

## MolMed's Board of Directors reviewed business performance and approved Interim Results at March 31st, 2017

- Zalmoxis: market access and commercialization preparatory activities proceeded:
  - negotiations with National health authorities to define pricing & reimbursement intensified in some of the main European countries
  - a term-sheet for the distribution in selected Asian countries signed with TTY Biopharm
- CAR-CD44v6: further confirmation from preclinical research of potential use also in solid tumours
- NGR-hTNF: interactions on CMA request started with EMA
- Expanded portfolio of development and GMP production collaborations due to an agreement signed with Rocket Pharma in the field of gene therapy for rare diseases
- Financial results:
  - Total revenues of Euro 4,409 thousand, in line with expectations
  - Operating and net results further improved due to a 14% reduction in operating costs
  - Positive net financial position of Euro 15.2 million (Euro 19.7 million at December 31, 2016)



(amounts in Euro thousand)	1st quarter 2017 (a)	1st quarter 2016 (b)	Variation (a-b)	Variation %
	4.400	5.040	(00.1)	(47.50()
Operating Revenues	4,409	5,343	(934)	(17.5%)
Revenues from activities for third parties	3,741	4,408	(667)	(15.1%)
Operating costs	8,074	9,383	(1,309)	(14.0%)
Operating result	(3,665)	(4,040)	375	9.3%
Net financial income & charges	(15)	(86)	71	82.6%
Result for the period	(3,680)	(4,126)	446	10.8%
(amounts in Euro thousand)	March 31, 2017 (a)	December, 31 2016 (b)	Variation (a-b)	Variation %
Net financial position	15,203	19,702	(4,499)	(22.8%)

Milan, May 8, 2017 – The Board of Directors of MolMed S.p.A. (Milan: MLM), met today under the chairmanship of Professor Claudio Bordignon, reviewed and approved interim financial results at March 31<sup>st</sup>, 2017, on a voluntary basis<sup>1</sup>.

Riccardo Palmisano, MolMed's CEO, commented the first quarter 2017 business evolution as follows: "During the first three months of 2017 the Company worked on implementing actions needed to valorise important results achieved in 2016, both for the development of proprietary products and expansion of the industrial collaborations portfolio.

Activities preparatory to market access of Zalmoxis in the main European countries proceeded: we met the GB-A in Germany and AIFA's CTS in Italy. As regards commercialisation, we signed the first license and distribution agreements for Zalmoxis in Israel and some Asian Countries, and contemporaneously further explored potential collaborations in Europe and other non-European territories. Furthermore, the market exclusivity extension until 2030 for Zalmoxis in Italy, thanks to the supplementary protection certificate granted by the Italian Patent and Trademark Office, represents an additional means to support the commercial strategy we defined for Zalmoxis.

Concerning NGR-hTNF, we started interacting with the European authorities on the CMA request submitted in late December 2016.

Finally, preclinical research on proprietary immuno-gene therapy project, CAR CD44v6, proceeded in the first quarter 2017, and confirmed its therapeutic potential in solid tumours, thereby suggesting the best development course and its place in therapy and consequently the most appropriate path to follow to initiate trials in man, potentially in 2018.

<sup>&</sup>lt;sup>1</sup> Italian Legislative Decree n. 25/2016 implementing Directive 2013/50/EU (the "Decree") eliminated the mandatory requirement to publish the quarterly interim financial reports, previously requested pursuant to paragraph 5, art.154-ter of Italian Legislative Decree n. 58/1998 (the "TUF"). For additional information, please refer to the press release issued on January 30 2017.



Development and production activities for third parties also reinforced during the first quarter of 2017 due to an agreement signed with Rocket Pharma, a US company focused on the development of gene therapies for rare diseases.

In conclusion, business is proceeding as planned and the Company is implementing, all activities needed to valorise its important assets and for future growth, in accordance with the strategy."

#### Main events occurred in the first quarter 2017

Zalmoxis: proceedings for access to the Italian market begun, by filing the related dossier for definition of pricing & reimbursement in December 2016, the Company recently met with AIFA's scientific and technical commission (CTS). During the first quarter of 2017, the Company met with the German authority GB-A so as to fine-tune preparation of the pricing & reimbursement request in Germany. Furthermore, activities preparatory to negotiations in other major European countries started. Regarding commercialization of Zalmoxis, on February 7th MolMed and TTY Biopharm Company Ltd signed a term-sheet defining the main terms and conditions under which MolMed will grant TTY an exclusive license agreement for the commercialization of Zalmoxis in selected Asian countries. The term-sheet foresees that terms provided for therein be incorporated in a definitive agreement by June 30th, 2017. For additional information, please refer to the relative press release, issued on February 7, 2017.

**NGR-hTNF**: after validation of CMA request by the EMA (December 23rd, 2016), as second-line treatment for adult patients affected by malignant pleural mesothelioma with disease progressing within 6 months from end of first- line treatment, EMA appointed *Rapporteur* and *Co-Rapporteur* in charge of the CMA procedure, and CHMP adopted the first List of Questions (LoQ), in accordance with the standard *iter* that rules interactions with the authority.

**CAR CD44v6**: following up on preclinical data shown last December during the 58<sup>th</sup> ASH Congress, research and pre-clinical development activities proceeded, confirming the project's therapeutic potential in a second tumour istotype. At the same time, syngeneic tumour models were developed in immunocompetent mice. A protocol suitable for transduction of murine lymphocytes with the CAR 44v6 and the HSV-TK suicide genes was developed. Preliminary experiments were performed to evaluate the dose of lymphocytes suitable for the treatment and their ability to migrate to the tumour controlling its growth *in situ*. On February 27th and 28ththe kick off meeting for the EURE-CART project (EURopean Endeavour for Chimeric Antigen Receptor Therapies) took place. The European Commission awarded the EURE-CART project a Euro 5,903 thousand grant. The project's main aim is to conduct a multicentre, first-in-man Phase I/IIa clinical trial to demonstrate safety and efficacy of CD44v6 CAR T-cell immunotherapy in acute myeloid leukaemia and multiple myeloma.

**Development and GMP manufacturing activities**: activities proceeded according to plans scheduled with third parties (GSK, Telethon and Genenta) on therapeutics covered by existing collaborations, as well as on setting up new ones. MolMed and Rocket Pharmaceuticals Ltd. signed a development and manufacturing service agreement on a gene therapy for the treatment of Fanconi Anemia. For additional information, please refer to the press release issued on February 27th, 2017. , Leveraging on our particular and acknowledged skills in the field of cell and gene therapy, we concurrently pursued interactions with new potential partners and clients with the aim of further expanding the collaboration portfolio.



Regarding the new facility located at Open Zone in Bresso, the validation activities proceeded and the dossier for the authorization of an additional GMP Manufacturing area will be presumably submitted within the first half of 2017.

#### Comments on financial results of First Quarter 2017

**Revenues** in first quarter 2017 totalled Euro 4,409 thousand (Euro 5,343 thousand first quarter 2016), in line with Company expectations and essentially mirrors activities planned by GlaxoSmithKline for this period.

Other income, for an amount of Euro 668 thousand, includes R&D public grants (Euro 144 thousand), tax credit income on R&D activities (Euro 323 thousand) recorded pursuant to Italian Decree of May 27, 2015, implementing Law n. 190 of 23 December 2014 ("Stability Law 2015") and tax credit income on recruitment of highly skilled people (Euro 196 thousand), recorded pursuant to Ministerial Decree of October 23, 2015.

In first quarter 2017 **operating costs** further improved by 14.0%, decreasing from Euro 9,383 thousand in the first three months of 2016 to Euro 8,074 thousand, due to the following reasons:

- service costs decreased by 34.6% from Euro 4,750 thousand in the first quarter 2016 to Euro 2,991 thousand in the first quarter 2017, when higher consultancy costs for activities preparatory to Zalmoxis' pricing & reimbursement have been more than offset by lower external development costs, due to the termination of the SUPERSIST project (October 2016) and lower development costs for one of the proprietary product;
- personnel costs, equal to Euro 3,214 thousand in the first quarter 2017, increased by 4.8% compared to Euro 3,066 thousand in the same period of 2016, as a result of the strengthening of the Company's operational functions and units;

In the first three months of 2017, **investments** amounted to Euro 187 thousand, mainly related to the construction of the operating unit in Bresso (Milan) and, to a lesser extent, to the ordinary renovation of laboratory equipment and purchase of new equipment for Zalmoxis's industrial production process, as well as to revamping and optimisation of the existing GMP facility.

The above-described trend in operating costs resulted in a 9.3% improvement of the **operating result** in the first quarter 2017, equal to a loss of Euro 3,665 thousand compared to a loss of Euro 4,040 in the same period of 2016.

For the same reasons, the **net result** at March 31<sup>st</sup>, 2017 clearly improved by 10.8%, recording a loss of Euro 3,680 thousand from a loss of Euro 4,126 thousand at March 31<sup>st</sup>, 2016.

The **net financial position** at March 31<sup>st</sup>, 2017 is positive for Euro 15,203 thousand (Euro 19,702 thousand at December 31<sup>st</sup>, 2016) and consists solely of cash, cash equivalents and current financial receivables in the form of time deposit, with no financial debt.



#### Key events occurred after the period

## MolMed and Megapharm enter into a license and distribution agreement for Zalmoxis in Israel

On April 28th, 2017, MolMed S.p.A. and Megapharm Ltd announced having signed a distribution and license agreement which defines all terms and conditions for the supply, registration, promotion and distribution of Zalmoxis in Israel, as anticipated on December 1st, 2016, when the companies signed a term sheet defining the main terms and conditions.

Under the terms and conditions of the agreement Zalmoxis will be distributed and marketed by Megapharm, once approved by the Israeli Ministry of Health (MOH) and included in the Israeli National Health Basket of drugs by the MOH. Furthermore, Megapharm will be responsible for conducting all regulatory activities after marketing authorisation in Israel, including market access and pricing & reimbursement.

#### Market exclusivity in Italy for Zalmoxis extended until 2030

On May 4th, 2017, the Italian Patent and Trademark Office granted Zalmoxis a supplementary protection certificate (SPC) on the Italian portion of the EP 1 781 789 European patent covering the product, which describes and claims the active ingredient of Zalmoxis, based on the Conditional Marketing Authorization obtained last August in Europe.

The granted SPC extends by 5 years, up to June 17th, 2030, Zalmoxis' market exclusivity in Italy.

The SPC application is a national procedure initiated by MolMed in the 26 countries where the European patent is in force and the law provides for this kind of protection tool. In addition to the Italian Patent and Trademark Office, the SPC has also been issued in Luxembourg, while the request is under evaluation in other countries.

#### Business outlook

In 2017, the Company plans to continue clinical and industrial development of its main proprietary investigational products, as well as market access activities for Zalmoxis in several European countries, and to pursue expansion of collaboration agreements for development and GMP production of cell and gene therapies for third parties.

With regard to Zalmoxis, following the European Commission's granting of a conditional marketing authorization, in 2017 the Company will pursue interactions with European national health authorities to define pricing & reimbursement of the therapy and, at the same time, will carry on activities aimed at signing further commercialisation agreements, according to MolMed's strategy. Following initial feedback received on activities already implemented in the last part of 2016, the Company estimates it will be able to enter the first European market in the second half of 2017. As concerns access to the U.S. market, the Company is involving some of the most important KOL in the field of haematopoietic stem cells transplant in order to define the best strategy to gain an accelerated access from the FDA.

As for NGR-hTNF, after the first LoQ adoption by the CHMP, in 2017 the activities will be proceed as follows: interactions with the European authorities will continue, in accordance with the stages of the authorisation



process; scouting for possible financial or industrial/commercial partners will be pursued, with the goal of signing a collaboration agreement for its further development and commercialisation; depending on the outcome of these activities, industrial development of NGR-hTNF, aimed at validating the manufacturing process, will be defined.

With regard to the CAR CD44v6 project, based on the promising preclinical data collected in 2016, the grant obtained from the European Commission for the EURE-CART project, and profiting from the established development expertise within the Company, MolMed will continue investing in preclinical research and development activities, in order to valorise the unique distinguishing characteristics of the project.

With regard to contract development and manufacturing activities, the Company will continue interactions started in the previous months with several potential industrial partners, aimed at signing new service contracts.

Finally, in 2017 the new facility in Bresso will gradually be activated in line with the evolution of existing and future collaborations.

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's (Italian securities & exchange commission) Issuers Regulation.

#### 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 prophylaxis, currently in Phase III in high-risk acute leukaemia and granted a Conditional Marketing Authorisation by the European Commission; 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 is an immune 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 manufacturing of viral vectors and patient-specific genetically engineered cells. MolMed is headquartered at the San Raffaele Biotechnology Department (DIBIT) in Milan, Italy, and an operating unit at OpenZone in Bresso (Milan, Italy). 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 2017 Income statement

(amounts in Euro thousand)	1 <sup>st</sup> quarter 2017	1 <sup>st</sup> quarter 2016
Revenues (from activities from third parties)	3,741	4,408
Other income	668	935
Total operating revenues	4,409	5,343
Purchases of raw materials and consumables	1,144	1,125
Costs for services	2,991	4,570
Costs for use of third-party assets	362	350
Personnel costs	3,214	3,066
Other operating costs	46	41
Amortization, depreciation and write-downs	317	231
Total operating costs	8,074	9,383
Operating result	(3,665)	(4,040)
Financial income	10	30
Financial charges	(25)	(116)
Net financial income (charges)	(15)	(86)
Pre-tax result	(3,680)	(4,126)
Income taxes	-	-
Profit (loss) for the period	(3,680)	(4,126)

### Statement of comprehensive income

(amounts in Euro thousand)	1 <sup>st</sup> quarter 2017	1 <sup>st</sup> quarter 2016
Profit (loss) for the period	(3,680)	(4,126)
Other comprehensive income (not subsequently reclassified to the income statement)	-	-
Profit (loss) actuarial	1	1
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)	1	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	(3,679)	(4,125)



### Financial statements at 31 March 2017 Net financial position

(amounts in Euro thousand)	March 31, 2017	December 31, 2016	
Cash on hand	12	13	
Other cash	10,190	19,688	
Cash equivalents	-	-	
A. Total cash and cash equivalents	10,202	19,701	
B. Current financial receivables and other financial assets	5,001	1	
Finance lease payables	-	-	
Current financial debt	-	-	
C.Current financial debt	-	-	
D. Net current financial position (A+B+C)	15,203	19,702	
Finance lease payables	-	-	
Non current financial debt	-	-	
E. Non-current financial debt	-	-	
F. Net financial position (D+E)	15,203	19,702	