

# MolMed Board of Directors approved the interim financial report ended September 30, 2015

- Revenues increased by 26.7%, of which revenues for third parties activities increased by 30.9%
- Positive Net Financial Position of 38.3 million euros (11.4 million euros at December, 31 2014)
- Reached the target of 100 patients enrolled in the NGR019 clinic trial
- Started activities related to the preclinical development of the CAR-CD44v6 project
- Co-optation of a new member of the Board of Directors
- Convened the Shareholders' Meeting

(importi in migliaia di Euro)	3rd quarter 2015	3rd quarter 2014	01.01.2015 - 30.09.2015	01.01.2014- 30.09.2014	Variation	Variation
			(a)	(b)	(a-b)	%
Operating revenues	3,147	3,444	10,321	8,148	2,173	26.7%
Revenues from activities for third parties	2,999	3,323	9,887	7,553	2,334	30.9%
Operating costs	8,291	4,893	26,564	18,388	8,176	44.5%
Operating result	(5,144)	(1,449)	(16,243)	(10,240)	(6,003)	(58.6%)
Net financial income & charges	(123)	(66)	(232)	(285)	53	18.6%
Result for the period	(5,267)	(1,515)	(16,475)	(10,525)	(5,950)	(56.5%)

Milan, November 9, 2015 – The Board of Directors of MolMed S.p.A. (Milan: MLM), meeting today under the chairmanship of Professor Claudio Bordignon, reviewed and approved the interim financial report at September 30, 2015.

Claudio Bordignon, Chairman and CEO of MolMed commented: "The first nine months of 2015 registered a solid growth in revenues from activities for third parties, confirming MolMed's technological leadership and know-how in the development and GMP Manufacturing of gene therapies. This competitive advantage, applied to Zalmoxis® and to the CAR-CD44v6 project, positions us among the pioneers of the tumour immunotherapy field, one of the fastest growing sectors of the innovative tumour therapies. These programs, combined with the clinical and industrial development of NGR-hTNF, have led to a steady strengthening of MolMed's positioning in the field of experimental treatment of cancer. The Company is therefore implementing steps

#### FROM GENES TO THERAPY



needed to support the ongoing process of consolidation and future growth. The recent co-optation of directors of great international standing and with the technical expertise in the Company's most important areas of activity follows the same rationale.

The following describes activities and main results achieved in the first nine months of the year, reviewed and approved by the Board of Directors today.

# Key significant events

Activities and main results obtained in the first nine months of the year and recently:

## Development activities on Zalmoxis® (TK)

- Further development in the discussion between the Company and the European Regulatory authority (EMA), concerning the Conditional Marketing Authorization submission. This procedure is possible in case of rarity of the clinical indication (Zalmoxis® (TK) was granted Orphan Drug designation in Europe in 2003 and in US in 2005), of a favourable risk/benefit ratio and evidence of clinical safety and efficacy.
- Presentation of cumulative data on over 130 patients treated with Zalmoxis® (TK) in different studies carried out in academia and in the Phase II trial TK007. This analysis showed that this therapeutic approach is able to offer patients with high-risk leukaemia abolition of immunosuppression post-transplantation, a rapid immune reconstitution and effective control of GvHD in the context of transplantation from a haploidentical donor. For the first time, also data on the anti-leukemic effect of TK cells have been presented. Overall, these effects show a significant increase in survival in treated patients compared with historical data.
- New presentation of the preliminary efficacy data on the TK008 Trial during the 41st Congress of the European Society for Blood and Marrow Transplantation (EBMT), held in Istanbul March 22nd to 25th, 2015. The analysis of disease-free survival at 1 year (the primary endpoint) in the first 24 patients enrolled in the Zalmoxis® (TK) arm of this randomised Phase III showed a rate of 74%, well above the rate in the default protocol set at 30% for the control arm.
- Activities continued on the development of an automated system for the production of Zalmoxis® (TK).

## Development activities on NGR-hTNF

- The target of 100 patients enrolled in NGR019 randomized Phase II trial of NGR-hTNF in mesothelioma as first-line maintenance therapy has been reached.
- On May 2015, the full results from the Phase III clinical trial of the investigational drug NGR-hTNF in patients with pleural mesothelioma were presented at the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO), held in Chicago:
  - a statistically significant increase of 45% in overall survival in patients who progress more quickly after the first-line treatment, characterized by the worst prognosis and accounting for 50% of the total number of enrolled patients, while the primary endpoint was not achieved for the entire population;
  - ✓ in patients with poor prognosis, the strength of the benefit induced by NGR-hTNF in
    combination with chemotherapy compared to chemotherapy alone was confirmed by the
    efficacy consistently reported for all groups of patients, predefined on the basis of recognized
    risk factors (including histology, performance status, age, sex, etc.), and for all the endpoints
    of the study, with NGR-hTNF able to extend progression-free survival, by 45%, to reduce early



tumour progression by 45% and to increase duration of survival in patients with disease control by 65%;

- ✓ NGR-hTNF effect on survival is correlated to the duration of the therapy, especially in patients under treatment since more than three months, whom median survival duration was almost double respect to the control arm;
- ✓ NGR-hTNF tolerability profile is favourable alone as well as in combination with the chemotherapy drugs (doxorubicin, gemcitabine or vinorelbine) administered in the study.
- In the first nine months of 2015 follow-up of patients enrolled in randomised Phase II trials in soft tissue sarcomas (NGR016) in ovarian carcinoma (NGR018), and Phase III trial in mesothelioma (NGR015) continued.
- On the basis of results obtained so far, we plan to continue scouting activity for an industrial partner, potentially leading to an out licensing agreement of the product and, in parallel, to start the process for the Conditional Marketing Authorisation submission with the EMA for the treatment of pleural mesothelioma, in second-line, in patients with more severe prognosis, once the industrial development of the product has been completed.

# Pipeline enlargement

On April 13, 2015, MolMed exercised the option right to purchase, from the San Raffaele Hospital, the immunegene therapy project against cancer, developed through the use of the chimeric receptor antigen CD44v6 (CAR-CD44v6), which can potentially be used for various forms of haematological cancers and carcinomas. The CAR-CD44v6 is part of the family of the CAR-T lymphocytes armed with chimeric receptors, which have shown great therapeutic potential especially against haematological malignancies, also when particularly aggressive and resistant to traditional therapies.

The CAR-CD44v6, which has already been successfully tested in appropriate murine models, is a project with a particularly elevated therapeutic potential, as it specifically recognizes the variant 6 (v6) antigen of CD44 (CD44v6) expressed by many hematologic malignancies - among which acute myeloid leukaemia and multiple myeloma - but also by many epithelial tumours, including carcinomas of the breast, lung, colon, pancreas, and head-and-neck.

The acquisition of this project allows the Company to significantly expand its pipeline, entering one of the most promising fields of new anticancer strategies, tumour "immune-gene therapy". The project on the CARCD44v6 will not only benefit from the experience and know-how of the company in the field of gene and cell therapies, but also from the conjugation with the suicide gene TK, with a chance of becoming the first CAR-T product that integrates a control system that has already been extensively tested and validated in clinical trials.

## Research and development in gene therapy

- During the first nine months of 2015, following the exercise of the above-mentioned option right, research and development activities on the CARCD44v6 project aimed at the characterization of the antitumor activity of lymphocytes expressing CARCD44v6 in animal models of human and murine tumours, and development of production systems for viral vectors encoding the CAR -CD44v6 in association with the suicide gene HSV-TK Mut2 began.
- Activities aimed at the development of a technology platform for the production of large-scale, semistable, stable lentiviral vectors continued.



On March 18, 2015, MolMed received the formal granting of a patent covering "packaging cell lines semi stable constitutive lentiviral vectors" from the European Patent Office, as published in the European Patent Bulletin on 18 March 2015. The new European patent (EP2480677) is part of a family of patents, owned by MolMed, which includes 10 patent applications and 22 patents (including 19 national patents stemming from the granted European patent) that protect packaging systems for constituent lentiviral vectors deposited in the major pharmaceutical markets, including the United States, Japan, Canada, Australia and China. The patent is valid until 2031, and guarantees market exclusivity in a number of European countries.

# Development and GMP production for third parties

- On the 19th of March, MolMed and GlaxoSmithKline further strengthened the existing strategic collaboration signing a new agreement under which MolMed will supply development, manufacturing and technology transfer services aimed at the clinical application of gene therapies based on viral vector cellular transduction. As part of the agreement, MolMed will provide its expertise in process development and its manufacturing skills and capacity for the production of viral vectors and cell transduction. In particular, the contract foresees approximately Euro 34 million revenues, minimum, for MolMed. over the next five years.
- During the first nine months of 2015, activities foreseen by exiting collaboration agreements signed with Fondazione Telethon and GSK for the development and production of highly innovative experimental gene therapies for the treatment of severe hereditary diseases continued. Specifically:
  - development of the process of GMP production of gene therapy for ADA-SCID, and production
    of the related transduced cells for the treatment of compassionate patients, as provided for in
    a contract signed with GlaxoSmithKline;
  - ✓ production of the lentiviral vectors transduced cells for the experimental treatment of patients affected by MLD and WAS, as provided for in a contract signed with GlaxoSmithKline;
  - ✓ production of lentiviral vectors for the development of gene therapies, on behalf of Telethon Foundation.
- During the first nine months of 2015, the construction of the new production facility at the scientific park "Open Zone" at Bresso (Milan) continued which, combined with the one already operating at the headquarters in Via Olgettina (Milan), will more than triplicate MolMed's current production capacity. With this expansion and well-recognized technology leadership in the treatment of rare genetic diseases and immune-gene therapy of tumors, MolMed will represent an important strategic partner for major companies in the pharmaceutical and biotechnology sector.

## Other significant events

- On April 2015 the capital increase, approved by the Extraordinary Shareholders Meeting held on the 3<sup>rd</sup> March 2014, was successfully completed. The share capital increase was completed on the 9<sup>th</sup> April 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 Euro 49,825 thousand, of which Euro 8,823 thousand by way of capital increase and Euro 41,002 thousand in share premium.
- On June 23, 2015, MolMed received from Mr. Carlos Moedas, the European Commissioner for research, science and innovation, the Annual Most Innovative EU Biotech SME Award (red biotech category), a prestigious reward awarded by the international scientific community and promoted by EuropaBio.



On October 22, 2015, the Board of Directors co-opted Dr. Riccardo Palmisano and Prof. Didier Trono as new members of the Board of Directors following the resignation from office, during the same meeting, of Mrs. Marina Del Bue, Mr. Germano Carganico and Mr. Lorenzo Salieri. Marina Del Bue and Germano Carganico, maintaining their positions respectively as General Manager Corporate Governance & Administration and Director of Business Development and Strategic Affairs of MolMed, will focus on advancing the numerous and significant activities of the Company and will continue to support the Board's activity as executives of the Company.

## Comments on financial results

**Total revenues** in the first nine months of 2015 increased by 26.7% compared with same period in 2014, from Euro 8,148 thousand to Euro 10,321 thousand, mainly driven by development and GMP production activities for third parties, which registered revenues for Euro 9,887 thousand, growing significantly (+30.9%) compared with the same period last year (Euro 7,553 thousand). These activities are mainly related to the above-mentioned collaborations with GlaxoSmithKline and Fondazione Telethon, and substantially benefited from the agreement signed with the British Company on the 19th of March 2015.

Other revenues of Euro 434 thousand are mainly connected to public funding of R&D activities and show a decrease of 27.1% respect to the first nine months of 2014.

Total revenues for the third quarter 2015 were Euro 3,147 thousand, compared with Euro 3,444 thousand in the third quarter 2014, almost totally generated by third parties activities.

**Operating costs** in the first nine months of 2015 totalled Euro 26,564 thousand, 44.5% higher respect to the same period in 2014, largely due to:

- service costs, equal to Euro 14,922 thousand (from Euro 8,309 thousand at September 30, 2014), significantly affected by external development costs, as a result of the acquisition of the abovementioned research project CAR-CD44v6, and by the industrial development of one of the products in our pipeline. "License fees" and IP expenditures decreased by Euro 476 thousand (-57.3%) respect to the same period of last year, when we paid a milestone for the regulatory development of a product in pipeline;
- raw material and consumables costs, increased from Euro 2,201 thousand at 30 September, 2014 to Euro 2,771 thousand at September 30, 2015, as a result of the intensification of development and GMP production activities and continuation of the clinical trial with Zalmoxis® (TK);
- personnel costs, increased by 12.4% in the first nine months of 2015 respect to the same period of last year (from Euro 6,547 thousand to Euro 7,356 thousand), as a result of the increased number of employees in operational areas of the Company.

It is worth mentioning that investments during the first nine months of 2015 amounted to Euro 4,692 thousand, mainly due to the construction of the Bresso site, to the ordinary maintenance of laboratory equipment, and to the supply of new equipment dedicated to the industrial production process of Zalmoxis® (TK), as well as to the fine-tuning and optimization of the existing GMP facility.

In the third quarter, 2015, operating costs were strongly influenced by the increase in service costs and rose from Euro 4,893 thousand in the third quarter of 2014 to Euro 8,291 thousand.

The first nine months of 2015 showed a negative **operating result** of Euro 16,243 thousand, compared with an operating result negative for Euro 10,240 thousand at September 30, 2014. This variation is essentially driven by important external development costs, mainly related to the acquisition of the research project CAR-



CD44v6 and to the development of one of the product in pipeline. In fact, given the Company's operating activities and the characteristics of trials conducted, research and development costs are fully expensed in the period they are incurred.

Operating result in the third quarter of 2015 was negative for Euro 5,144 thousand (compared with negative operating result of Euro 1,449 thousand in the same period of 2014), due to the industrial development activities.

The **net result** for the first nine months of 2015 registered a loss of Euro 16,475 thousand, compared with a loss of Euro 10,525 thousand in the corresponding period of the previous year, owing to activities and dynamics already described. Net results for the third quarter of 2015 was negative for Euro 5,267 thousand, compared with a loss of Euro 1,515 thousand recorded in the same period of 2014.

The **net financial position** at 30 September 2015, is positive for Euro 38,298 thousand (form Euro 11,390 thousand at December 31, 2014), and is entirely composed of cash and cash equivalents, and financial receivables mainly represented by bonds, in absence of financial indebtedness. The change in net financial position is mainly due to (i) proceeds from capital increase for Euro 39,858 thousand, (ii) Euro 1,552 thousand collected in February 2015 as advance payment on future share capital increase, (iii) proceeds from the above mentioned agreement signed with GSK on March 19, 2015, (iv) the acquisition of CAR-CD44v6 project for Euro 3,904 thousand, including VAT, and (v) the collection of Euro 2,561 thousand related to the VAT 2014 receivable occurred on September 30, 2015.

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During the same meeting, the Board of Directors, following the announcement made on October  $22^{nd}$ , continued to strengthen the corporate governance and co-opted Mrs. Monica Masolo, as a new member of the Board of Directors, complying with applicable legislation on "gender quotas". Furthermore, the Board of Directors verified the independence requirements and the compliance with the maximum number of offices held in other companies, as defined by the Company, of Mrs. Masolo as well as of Mr. Riccardo Palmisano and Prof. Didier Trono, already co-opted by the Board of Directors during the meeting held on the  $22^{nd}$  of October.

Monica Masolo graduated in Economics from Bocconi University - Milan, she has strong experience in management consultancy within an international environment: after two years in the Internal Auditing function at IntesaSanPaolo Group, in 1995, her career in consultancy began (at first in "boutique" consultancy firms, then Ernst&Young, and Deloitte Consulting in 2001) specializing in Banking and Financial Services, managing large scale complex projects, transformation, start up and integration projects at both national and international levels. In September 2013 she left the consultancy sector to start a new experience at IOR (Istituto per le Opere di Religione), as part of the team of directors in charge of the reform project of the Institute.

According to disclosures made to the public and to the Company, to date, Monica Masolo does not hold any ordinary shares of MolMed S.p.A..

The Board of Directors has also convened the Shareholders' Meeting on December 11, 2015 to decide on the composition of the administrative body and the possible consequent redefinition of its compensation.

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 tumour mass, currently investigated in a broad clinical programme; 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 secondary office 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 September 30, 2015 Income statement

(amounts in Euro thousands )	3rd quarter 2015	3rd quarter 2014	1.1.2015- 30.09.2015	1.1.2014- 30.09.2014	Variation	Variation %
			(a)	(b)		/0
Revenues	2,999	3,323	9,887	7,553	2,334	30.9%
Other revenue	148	121	434	595	(161)	(27.1%)
Total operating revenues	3,147	3,444	10,321	8,148	2,173	26.7%
Purchases of raw materials and consumables	855	545	2,771	2,201	570	25.9%
Costs for services	4,514	1,792	14,922	8,309	6,613	79.6%
Costs for use of third-party assets	372	330	1,054	920	134	14.6%
Personnel costs	2,402	2,091	7,356	6,547	809	12.4%
Other operating costs	38	27	93	88	5	5.5%
Amortization and depreciation	110	108	368	323	45	13.8%
Total operating costs	8,291	4,893	26,564	18,388	8,176	44.5%
Operating result	(5,144)	(1,449)	(16,243)	(10,240)	(6,003)	(58.6%)
Financial income	13	11	60	41	19	46.3%
Financial charges	(136)	(77)	(292)	(326)	34	(10.4%)
Net financial income (charges)	(123)	(66)	(232)	(285)	53	18.6%
Pre-tax result	(5,267)	(1,515)	(16,475)	(10,525)	(5,950)	(56.5%)
Income taxes	-	-	-	-	-	-
Profit (loss) for the period	(5,267)	(1,515)	(16,475)	(10,525)	(5,950)	(56.5%)

# Statement of comprehensive income

(amounts in Euro thousand)	3rd quarter 2015	3rd quarter 2014	1.1.2015 - 30.09.2015	1.1.2014 - 30.09.2014	Variation	Variation
			(a)	(b)	(a-b)	%
Profit (loss) for the period	(5,267)	(1,515)	(16,475)	(10,525)	(5,950)	(56.5%)
Other comprehensive income (not subsequently reclassified to the income statement)						
Profit (loss) actuarial	1	-	1	-	1	100.0%
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)	1	-	1	_	1	100.0%
Other comprehensive income (subsequently reclassified to the income statement)						
Fari value valuation reserve	-	-	-	-	-	0.0%
Other comprehensive income, net of taxes (subsequently reclassified to the income statement)	-	-	-	-	-	0.0%
Total comprehensive income (loss) for the period	(5,266)	(1,515)	(16,474)	(10,525)	(5,949)	(56.5%)



# Net financial position

(amounts Euro thousands )	September 30, 2015	December 31, 2014	
Cash on hand	15	10	
Other cash	20,149	11,374	
Cash equivalents	9,000	-	
A. Total cash and cash equivalents	29,164	11,384	
B. Current financial receivables and other financial assets	9,134	6	
Finance lease payables	-	-	
Current financial Debts	-	-	
C. Current financial debt	-	-	
D. Net current financial position (A+B+C)	38,298	11,390	
Finance lease payables	-	-	
Non current financial Debts	-	-	
E. Non-current financial debt	-	-	
F. Net financial position (D+E)	38,298	11,390	