

## *MolMed Board of Directors approves the interim financial report at 31 March 2015*

### *Highlights of financial data*

#### *Key income statements*

<i>(amounts in € thousand)</i>	1 <sup>ST</sup> QUARTER 2015 (A)	1 <sup>ST</sup> QUARTER 2014 (B)	CHANGE (A-B)	CHANGE %
OPERATING REVENUES	2,658	1,405	1,253	89.2%
REVENUES FROM ACTIVITIES FOR THIRD PARTIES	2,499	1,264	1,235	97.7%
OPERATING COSTS	6,799	6,564	235	3.6%
OPERATING RESULT	(4,141)	(5,159)	1,018	19.7%
NET FINANCIAL INCOME & CHARGES	(91)	(40)	(51)	(128.0%)
RESULT FOR THE YEAR	(4,232)	(5,199)	967	18.6%

#### *Net financial position*

<i>(amounts in € thousand)</i>	31 MARCH 2015 (A)	31 MARCH 2014 (B)	CHANGE (A-B)	CHANGE %
NET FINANCIAL POSITION	46,597	11,390	35,207	309.1%

Milan (Italy), 11 May 2015 – The Board of Directors of MolMed S.p.A. (MLM.MI), chaired by Prof. Claudio Bordignon, today reviewed and approved the interim financial report at 31 March 2015. The most important elements were:

- Signature, on 19 March 2015, of a strategic collaboration agreement with GSK in gene therapies;
- successful completion of a share capital increase with option rights, fully subscribed, for a total amount of € 49,824,834.53.

### *Key achievements in the first three months of 2015*

#### *Research & Clinical Development activities*

In the first three months of 2015, the Company's activities focused mainly on the clinical development of its two investigational anticancer therapeutics: TK for the treatment of high-risk leukaemia and NGR-hTNF for the treatment of a panel of solid tumours.

During the first quarter of 2015:

- with regard to TK, **interactions with the European regulatory body (EMA) for the evaluation of the dossier requesting marketing authorisation through a special procedure (Conditional**

#### **FROM GENES TO THERAPY**

#### **MOLMED S.p.A.**

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Share capital € 19,841,682.30 fully paid - Office of Milan Company Registry number 1506630 - Tax identification number 11887610159

**Marketing Authorisation) on the basis of Phase II clinical data.** The application was validated by the European Medicine Agency (EMA) on March 26th, 2014 formally initiating the evaluation process. This special procedure request is possible in the case of TK due to the rarity of the clinical indication (TK has been granted Orphan Drug designation), a favourable risk-benefit balance and demonstration of safety and clinical efficacy. The clinical efficacy data, and in particular those of long-term survival of patients treated with TK, will be used during the analysis and discussion of the dossier submitted to EMA;

- with regard to NGR-hTNF, **continuation of patient enrolment, in the 15 European centres, in the double-blind randomised Phase II maintenance study on mesothelioma (NGR019)**, in which patients exiting first line treatment are administered weekly doses of NGR-hTNF until confirmed evidence of disease progression. The primary endpoint of the study is Progression-Free Survival (PFS).

### *Development and GMP production for third parties*

Development and production activities of new cell and gene therapy treatments performed for third parties are consolidating the company's technological leadership in this field.

During 2014 and in the first three months of 2015, work continued under the agreement signed in 2011 with Telethon Foundation and the new strategic agreement signed with GlaxoSmithKline in March 2015, for the development and production of highly innovative experimental gene therapies for up to a total of seven rare diseases, all caused by the malfunctioning of a single gene, thus allowing for the development of a potential cure by inserting the correct form of the gene in stem cells obtained from the bone marrow of the patient, using *ex vivo* genetic engineering techniques.

During the first three months of 2015 the following activities related to the development of investigational gene therapies continued:

- development activities for the production of lentiviral vectors to be used in gene therapy clinical trials for beta-thalassemia and mucopolysaccharidosis I (MPS I), and support on validation activities of the vectors in GMP. These activities were carried out under the agreement with Telethon Foundation;
- characterization of two cell lines for the production of retroviral vectors to be used for the production of the ADA-SCID gene therapy and development of analytical methods for the GMP production of carriers. The activities were carried out under the agreements with GlaxoSmithKline;
- development activities for the production of lentiviral vectors to be used in gene therapy clinical trials for metachromatic leukodystrophy (MLD) and Wiskott-Aldrich syndrome (WAS) and support on validation activities of the vectors in GMP;
- development of the GMP production process of the gene therapy for ADA-SCID, second agreement with GSK, and production of transduced cells for the compassionate treatment of patients, always for GSK;
- production of cells transduced with lentiviral vectors for the experimental treatment of patients with MLD and WAS, always under the already mentioned agreement with Telethon Foundation;
- provision of service activities for Quality Control (sterility testing in accordance with Pharmacopoeia).

### *Strategic collaboration agreement with GSK*

On 19 March 2015 MolMed entered into a strategic agreement with GlaxoSmithKline (GSK), under which MolMed will supply development, manufacturing and technology transfer services aimed at the clinical application of gene therapies based on viral vector cell transduction.

As part of the agreement, MolMed will provide its expertise in process development and its manufacturing competencies and capacity for the production of viral vectors and cell transduction.

Under the terms of the agreement, MolMed is eligible for a minimum of € 34 million in the form of upfront, milestones, services and supply, over the next five years. In particular, GSK will pay MolMed during the next 12 months starting from the effective date of the agreement an amount related to the upfront and milestones equal to approximately € 6 million.

### *Capital increase completed in the first quarter of 2015*

During the first three months of 2015 the capital increase, approved by the Extraordinary Meeting of 3 March 2014, was carried out and successfully completed. The share capital increase was completed on April 9, 2015 with the subscription of 187,311,408 ordinary MolMed shares, newly issued in the ratio of 4 shares for each 5 ordinary shares held, for a total of € 49,825 thousand, of which € 8,822 thousand by way of capital increase and € 41,003 thousand in share premium.

### *Relevant activities immediately following the closure of the quarter*

On 13 April 2015 the company exercised its option right for the purchase of the San Raffaele Hospital (OSR) immune-gene therapy project against cancer developed using the Chimeric Antigen Receptor CD44v6 (CAR-CD44v6) with potential application in several haematological and solid tumour indications. The CAR-CD44v6 is part of the CAR-T family: lymphocytes armed with chimeric receptors that have demonstrated high anti-tumour potential, also against tumours - above all haematological - which are particularly aggressive and resistant to conventional therapies.

The CAR-CD44v6 project, which has already been successfully tested in appropriate murine models, represents a product candidate with a particularly high therapeutic potential, as it specifically recognises variant 6 (v6) of the antigen CD44 (CD44v6), expressed by many haematological malignancies, including acute myeloid leukaemia and multiple myeloma - as well as by several epithelial tumours, including breast, colon, pancreatic, head-and-neck and lung carcinomas.

### *Comments to financials*

MolMed's financials are peculiar to the business model of biotech companies focused on R&D of new biopharmaceutical products and with no products on the market. At this stage high costs must be sustained for the clinical and pharmaceutical development of investigational therapeutics, whose return is deferred to future years. Given the Company's operating activities and the characteristics of trials conducted, research and development costs are fully recorded in the period they are incurred.

### *First quarter of 2015 – financial results*

Operating revenues at March, 31 2015 totaled € 2,658 thousand and show an increase of 89.2% compared to the same period of the previous year. The increase in revenues is mainly due to the intensification of GMP development and production activities for third parties. Particularly, revenues from these activities increased from € 1,264 thousand in the first quarter 2014 to € 2,499 thousand in the first quarter of 2015 (+97.7%) thanks to activities related to the above mentioned agreements with GlaxoSmithKline (GSK) and Telethon

Foundation, for development activities and GMP production of new treatment of gene therapies for rare diseases.

Operating revenues include other revenues mainly related to public funding of R&D activities.

Operating costs for the first quarter of 2015 amounted to € 6,799 thousand, slightly higher (+3.6%) with respect to the same period of the previous year.

Operating loss for the first quarter of 2015 amounted to € 4,141 thousand, improved by € 1,018 thousand (19.7%) with respect to the loss recorded in the same period of the previous year (€5,159 thousand).

Financial result, negative for €91 thousand in the first quarter of 2015 lower by €51 thousand with respect to the corresponding period of 2014.

Net result for the first quarter 2015 recorded a loss for € 4,232 thousand, compared to € 5,199 thousand recorded in the same period of 2014.

### *Net financial position*

Net financial position at March 31, 2015 is positive for € 46,597 thousand and entirely composed by cash and cash equivalents in absence of financial indebtedness. Net financial position equal to € 11,390 thousand at 31 December 2014, showed an increase of € 35,207 thousand in the first quarter of 2015 due to (i) the proceeds from the operation of share capital increase completed at 99,24% for € 39,303 thousand as at 31 March 2015, (ii) the advance payment on future share capital increase executed in February 2015 for € 1,552 thousand and (iii) the Company's ordinary operations for € 5,647 thousand.

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*The official Chief Financial Reporting Manager of MolMed S.p.A., Andrea Quaglino, herewith attests, pursuant to Article 154-bis, paragraph 2 of the Italian Consolidated Law on Finance (Legislative Decree 58/1998 as subsequently amended), 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 3 November 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.*

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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 biotechnology company focused on research, development and clinical validation of novel anticancer therapies. MolMed's pipeline includes two antitumour therapeutics in clinical development: TK, a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, in Phase III in high-risk acute leukaemia; NGR-hTNF, a novel vascular targeting agent, in Phase III in malignant pleural mesothelioma and in Phase II in six more indications: colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer, and soft tissue sarcomas. 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 is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The Company's shares are listed on the main market (MTA) of the Milan Stock Exchange. (Ticker Reuters: MLMD.MI)

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*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 2015

### Income statement

(amounts in € thousand)

	1st quarter 2015	1st quarter 2014
	(a)	(b)
Revenues (from activities from third parties)	2,499	1,264
Other income	159	141
<b>Total operating revenues</b>	<b>2,658</b>	<b>1,405</b>
Purchases of raw materials and consumables	840	796
Costs for services	3,018	3,115
Costs for use of third-party assets	381	267
Personnel costs	2,426	2,249
Other operating costs	29	29
Amortization, depreciation and write-downs	105	108
<b>Total operating costs</b>	<b>6,799</b>	<b>6,564</b>
<b>Operating result</b>	<b>(4,141)</b>	<b>(5,159)</b>
Financial income	2	6
Financial charges	(93)	(46)
<b>Net financial income (charges)</b>	<b>(91)</b>	<b>(40)</b>
<b>Pre-tax result</b>	<b>(4,232)</b>	<b>(5,199)</b>
Income taxes	-	-
<b>Profit (loss) for the period</b>	<b>(4,232)</b>	<b>(5,199)</b>

### Statement of comprehensive income

(amounts in € thousand)

	1st quarter 2015	1st quarter 2014
	(a)	(b)
<b>Profit (loss) for the period</b>	<b>(4,232)</b>	<b>(5,199)</b>
<b>Other comprehensive income (not subsequently reclassified to the income statement)</b>	-	-
Profit (loss) actuarial	-	(1)
Tax effect on other components of comprehensive income	-	-
<b>Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)</b>	-	<b>(1)</b>
<b>Other comprehensive income (subsequently reclassified to the income statement)</b>	-	-
Gains and losses on available-for-sale financial assets	-	-
<b>Other comprehensive income, net of taxes (subsequently reclassified to the income statement)</b>	-	-
<b>Total comprehensive income (loss) for the period</b>	<b>(4,232)</b>	<b>(5,200)</b>

*Financial statements at 31 March 2015*

*Net financial position*

<i>(amounts in € thousand)</i>	March, 31 2015	December, 31 2014
Cash on hand	10	10
Other cash	46,587	11,374
Cash equivalents	-	-
<b>A. Total cash and cash equivalents</b>	<b>46,597</b>	<b>11,384</b>
<b>B. Current financial receivables and other financial assets</b>	<b>-</b>	<b>6</b>
Finance lease payables	-	-
Current financial debt	-	-
<b>C. Current financial debt</b>	<b>-</b>	<b>-</b>
<b>D. Net current financial position (A+B+C)</b>	<b>46,597</b>	<b>11,390</b>
Finance lease payables	-	-
Non current financial debt	-	-
<b>E. Non-current financial debt</b>	<b>-</b>	<b>-</b>
<b>F. Net financial position (D+E)</b>	<b>46,597</b>	<b>11,390</b>