

MolMed's Board of Directors approved the interim financial report ended March 31, 2016

- Total Revenues doubled: revenues for third parties increased by 76.4%, compared to first quarter 2105
- Operating result improved by 2.4%, compared to first quarter 2015
- Net result improved by 2.5%, compared to first quarter 2015
- Positive Net Financial Position of 23.8 million euros (29.9 million euros at December 31, 2015)

(amounts in Euro thousand)	1st quarter 2016	1st quarter 2015	Variation	
	(a)	(a)	(a-b)	%
Operating Revenues	5,343	2,658	2,685	101.0%
Revenues from activities for third parties	4,408	2,499	1,909	76.4%
Operating costs	9,383	6,799	2,584	38.0%
Operating result	(4,040)	(4,141)	101	2.4%
Net financial income & charges	(86)	(91)	5	5.5%
Result for the period	(4,126)	(4,232)	106	2.5%
(amounts in Euro thousand)	March 31, 2016	December, 31 2015	Variation	
	(a)	(a)	(a-b)	%
Net financial position	23,831	29,938	(6,107)	(20.4%)



Milan, May 10, 2016 – The Board of Directors of MolMed S.p.A. (Milan: MLM), met today under the chairmanship of Professor Claudio Bordignon, reviewed and approved, as voluntary reporting¹, the interim financial report at March 31, 2016.

Proprietary pipeline development

During the first quarter 2016, core business activities for the development of proprietary pipeline proceeded as planned:

Zalmoxis[®] (TK): in the first three months of 2016, MolMed continued interaction with the European authorities in order to obtain a Conditional Marketing Authorisation (CMA) for Zalmoxis[®] and, after March 31, processed a third list of outstanding issues (LoOi) on details requested by the committees called upon to provide the final opinion on the application filed. At the same time, the Company started preparatory activities for access of the product on different European markets, which may be managed both directly and through distributors/dealers, after the Committee for Medicinal Products for Human Use (CHMP) issues any positive opinion.

NGR-hTNF: in the first quarter of 2016, MolMed carried on the analysis aimed at in-depth insight on the product's effects on the immune system, already highlighted in previous Phase II trials, in order to strengthen and better define the potential of the product in combination with immunotherapeutic agents too. NGR-hTNF industrial development, heading for the validation of the manufacturing process to be used for the market, is proceeding as planned.

CAR CD44v6: the CAR CD44v6 project was purchased in March 2015 from the San Raffaele Hospital. This project, thanks to its specific characteristics, highlighted by the ongoing preclinical research activities, will allow the Company to play a significant role in the promising field of immune-gene therapy against cancer, since it can potentially be used for various forms of haematological and solid cancers. Therefore, during the first quarter 2016, research and development activities aimed at the characterisation of the anti-tumour activity of CAR CD44v6-expressing T cells in animal models of human (both solid and liquid) and murine tumours, as well as at the development of production systems for viral vectors encoding CAR CD44v6 in association with the suicide gene HSV-TK have been strengthen.

Development and GMP production activities

In the first quarter 2016, the new production facility located at the Open Zone science park in Bresso (Milan) has been completed. On the 20th of April, following an official notification by AIFA (*Agenzia Italiana del Farmaco*), the Company started the activities for the authorisation process of the facility, which should be gradually authorised by the authority starting from the second part of 2016.

Regarding development and GMP production for third parties, in the first months of 2016 MolMed's client portfolio has been enlarged and, among existing collaborations, a major achievement has been reached. Regarding the former, during the first quarter 2016 a multi-year agreement for a new industrial collaboration was signed with Genenta Science (Genenta) to develop and manufacture a gene therapy for the treatment of multiple myeloma. Regarding long lasting collaborations, on the 1st of April, 2016, EMA's CHMP issued a positive opinion, recommending marketing authorisation, on GlaxoSmithKline's stem cell-based gene therapy for patients affected by ADA-SCID (Adenosine Deaminase - Severe Combined Immune Deficiency) for whom

¹ It is recalled that by means of Legislative Decree no.25/2016, implementing the European provision 2013/50/EU, abolished the requirement of the interim financial reporting, previously provided by Legislative Decree no 58/1998, art 154-ter, paragraph 5.



no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available.

This genetic treatment is the first receiving the European authorisation and represents the tangible and promising result of the strategic collaboration involving GSK, the San Raffaele Telethon Institute for Gene Therapy (HSR-TIGET) and MolMed. As provided for in the agreement signed with GSK in March 2015, and based on the authorisation granted by AIFA to the operating facility located in Milan at DIBIT in December, MolMed will produce, as exclusive manufacturer, this gene therapy once it will be fully authorised for commercialisation by EMA.

Comments on financial results

In first quarter 2016, **revenues** totalled Euro 5,343 thousand, doubling first quarter 2015 result. This increase was mainly driven by development and GMP production activities for third parties, which grew by 76.4% to Euro 4,408 thousand. In particular, first quarter 2016 benefitted from new client activities and from the agreement signed with GlaxoSmithKline on the 19 of March 2015.

Other revenues for a total of Euro 935 thousand are connected to financial grants (Euro 535 thousand) and to tax credit (Euro 400 thousand), accounted according to Decree "*Attuazione del credito d'imposta per attività di ricerca e sviluppo*" of May 27, 2015.

In the first quarter 2016 **Operating costs** totalled Euro 9,383 thousand, higher respect to first quarter 2015 (Euro 6,799 thousand), largely due to:

- service costs, equal to Euro 4,570 thousand (from Euro 3,018 thousand as March 31, 2015), grown as a result of external development costs, mainly affected by the industrial development of NGR-hTNF, of the advancement of the SUPERSIST project, granted by the European Union, as well as of the increasing activities for third parties. Regarding "License fees" and IP expenditures it is worth mentioning that the agreement signed in 2001 between MolMed, the shareholder Science Park Raf (in liquidation) and its holding Ospedale San Raffaele, under which the Company holds an option right on the intellectual property generated from research projects conducted by the San Raffaele Scientific Institute, expired in March 2016.
- raw material and consumables costs, increased from Euro 840 thousand in first quarter 2015 to Euro 1,125 thousand in the same period of 2016, as a result of the intensification of development and GMP production activities;
- personnel costs, equal to Euro 3,066 thousand in the first quarter 2016, grew from Euro 2,426 thousand as March 31, 2015, as a result of the increased number of employees in operational areas of the Company, bringing the number of employees to 162 employees (from 152 as December 31, 2015).

It is worth mentioning that investments in the first quarter 2016 amounted to Euro 211 thousand, mainly related to the construction of the second facility located at Bresso (Milan), but also to the upgrading of laboratory equipment, purchasing of new equipment for the industrial production process of Zalmoxis[®] (TK) and revamping and optimizing of the existing GMP facility.

The above mentioned changes in operating costs, offset by the significant increase in revenues, produced in first quarter 2016 an **operating result** negative for Euro 4,040 thousand, and a **net result** negative for Euro 4,126 thousand, slightly improved respect to losses of, respectively, Euro 4,141 thousand and Euro 4,232 thousand, in the same period of last year.



The **net financial position** at March 31, 2016, is positive for Euro 23,831 (form Euro 29,938 thousand at December 31, 2015), and is entirely composed of cash and cash equivalents, and financial receivables mainly represented by time deposits, in absence of financial indebtedness.

Business outlook

In light of the events that occurred during the first quarter 2016, top management confirms the outlook already provided for FY 2016 (please refer to the press release issued on March 7, 2016), with respect to pursuance of the clinical and industrial development of its main investigational products, as well as for activities and investments designed to significantly increase its manufacturing capacity, which will be dedicated to development and manufacturing, both of MolMed's cell and gene therapy products as well as those for third parties.

The official manager responsible for preparing the Company's financial reports, Andrea Quaglino, herewith attests, pursuant to Article 154-bis, paragraph 2 of the Legislative Decree 58/1998 ("Testo Unico della Finanza"), that the accounting disclosure contained in this press release matches documentary evidence, corporate books, and accounting records.

In this press release, use is made of "alternative performance indicators" which are not provided for under European IFRS, and whose significance and content - in line with Recommendation CESR/05-178b published on November 3, 2005 - are illustrated below:

- Operating Result: defined as the difference between sales revenues and other income and costs for materials, costs of services received, costs for use of third-party assets, personnel costs and amortisation, depreciation & write downs. It represents the profit before financial flows and taxes;
- Net Financial Position: is the algebraic sum of cash, cash equivalents, financial receivables and other financial assets, and current and non-current financial debt.

This press release is written in compliance with public disclosure obligations established by CONSOB (Italian securities & exchange commission) resolution no. 11971 of 14 May 1999, as subsequently amended.



About MolMed

MolMed S.p.A. is a medical biotechnology company focused on research, development and clinical validation of novel anticancer therapies. MolMed's pipeline includes anti-tumour therapeutics in clinical and preclinical development: Zalmoxis® (TK) is a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, currently in Phase III in high-risk acute leukaemia and under evaluation by EMA for a Conditional Marketing Authorization; NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the cancer and to the concentration of immune system cells into the tumour mass, currently investigated in a broad clinical programme, involving more than 1000 treated patients; CAR-CD44v6, an immuno-gene therapy project potentially effective for many haematological malignancies and several epithelial tumours, currently in preclinical development. MolMed also offers top-level expertise in cell and gene therapy to third parties to develop, conduct and validate projects from preclinical to Phase III trials, including scale-up and cGMP production of clinical-grade viral vectors, and manufacturing of patient-specific genetically engineered cells. MolMed has its headquartered at the San Raffaele Biotechnology Department (DIBIT) in Milan, Italy, and a local unit at OpenZone, in Bresso (Milan). MolMed is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana (ticker Reuters: MLMD.MI).

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DISCLAIMER

This press release may contain certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, including scientific, business, economic and financial factors, which could cause actual results to differ materially from those anticipated in the forward-looking statements. The company assumes no responsibility to update forward-looking statements or adapt them to future events or developments. This document does not constitute an offer or invitation to subscribe or purchase any securities of MolMed S.p.A..



Financial statements at 31 March 2016 Income statement

(amounts in € thousand)	1st quarter 2016	1st quarter 2015
Revenues (from activities from third parties)	4,408	2,499
Other income	935	159
Total operating revenues	5,343	2,658
Purchases of raw materials and consumables	1,125	840
Costs for services	4,570	3,018
Costs for use of third-party assets	350	381
Personnel costs	3,066	2,426
Other operating costs	41	29
Amortization, depreciation and write-downs	231	105
Total operating costs	9,383	6,799
Operating result	(4,040)	(4,141)
Financial income	30	2
Financial charges	(116)	(93)
Net financial income (charges)	(86)	(91)
Pre-tax result	(4,126)	(4,232)
Income taxes		-
Profit (loss) for the period	(4,126)	(4,232)

Statement of comprehensive income

(amounts in € thousand)	1st quarter 2016	1st quarter 2015
Profit (loss) for the period	(4,126)	(4,232)
Other comprehensive income (not subsequently reclassified to		
the income statement)	-	-
Profit (loss) actuarial	1	-
Other comprehensive income, net of taxes (not subsequently		
reclassified to the income statement)	1	-
Other comprehensive income (subsequently reclassified to the		
income statement)	-	-
Gains and losses on available-for-sale financial assets	-	-
Other comprehensive income, net of taxes (subsequently		
reclassified to the income statement)	-	-
Total comprehensive income (loss) for the period	(4,125)	(4,232)



Financial statements at 31 March 2016 Net financial position

(amounts in € thousand)	March, 31 2016	December, 31 2015
Cash on hand	18	14
Other cash	13,776	11,756
Cash equivalents	-	-
A. Total cash and cash equivalents	13,793	11,770
B. Current financial receivables and other financial assets	10,038	18,168
Finance lease payables	-	-
Current financial debt	-	-
C.Current financial debt	-	-
D. Net current financial position (A+B+C)	23,831	29,938
Finance lease payables	-	-
Non current financial debt	-	-
E. Non-current financial debt	-	-
F. Net financial position (D+E)	23,831	29,938