015, and the corresponding one-time gain was recognized in the income statement as other income.

#### **Operating Result**

Operating income was DKK 16 million in the first guarter of 2016 compared to DKK 173 million in the corresponding period for 2015. The decrease of DKK 157 million was driven by the one-time reversal of the ofatumumab funding liability of DKK 176 million in 2015 combined with increased operating expenses, which were partly offset by higher revenue.

As of March 31, 2016, the total number of employees was 189 compared to 175 employees as of March 31, 2015. The increase was due to the expansion our clinical product pipeline and our pre-clinical programs and administrative support functions.

Workforce		March 31, 2016	March 31, 2015	
Research and deve	elopment employees	162	154	
Administrative emp	loyees	27	21	
Total employees		189	175	
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## **Net Financial Items**

The net financial items for the first quarter of 2016 were a net loss of DKK 28 million compared to a net income of DKK 44 million in the first quarter of 2015. The main driver for the variance between the two periods is foreign exchange movements which impacted our USD denominated cash holdings and portfolio. The USD weakened significantly against the DKK during the first quarter of 2016, resulting in realized and unrealized exchange rate losses. In the first quarter of 2015, the USD strengthened significantly resulting in realized and unrealized exchange rate gains.

MDKK	Q1 2016	Q1 2015
Interest and other financial income	8	9
Adjustments of derivative financial instruments, net	-	5
Realized and unrealized gains on marketable securities, net	2	-
Realized and unrealized exchange rate gains, net	-	30
Financial income	10	44
Interest and other financial expenses	-	-
Realized and unrealized losses on marketable securities, net	-	-
Realized and unrealized exchange rate losses, net	(38)	-
Financial expenses	(38)	-
Net financial items	(28)	44

## **Corporate Tax**

Corporate tax consists of current tax and the adjustment of deferred taxes during the year. There was no change in corporate tax in the first guarter of 2016 compared to the first guarter of 2015.

#### **Net Result**

Net result for the first quarter of 2016 was a net loss of DKK 12 million compared to a net income of DKK 217 million in the corresponding period of 2015. The decrease was driven by the items described above.

#### **Cash Position**

As of March 31, 2016, Genmab's cash, cash equivalents and marketable securities (cash position) amounted to DKK 3,491 million, which was similar to the cash position of DKK 3,493 at December 31, 2015. During first quarter of 2015 our cash position increased by DKK 285 million which was primarily related to the proceeds from the exercise of warrants for DKK 317 million, partly offset by the ongoing investment in our research and development activities.

MDKK	March 31, 2016	December 31, 2015
Marketable securities	2,856	2,619
Cash and cash equivalents	635	874
Cash position	3,491	3,493

As of March 31, 2016, 98% of our marketable securities had a triple A-rating which was unchanged since the end of December 2015. Refer to note 2 in this interim report for additional information about our marketable securities.

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Cash and cash equivalents included short term marketable securities of DKK 100 million at the end of March 2016 compared to DKK 14 million at the end of March 2015. In accordance with our accounting policy, these securities are classified as cash and cash equivalents as the securities have a maturity of less than three months at the date of acquisition. The remaining cash and cash equivalents is related to bank deposits. Genmab maintains the major part of its bank deposits in highly rated financial institutions to reduce credit risk.

## **Balance Sheet**

As of March 31, 2016, total assets were DKK 3,911 million compared to DKK 3,903 million as of December 31, 2015. As of March 31, 2016, the assets are mainly comprised of a cash position of DKK 3,491 million and receivables of DKK 199 million. The receivables consist primarily of royalties and milestones from our collaboration agreements and non-interest bearing receivables, which are due less than one year from the balance sheet date. The credit risk on receivables is considered to be limited.

Shareholders' equity as of March 31, 2016 was DKK 3,521 million compared to DKK 3,487 million at the end of December 2015. On March 31, 2016, Genmab's equity ratio was 90% compared to 89% at the end of 2015. The increase was driven by the exercise of warrants in the first quarter of 2016, partly offset by the net loss for the period.



# STATEMENT OF COMPREHENSIVE INCOME FOR THE 1ST QUARTER OF 2016

#### **Income Statement**

	1st quarter of 2016 DKK'000	1st quarter of 2015 DKK'000
Revenue	170,171	106,778
Research and development expenses General and administrative expenses <b>Operating expenses</b>	(127,116) (26,716) (153,832)	(85,532) (24,524) <b>(110,056)</b>
Other income	-	176,218
Operating result	16,339	172,940
Net financial items	(27,850)	44,364
Net result before tax	(11,511)	217,304
Corporate tax	(14)	(14)
Net result	(11,525)	217,290
Basic net result per share Diluted net result per share	(0.19) (0.19)	3.80 3.64
Statement of Comprehensive Income		
Net result	(11,525)	217,290
Other comprehensive income:		
Amounts which will be re-classified to the income statement: Adjustment of foreign currency fluctuations on subsidiaries Fair value adjustments of cash flow hedges: Fair value adjustments during the period Fair value adjustments reclassified to the income statement	(4,367) -	11,723 - -
Total comprehensive income	(15,892)	229,013

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# **BALANCE SHEET – ASSETS**

	Note	March 31, 2016 DKK'000	December 31, 2015 DKK'000	March 31, 2015 DKK'000
Intangible assets Property, plant & equipment Receivables Deferred tax assets		184,748 30,521 6,754 6,078	192,642 28,812 6,863 6,342	105,464 23,810 6,892 6,448
Total non-current assets		228,101	234,659	142,614
Receivables		192,510	174,660	87,499
Marketable securities	2	2,855,608	2,619,243	2,616,596
Cash and cash equivalents		634,914	873,986	328,538
Total current assets		3,683,032	3,667,889	3,032,633
Total assets		3,911,133	3,902,548	3,175,247

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# **BALANCE SHEET – SHAREHOLDERS' EQUITY AND LIABILITIES**

	2015	2015
 DKK'000	DKK'000	DKK'000
59,678	59,531	58,134
7,599,288	7,560,991	7,236,241
90,109	94,476	95,824
(4,227,822)	(4,228,278)	(4,802,051)
3,521,253	3,486,720	2,588,148
1 422	1 400	1 4 2 2
1,433	1,433	1,433 59
-	-	59
-		-
1,433	1,433	1,492
-	-	-
59	118	237
260,081	282,708	478,088
128,307	131,569	107,282
388,447	414,395	585,607
389,880	415,828	587,099
3,911,133	3,902,548	3,175,247
	59,678 7,599,288 90,109 (4,227,822) <b>3,521,253</b> 1,433 - - <b>1,433</b> - - 59 260,081 128,307 <b>388,447</b> <b>389,880</b>	59,678       59,531         7,599,288       7,560,991         90,109       94,476         (4,227,822)       (4,228,278)         3,521,253       3,486,720         1,433       1,433         1,433       1,433         -       -         -       -         1,433       1,433         -       -         -       -         59       118         260,081       282,708         128,307       131,569         388,447       414,395         389,880       415,828

Share-based instruments	3
Shareholdings by the Board of Directors and Executive Management	4
Subsequent events to the balance sheet date	5

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# STATEMENT OF CASH FLOWS

	Note	1st quarter 2016 DKK'000	1st quarter 2015 DKK'000
Net result before tax		(11,511)	217,304
Reversal of financial items, net		27,850	(44,364)
Adjustments for non-cash transactions Changes in working capital		22,164 (57,533)	13,935 (258,081)
Cash flow from operating activities before financial items		(19,030)	(71,206)
Financial interest received		10,466	15,844
Financial expenses paid Corporate taxes received/(paid)		(58) (14)	(23) (14)
Cash flow from operating activities		(8,636)	(55,399)
Investments in intangible assets		-	(19,360)
Investments in tangible assets		(4,104)	(380)
Marketable securities bought Marketable securities sold	2	(424,385) 183,672	(1,190,856) 882,285
Cash flow from investing activities		(244,817)	(328,311)
Warrants exercised		38,444	317,182
Paid installments on lease liabilities		(60)	(60)
Cash flow from financing activities		38,384	317,122
Change in cash and cash equivalents		(215,069)	(66,588)
Cash and cash equivalents at the beginning of the period Exchange rate adjustments		873,986 (24,003)	359,087 36,039
Cash and cash equivalents at the end of the period		634,914	328,538
Cash and cash equivalents include:			
Bank deposits and petty cash		534,882	314,683
Short-term marketable securities		100,032	13,855
Cash and cash equivalents at the end of the period		634,914	328,538

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# STATEMENT OF CHANGES IN EQUITY

	Number of shares	Share capital DKK'000	Share premium DKK'000	Translation reserves DKK'000	Cash flow hedges DKK'000	Accumulated deficit DKK'000	Shareholders' equity DKK'000
December 31, 2014	56,967,419	56,967	6,920,226	84,101	-	(5,028,355)	2,032,939
Total comprehensive income				11,723	-	217,290	229,013
Transactions with owners: Exercise of warrants	1,166,245	1,167	316,015				317,182
Share-based compensation expenses						9,014	9,014
March 31, 2015	58,133,664	58,134	7,236,241	95,824		(4,802,051)	2,588,148
Total comprehensive income				(1,348)	-	546,223	544,875
Transactions with owners: Exercise of warrants	1,397,599	1,397	324,750				326,147
Share-based compensation expenses						27,550	27,550
December 31, 2015	59,531,263	59,531	7,560,991	94,476		(4,228,278)	3,486,720
Total comprehensive income				(4,367)	-	(11,525)	(15,892)
Transactions with owners: Exercise of warrants	146,321	147	38,297				38,444
Share-based compensation expenses						11,981	11,981
March 31, 2016	59,677,584	59,678	7,599,288	90,109	-	(4,227,822)	3,521,253

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# NOTES TO THE FINANCIAL STATEMENTS

## **Note 1 – Accounting Policies**

#### **Basis of Presentation**

The interim report is prepared in accordance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting" and additional Danish disclosure requirements for interim reports of listed companies. The interim report has not been reviewed or audited by Genmab's external auditors.

#### **Accounting Policies**

Except as outlined below, the interim report has been prepared using the same accounting policies as outlined in section 1 – Basis of Presentation in the financial statements in the 2015 annual report.

Genmab has, with effect from January 1, 2016, implemented the amendments to IAS 27, IAS 16, IAS 38, IFRS 11, IFRS 10, IAS 28, IAS 1 and the improvements to IFRSs 2012-2014 cycles. The implementation has not impacted the recognition and measurement of Genmab assets and liabilities.

### Management Judgments and Estimates under IFRS

In preparing interim reports, certain provisions under IFRS require management to make judgments (various accounting estimates and assumptions) which may significantly impact the group's financial statements. The most significant judgments include, among other things, revenue recognition, share-based compensation, and recognition of internally generated intangible assets. For additional descriptions of significant judgments and estimates, refer to note 1.3 in the 2015 annual report.

#### Fair Value Measurement

For financial instruments that are measured in the balance sheet at fair value, IFRS 13 for financial instruments requires disclosure of fair value measurements by level of the following fair value measurement hierarchy for:

- Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 Inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices)
- Level 3 Inputs for the asset or liability that are not based on observable market data (that is, unobservable inputs).

(MDKK)		March	31, 2016	Decembe	er 31, 2015
Assets Measured at Fair Value	Note Level 1 Level 2			Level 1	Level 2
Marketable securities	2	2,856	-	2,619	-

## **Marketable Securities**

All fair market values are determined by reference to external sources using unadjusted quoted prices in established markets for our marketable securities (Level 1).

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## Note 2 – Marketable Securities

	March 31, 2016 DKK'000	December 31, 2015 DKK'000 (full year)	March 31, 2015 DKK'000
Cost at the beginning of the period Additions for the period Disposals and maturities for the period	2,636,642 424,386 (180,622)	2,319,174 2,075,458 (1,757,990)	2,319,174 1,190,856 (888,780)
Cost at the end of the period	2,880,406	2,636,642	2,621,250
Fair value adjustment at the beginning of the period Fair value adjustment for the period	(17,399) (7,399)	(17,746) 347	(17,746) 13,092
Fair value adjustment at the end of the period	(24,798)	(17,399)	(4,654)
Net book value at the end of the period	2,855,608	2,619,243	2,616,596
Net book value in percentage of cost	99.1%	99.3%	99.8%
Average effective duration	1.39	1.69	1.40

In accordance with the group's risk management guidelines, Genmab's marketable securities are administrated by two external investment managers who solely invest in securities from investment grade issuers.

As of March 31, 2016, Genmab had only invested its cash in deposits with major financial institutions, Danish mortgage bonds and notes issued by Danish, European, and American governments.

## **Note 3 – Share-Based Instruments**

#### **Restricted Stock Unit Program**

Genmab A/S established a Restricted Stock Unit (RSU) program as an incentive for the members of the Board of Directors and members of the Executive Management in 2014.

Each restricted stock unit provides the owner with a right and obligation to receive one share in Genmab A/S of nominally DKK 1. The fair value of each restricted stock unit is equal to the closing market price on the date of grant of one Genmab A/S share.

Genmab A/S intends to purchase its own shares in order to cover its obligations in relation to the RSUs. Authorization to purchase Genmab A/S' own shares up to a nominal value of DKK 500,000 was given at the Annual General Meeting in March 2016. No shares have been purchased as of March 31, 2016.

## **RSU Activity**

The RSU activity in the first quarter of 2016 and 2015, respectively, is outlined below.

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	1st quarter 2016	1st quarter 2015
Outstanding RSUs at January 1 Granted Vested Forfeited/Cancelled	72,895 - - (3,256)	44,350 5,400 - -
Outstanding RSUs at March 31	69,639	49,750

There were no RSUs granted during the first quarter of 2016.

## Warrant Program

Genmab A/S established warrant programs as an incentive for the members of the Executive Management and the group's employees.

## Warrants Granted from August 2004 until April 2012

Under the August 2004 warrant program, warrants vest annually over a four year period on the anniversary of the grant date. Warrants granted under the August 2004 warrant program will lapse on the tenth anniversary of the grant date. As a general rule, the warrant holder may only exercise 25% of the warrants granted per full year of employment or affiliation with Genmab after the grant date.

However, the warrant holder will be entitled to retain rights to exercise all warrants on a regular schedule in instances where the employment relationship is terminated by Genmab without cause.

## Warrants Granted from April 2012

In April 2012, a new warrant program was adopted by the Board of Directors. Whereas warrants granted under the August 2004 warrant program will lapse on the tenth anniversary of the grant date, warrants granted under the new April 2012 warrant program will lapse at the seventh anniversary of the grant date. All other terms in the warrant programs are identical.

## Warrant Activity

The warrant activity in the first quarter of 2016 and 2015, respectively, is outlined below.

	1st quarter 2016	1st quarter 2015
Outstanding warrants at January 1 Granted Exercised Expired/lapsed/cancelled	2,876,517 24,350 (146,321) (8,526)	5,278,589 22,050 (1,166,245) (1,625)
Outstanding warrants at March 31	2,746,020	4,132,769
Weighted average exercise price	DKK 259.26	DKK 225.76

During the first quarter of 2016, 24,350 warrants were granted to our employees with a weighted average exercise price of DKK 815.50 per warrant and a weighted average Black-Scholes fair market value of DKK 286.20 per warrant. During the first quarter of 2015, 22,050 warrants were granted to our employees with a weighted average exercise price of DKK 466.20 per warrant and a weighted average Black-Scholes fair market value of Scholes fair market value of DKK 466.20 per warrant and a weighted average Black-Scholes fair market value of DKK 466.20 per warrant and a weighted average Black-Scholes fair market value of DKK 154.92 per warrant.

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In the first quarter of 2016, 146,321 warrants were exercised with proceeds to Genmab of DKK 38 million. The warrants exercised increased Genmab's share capital accordingly and corresponded to approximately 0.2% of Genmab's share capital. In the first quarter of 2015, 1,166,425 warrants were exercised with proceeds to Genmab of DKK 317 million.

Share-based compensation expenses for the first quarter of 2016 totaled DKK 12 million compared to DKK 9 million in the corresponding period for 2015. The group accounts for share-based compensation by recognizing compensation expenses related to share-based instruments granted to the Board of Directors, Executive Management and employees in the income statement. Such compensation expenses represent the fair market values of RSUs and warrants granted and do not represent actual cash expenditures.

## Note 4 - Shareholdings by the Board of Directors and Executive Management

The tables below set forth certain information regarding the beneficial ownership of the issued share capital and the outstanding share-based instruments held by the members of the Board of Directors and the Executive Management as of March 31, 2016.

	December 31, 2015	Acquired	Sold	Transferred	March 31, 2016
Number of ordinary shares owned		<u></u>			
Board of Directors					
Mats Pettersson	10,000	-	-	-	10,000
Anders Gersel Pedersen	-	7,500	-	-	7,500
Burton G. Malkiel	16,375	3,000	-	-	19,375
Pernille Erenbjerg	-	-	-	-	-
Paolo Paoletti	-	-	-	-	-
Peter Storm Kristensen	-	-	-	-	-
Rick Hibbert	-	-	-	-	-
Daniel Bruno	-	-	-	-	-
Tom Vink	-	-	-	-	-
Nedjad Losic	1,000		-	(1,000)	-
	27,375	10,500	-	(1,000)	36,875
Executive Management					
Jan van de Winkel	600,000	-	-	-	600,000
David A. Eatwell			-		
	600,000		-		600,000
Total	627,375	10,500	-	(1,000)	636,875

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	December 31, 2015	Granted	Exercised	Transferred	March 31, 2016
Number of warrants held				·	
Board of Directors					
Mats Pettersson	38,750	-	-	-	38,750
Anders Gersel Pedersen	90,000	-	(22,500)	-	67,500
Burton G. Malkiel	26,500	-	(12,000)	-	14,500
Pernille Erenbjerg	-	-	-	-	-
Paolo Paoletti	-	-	-	-	-
Peter Storm Kristensen	-	-	-	1,563	1,563
Rick Hibbert	-	-	-	1,850	1,850
Daniel Bruno	-	-	-	15,250	15,250
Tom Vink	34,550	-	-	(34,550)	-
Nedjad Losic	41,500			(41,500)	-
	231,300		(34,500)	(57,387)	139,413
Executive Management					
Jan van de Winkel	494,900	-	-	-	494,900
David A. Eatwell	515,875				515,875
	1,010,775			<u> </u>	1,010,775
Total	1,242,075		(34,500)	(57,387)	1,150,188

	December 31, 2015	Granted	Settled	Transferred	March 31, 2016
Number of RSUs held					
Board of Directors					
Mats Pettersson	3,257	-	-	-	3,257
Anders Gersel Pedersen	2,443	-	-	-	2,443
Burton G. Malkiel	1,628	-	-	-	1,628
Pernille Erenbjerg	3,178	-	-	-	3,178
Paolo Paoletti	3,178	-	-	-	3,178
Peter Storm Kristensen	-	-	-	-	-
Rick Hibbert	-	-	-	-	-
Daniel Bruno	-	-	-	-	-
Tom Vink	1,628	-	-	(1,628)	-
Nedjad Losic	1,628			(1,628)	
	16,940			(3,256)	13,684
Executive Management					
Jan van de Winkel	33,787	-	-	-	33,787
David A. Eatwell	21,018			<u> </u>	21,018
	54,805			<u> </u>	54,805
Total	71,745			(3,256)	68,489
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Following Genmab A/S' Annual General Meeting on March 17, 2016, the Board of Directors is comprised of four independent directors, one non-independent director, and three employee-elected directors. Mats Pettersson, Dr. Anders Gersel Pedersen, Dr. Burton G. Malkiel, Dr. Paolo Paoletti and Pernille Erenbjerg were re-elected to the Board of Directors for a one year period. Peter Storm Kristensen, Dr. Rick Hibbert and Daniel Bruno were elected to the Board of Directors by the employees for a three year period. Nedjad Losic and Dr. Tom Vink stepped down from the Board of Directors. The reclassification of the employee elected board members' shares and share-based instruments is shown in the transferred column of the tables above. The Board of Directors convened and constituted itself with Mr. Pettersson as Chairman and Dr. Pedersen as Deputy Chairman.

Other than the remuneration to the Board of Directors and the Executive Management and the transactions detailed in the tables above, no other significant transactions took place during the first quarter of 2016. For further information on the remuneration of the Board of Directors and the Executive Management, refer to note 5.1 in the 2015 annual report.

# Note 5 - Subsequent Events to the Balance Sheet Date

- On April 20, Genmab reported additional data from the Phase III Castor study of daratumumab in combination with bortezomib and dexamethasone versus bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma. The study met the primary endpoint of improving PFS; HR = 0.39, p<0.0001. The median PFS for patients treated with daratumumab has not been reached, compared to median PFS of 7.2 months for patients who did not receive daratumumab. Data from this study were accepted for oral presentation in a Plenary Session at the 2016 ASCO Annual Meeting.</li>
- On April 4, 2016 Genmab announced that MorphoSys filed a complaint at the U.S. District Court
  of Delaware against Genmab and Genmab's collaboration partner Janssen, for patent
  infringement under U.S. patent no. 8,263,746 based on activities relating to manufacture, use and
  sale of DARZALEX in the United States. Genmab and Janssen disagree with the allegations
  made by MorphoSys in its complaint for patent infringement related to CD38 antibodies and
  intend to vigorously contest those allegations.
- On April 1, 2016 Genmab announced that the CHMP of the EMA adopted a positive opinion recommending the granting of a conditional marketing authorization for DARZALEX intended for the treatment of relapsed and refractory multiple myeloma. The recommendation is for the use of DARZALEX as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

No other events have occurred subsequent to the balance sheet date that could significantly affect the financial statements as of March 31, 2016.

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## DIRECTORS' AND MANAGEMENT'S STATEMENT ON THE INTERIM REPORT

The Board of Directors and the Executive Management have today considered and adopted the unaudited interim report of the Genmab group for the three months ended March 31, 2016.

The interim report is prepared in accordance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting", as endorsed by the EU and additional Danish disclosure requirements for interim reports of listed companies.

We consider the applied accounting policies to be appropriate and, in our opinion, the interim report gives a true and fair view of the assets and liabilities, financial position, results of operation and cash flows of the group.

Furthermore, we consider the Directors' Report, pages 4-20, to give a true and fair account of the development in the group's activities and financial affairs, results of operations and the group's financial position as a whole as well as a description of the significant risks and uncertainties which the group faces.

Copenhagen, May 10, 2016

#### **Executive Management**

Jan van de Winkel	David A. Eatwell
(President & CEO)	(Executive Vice President & CFO)

# **Board of Directors**

Mats Pettersson (Chairman) Anders Gersel Pedersen (Deputy Chairman)

Burton G. Malkiel

Pernille Erenbjerg

Paolo Paoletti

Rick Hibbert (Employee elected)

Daniel J. Bruno (Employee elected) Peter Storm Kristensen (Employee elected)

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