

MolMed Board of Directors approves the interim financial report at 30 September 2014

Milan (Italy), 10 November 2014 – 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 30 September 2014. The most important elements were:

- The important increase of third party revenues to € 7.6 million which represents a positive variation of +143.6% compared to the first 9 months 2013 (€ 3.1 million) demonstrates the Company's leadership in the development of new cell and gene therapy treatments;
- TK: submission of the Conditional Marketing Authorisation dossier to the European Regulatory Agency (EMA) for the commercial authorization and the presentation of the first results of the pivotal Phase III trial (TK008) for high-risk leukaemia patients;
- NGR-hTNF: presentation of the results of the phase III clinical trial in malignant pleural mesothelioma that, despite not having met the primary endpoint on overall survival in the entire population, showed a statistically significant increase of 40% both on overall survival and progression-free survival in patients with poorer prognosis, which represents 50% of the total patients.

Claudio Bordignon, Chairman of the Board and CEO of MolMed, commented: *"In the first nine months of 2014 MolMed consolidated its technological leadership in the field of immunogenetherapy of cancer highlighted by the positive results of patients treated with TK technology showing survival rates higher than those predicted in the trial. Particularly relevant is the demonstration of an increased anti-leukemic activity closely related to the number of TK cells infused. The value of our technological platform for gene and cell therapies is further confirmed by the strong increase in revenues"*.

Highlights of financial data

Key income statements

(amounts in Euro thousand)	3 rd quarter 2014	3 rd quarter 2013	1/1/2014 - 30/9/2014(a)	1/1/2013 - 30/9/2013(b)	Variation (a-b)	%
OPERATING REVENUES	3,444	685	8,148	3,409	4,739	139.0
REVENUES FROM ACTIVITIES FOR THIRD PARTIES	3,323	613	7,553	3,101	4,452	143.6
OPERATING COSTS	4,893	5,119	18,388	17,893	495	2.8
OPERATING RESULT	(1,449)	(4,434)	(10,240)	(14,484)	4,244	29.3
NET FINANCIAL INCOME & CHARGES	(66)	(24)	(285)	(170)	(115)	67.6
RESULT FOR THE PERIOD	(1,515)	(4,457)	(10,525)	(14,654)	4,129	28.2

FROM GENES TO THERAPY

MOLMED S.p.A.

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Net financial position

<i>(amounts in Euro thousand)</i>	30 September 2014(a)	30 June 2014(b)	31 December 2013	Variation (a-b)	%
NET FINANCIAL POSITION	12,064	5,723	7,528	6,341	110.80

Key achievements in the first nine months of 2014

Research & Clinical Development activities

In the first nine months of 2014, the Company's activities focused mainly on clinical development of its two investigational anticancer therapeutics: TK for the treatment of high-risk leukaemia and NGR-hTNF for the treatment of a number of solid tumours.

TK main achievements include:

- presentation at the 50th American Society for Clinical Oncology (ASCO) Congress of the analysis of the first 24 patients enrolled in the TK treatment arm of the randomised Phase III study indicate a disease-free survival at 1 year (study primary endpoint) of 74%: this result by far exceeds the study design goal of 52% in TK arm versus 30% for the control arm;
- in the first nine months of 2014 cumulative data of over 130 patients treated with the TK technology in the various studies carried out in academia, in the Phase I / II study and in the Phase III study currently in progress were also presented. The analysis showed that this therapeutic approach is able to offer patients with high-risk leukemia abolition of post-transplant immunosuppression, a rapid immune reconstitution and effective control of GVHD in the context of haploidentical donor transplantation;
- submission of an application for marketing authorization to the European regulatory agency (EMA) through a specific procedure (Conditional Marketing Authorisation), which is based on the clinical data of Phase II. The submission was validated by EMA on March 26th, 2014, initiating the process of evaluation of the dossier. The request for this special procedure is possible in the case of TK because of the rarity of the indication (TK has been granted Orphan Drug designation), a favourable risk / benefit ratio and the demonstration of clinical safety and efficacy. The clinical efficacy data, especially those of long-term survival of patients treated with TK, will be used during the analysis and discussion of the dossier submitted to the EMA.
- the continuation of the project to develop an automated system, in cooperation with the German Company Miltenyi and the possible application of the automated system CliniMACS Prodigy to the protocol TK.

NGR-hTNF main achievements include:

- presentation at the 50th American Society for Clinical Oncology (ASCO) Congress of the results of the Phase III clinical trial in malignant pleural mesothelioma (NGR015): despite not having met its primary endpoint of overall survival (OS) in the whole population, the clinical study showed a statistically significant increase ($p = 0.02$, non-stratified analysis, $P = 0.01$, stratified analysis) of 40% for both overall survival and progression-free survival in the patient population with poorer prognosis, who went into progression during or shortly after the first-line chemotherapy. These patients

represent 50% of the entire population and were identified by a protocol pre-specified analysis based on the interval-free treatment after completion of first-line chemotherapy. Furthermore, the results show an increase of the impact of NGR-hTNF on survival in parallel with the duration of therapy, which was particularly marked in patients treated for at least three months, in which the median duration of survival was almost doubled compared to those of the control group: 16.5 vs. 9.8 months;

- presentation at the 50th American Society for Clinical Oncology (ASCO) Congress of the results of the randomized four-arm Phase II trial in patients with sarcoma, in which the weekly treatment with low doses of NGR-hTNF in combination with doxorubicin induced a statistically significant doubling of survival compared to the other regimens evaluated, which included the combination of NGR-hTNF high-dose doxorubicin monotherapy at with low or high doses. The survival rate at 3 years with this treatment schedule has exceeded 40% and, in particular, similar results were obtained in both chemo-naïve and pre-treated patients, further confirming the high efficacy of NGR-hTNF in more aggressive disease and chemo-resistant.

Development and GMP production for third parties

Development and production of new cell and gene therapy treatments for third parties are consolidating the company's technological leadership in this field, and are also generating a significant increase in revenues (as described in the Comments to financials). During the first nine months of 2014, activities continued under two major agreements signed in 2011, respectively with Telethon Foundation and GlaxoSmithKline, for the development and production of investigational gene therapies for a total of seven rare diseases. Furthermore, the GMP production facility has been upgraded and optimized.

Moreover, continues the planned construction of the new production facility at the science park called "Open Zone" in Bresso (Milan). The Bresso site will provide MolMed an additional production facility of 3,300 m² which will add to the one already operating at the headquarters site in Via Olgettina of about 1400 m², more than tripling the current production capacity. This expansion, necessary to support the treatment of patients with TK, will also enable, combined to the Company's technological leadership in the field of treatment of rare genetic diseases and cancer immunogenetherapy, to position MolMed as a strategic partner for big pharma and biotech.

Comments to financials

First nine months of 2014

Operating revenues in the first nine months of 2014, amounting to € 8.1 million, increased by 139.0% compared to the first nine months of 2013. This increase is mainly due to the intensification of the development and GMP production activities for third parties. The above mentioned activities generated revenues of € 7.6 million compared to € 3.1 million in the corresponding period of 2013, with a 143.6% increase respect to the first nine months of last year. Other revenues related to public funding for research and development activities for € 595 thousand, showed an increase compared to the same period of 2013 (+93.2%).

Operating costs for the first nine months of 2014 totaled € 18.4 million and show an increase of € 0.5 million respect to the first nine months of 2013 (€ 17.9 million) representing a percentage of 2.8% mainly due to the increase in raw material and consumable purchased and costs for use of third-party assets.

The operating loss for the first nine months of 2014, € 10.2 million, has been significantly reduced by 29.3% respect to the same figure of previous year, € 14.5 million.

Financial results are negative for € 285 thousand, decreasing by € 115 thousand respect to the first nine months of 2013. Financial income, € 41 thousand (€ 143 thousand at 30 September, 2013) is primarily derived from the management of the Company's cash. The decrease in such income in the period is due to the progressive reduction of financial resources connected to the absorption of liquidity for ordinary business and to lower rates of return of the market. Financial costs, € 326 thousand in the first nine months of 2014, are mainly due to the pro solute of VAT receivables transactions finalized in the second quarter of 2013 and of 2014.

The result for the first nine months of 2014 shows a loss of € 10.5 million, compared to a loss of € 14.7 million in the corresponding period of 2013.

Third quarter of 2014

In the third quarter of 2014, operating revenues totalled € 3.4 million, compared to € 0.7 million in the third quarter of 2013. Operating revenues include € 3.3 million from development and production activities for third parties, whose trend is higher with respect to the same period of last year, mainly due to the development and GMP production activities.

Operating revenues also consist of € 0.1 million which derive from public funding for research and development activities.

In the third quarter of 2014, operating costs amounted to € 4.9 million, respect to € 5.1 million in the third quarter of 2013. This trend mainly reflects a decrease in services due to the concentration of costs for the pivotal Phase III trial of NGR015 in the same period of last year.

The operating result for the third quarter of 2014 is negative for € 1.4 million, compared to a loss of € 4.4 million in the corresponding period of 2013.

In the third quarter of 2014 the financial result is negative for € 66 thousand. The negative result is mainly due to financial costs related to the VAT receivables pro solute transactions finalized in the second quarter of 2013 and 2014.

The result for the third quarter of 2014 shows a loss of € 1.5 million, respect to a loss of € 4.5 million in the corresponding period of 2013.

Net financial position

The net financial position at 30 September 2014, positive for € 12.1 million, includes cash and cash equivalents for € 13.1 million and short term financial debts for € 1.0 million related to the recording of the pro solute transaction of VAT receivable 2013.

The official Corporate 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), 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.*

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)

Financial statements at 30 September 2014

Income statement

(amounts in Euro thousand)

	3rd quarter 2014	3rd quarter 2013	1.1.2014 - 30.09.2014 (a)	1.1.2013 - 30.09.2013 (b)	Variation (a-b)	Variation %
Revenues	3,323	613	7,553	3,101	4,452	143.6%
Other income	121	72	595	308	287	93.2%
Total operating revenues	3,444	685	8,148	3,409	4,739	139.0%
Purchases of raw materials and consumables	545	444	2,201	1,620	581	35.9%
Costs for services	1,792	2,220	8,309	8,364	(55)	(0.7%)
Costs for use of third-party assets	330	289	920	820	100	12.2%
Personnel costs	2,091	2,021	6,547	6,532	15	0.2%
Other operating costs	27	46	88	122	(34)	(27.9%)
Amortization, depreciation and write-downs	108	98	323	435	(112)	(25.7%)
Total operating costs	4,893	5,119	18,388	17,893	495	2.8%
Operating result	(1,449)	(4,434)	(10,240)	(14,484)	4,244	29.3%
Financial income	11	39	41	143	(102)	(71.3%)
Financial charges	77	62	326	312	14	4.5%
Net financial income (charges)	(66)	(24)	(285)	(170)	(115)	67.6%
Pre-tax result	(1,515)	(4,457)	(10,525)	(14,654)	4,129	28.2%
Income taxes	-	-	-	-	-	-
Profit (loss) for the period	(1,515)	(4,457)	(10,525)	(14,654)	4,129	28.2%

Statement of comprehensive income

(amounts in Euro thousand)

	3rd quarter 2014	3rd quarter 2013	1.1.2014 - 30.09.2014 (a)	1.1.2013 - 30.09.2013 (b)	Variation (a-b)	Variation %
Profit (loss) for the period	(1,515)	(4,457)	(10,525)	(14,654)	4,129	(28.2%)
Other comprehensive income (not subsequently reclassified to the income statement)						
Profit (loss) actuarial	-	(2)	-	(2)	2	(100.0%)
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)	-	(2)	-	(2)	2	(100.0%)
Other comprehensive income (subsequently reclassified to the income statement)						
Fair value valuation reserve	-	-	-	(15)	15	(100.0%)
Other comprehensive income, net of taxes (subsequently reclassified to the income statement)	-	-	-	(15)	15	(100.0%)
Total comprehensive income (loss) for the period	(1,515)	(4,459)	(10,525)	(14,671)	4,146	(28.3%)

Net financial position

<i>(amounts in Euro thousand)</i>	September, 30 2014	December, 31 2013
Cash on hand	13	11
Other cash	13,063	8,551
Cash equivalents	-	-
A. Total cash and cash equivalents	13,076	8,562
B. Current financial receivables and other financial assets		1
Finance lease payables	-	(3)
Current financial debts	(1,012)	-
C. Current financial debt	(1,012)	(3)
D. Net current financial position (A+B+C)	12,064	8,560
Finance lease payables	-	-
Non current financial debts	-	(1,032)
E. Non-current financial debt	-	(1,032)
F. Net financial position (D+E)	12,064	7,528

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