

## MolMed Board of Directors approves the interim financial report as of 30 September 2009

- Operating revenues of € 3.9 million, increased compared to the first nine months of year 2008, while operating costs of € 17.1 million were in line with the same period of 2008
- Positive net financial position of € 23.1 million, consisting mainly of cash, cash equivalents and current financial assets
- Update of five trials of the investigational antitumour drug NGR-hTNF presented at ECCO-ESMO 2009

Milan (Italy), 9 November 2009 - The Board of Directors of MolMed S.p.A. (Milan:MLM), chaired by Professor Claudio Bordignon, today approved the interim financial report as of September 30, 2009.

### FINANCIAL HIGHLIGHTS

#### Key income statement data

(amounts in thousands of Euro)	3 <sup>rd</sup> Quarter 2009	3 <sup>rd</sup> Quarter 2008	1.1.2009- 30.9.2009 (a)	1.1.2008- 30.9.2008 (b)	Change	
					(a-b)	%
Revenues and other income	1.001	2.311	3.880	3.223	657	20,4%
Operating Costs	(6.001)	(5.358)	(17.055)	(16.865)	(190)	1,1%
Operating income (loss)	(5.000)	(3.047)	(13.175)	(13.641)	466	(3,4%)
Net finance income (loss)	115	484	502	1.207	(705)	(58,4%)
Profit (loss) for the period	(4.885)	(2.563)	(12.673)	(12.434)	(239)	1,9%

#### Net financial position

(amounts in thousands of Euro)	September 30, 2009 (a)	June 30, 2009 (b)	December 31, 2008	Change	
				(a-b)	%
Net financial position	23.123	26.935	35.281	(3.812)	(14,2%)

### HIGHLIGHTS OF DEVELOPMENT ACTIVITIES

In the first nine months of 2009, progress focused on the clinical and pharmaceutical development of MolMed's investigational drug NGR-hTNF for the treatment of solid tumours:

- Extensive update on clinical trials of NGR-hTNF was presented in September at ECCO-ESMO 2009 - the joint annual meeting of the European Cancer Organisation and of the European Society of Medical Oncology - and in June at ASCO 2009, the annual meeting of the American Society of Clinical Oncology. New data presented at ECCO-ESMO included:
  - top-line results on a Phase II trial in hepatocellular carcinoma (NGR008), involving 40 patients, showing a median survival time of 8.9 months, 1-year and 2-year survival rates of 27% and 17%, respectively, disease control achieved in 30% of patients with a median duration of 4.3 months, and one case of complete tumour eradication ongoing since May 2008;

- first results of a Phase II trial in combination with Xelox for the treatment of colorectal cancer (NGR005), showing the safety of the combination and first data of antitumour activity.

Data presented at ASCO included the positive outcome of a Phase II trial as single agent in malignant pleural mesothelioma (NGR010) and of a Phase I trial of NGR-hTNF in combination with cisplatin (NGR004). Other data presented included long-term follow up data for a Phase II trial as single agent in colorectal cancer (NGR006).

- A randomised Phase II trial of NGR-hTNF in combination with either of two cisplatin-based standard regimens - cisplatin+gemcitabine (cis/gem) or cisplatin+pemetrexed (cis/pem) - was started as first-line treatment for a new indication, non-small cell lung cancer (NGR014).
- Patient recruitment progressed in two Phase II trials of NGR-hTNF in combination with doxorubicin, in small-cell lung cancer (NGR007) and in ovarian cancer (NGR012), and in a Phase I trial aimed at the exploration of safety and clinical benefit of high doses of NGR-hTNF as single agent in solid tumours (NGR013). Recruitment was completed in the Phase II trial in combination with Xelox in colorectal cancer (NGR005).
- The results of a Phase I trial of NGR-hTNF in combination with doxorubicin (NGR003), completed in 2007 and opening the way to the currently ongoing Phase II trials in small-cell lung cancer and in ovarian cancer, were published by the *British Journal of Cancer* (*BJC* 2009; 101(2), 219-224).
- Data showing the mechanism of action of NGR-hTNF were presented in August at the Gordon Research Conference on Angiogenesis, and were also selected for oral presentation at the Annual Meeting of the American Association of Cancer Research (AACR) in April, and at ANGIO 2009 - the international symposium on anti-angiogenic agents - in February.
- MolMed also continued the pharmaceutical development of NGR-hTNF: industrialisation of the drug manufacturing process is ongoing, and will allow MolMed to put in place a manufacturing process meeting regulatory and market requirements for drug supply in view of future commercialisation.

MolMed was granted two novel patents on NGR-hTNF by the European Patent Office: in March, a key product patent providing for a broad coverage of the molecule (EP1255845), and in May a patent covering the therapeutic use of NGR-hTNF in combination with interferon- $\gamma$  (EP1562620).

Concerning TK, MolMed's cell-based therapy for leukaemia, progress made in the first nine months of 2009 include:

- Expansion of the clinical development in Japan by MolMed's partner for the Asian markets, Takara Bio Inc., with two Phase I trials in leukaemia patients, both conducted at the National Cancer Center in Tokyo.
- Publication of the results obtained in the European multicentric Phase I/II study (TK007) by *The Lancet Oncology* (2009 May 1;10:489-50). The article gives insight into the outcome of the trial, conducted on adult patients affected by high risk acute leukaemia and receiving bone marrow transplants from a partially compatible family donor (haplo-transplants). The introduction of TK therapy allowed add-backs of donor T lymphocytes, that promote a rapid and wide immune reconstitution, reducing transplant-related mortality and leading to long-term survival. The very positive outcome of Phase I/II trial TK007 allowed MolMed to start in Italy in spring 2008 a randomised Phase III trial of TK for high-risk leukaemia. Expansion of the trial to other European clinical centres is under way, and will be implemented within the first half of 2010.

## SUMMARY ON FINANCIAL RESULTS

### First nine months of 2009

In the first nine months of 2009, MolMed reported operating revenues of € 3.9 million, increased compared to € 3.2 million in the corresponding period of 2008. Increased revenues for service activities to third parties, including ongoing agreements and new collaboration agreements, were partially offset by lower grants accounted for as of 30 September 2008 and related to projects ended in 2008.

In the first nine months of 2009, operating costs totalled € 17.1 million, with no significant changes compared to the same period of 2008.

The operating result for the first nine months of 2009 shows a loss of € 13.2 million, as compared to a loss of € 13.6 million in the first nine months of 2008. This improvement is mainly due to the increase in revenues.

A negative bottom-line result is consistent with the business model for biotech companies during the period when they are developing new therapeutic products, and do not yet have a product on the market. At this stage, high costs must be sustained, linked to the clinical and pharmaceutical development of investigational new therapies, and return is expected in forthcoming years.

The result as of 30 September 2009 shows a loss of € 12.7 million, compared to a loss of € 12.4 million in the same period of 2008.

The net financial position as of 30 September 2009 amounts to € 23.1 million, including cash and cash equivalents for € 3.1 million, and other current financial assets for € 20.5 million, net of € 0.5 million for leasing payables connected to the accounting of leasing contracts for laboratory equipment.

### Third quarter of 2009

In the third quarter of 2009 operating revenues amounted to € 1.0 million, compared to € 2.3 million in the third quarter of 2008. The decrease is due to the fact that, in the third quarter of 2008, the fiscal benefit related to R&D activities, introduced by the Financial Bill 2007 and accrued for the first nine months of 2008, was recorded as "other income".

In the third quarter of 2009, operating costs amounted to € 6.0 million, up 12% compared to the € 5.4 million for the same period of 2008. The increase is mainly related to higher costs for services.

The operating result for third quarter 2009 shows a loss of € 5.0 million, as compared to a loss of € 3.0 million in the same period of 2008.

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*The official Corporate Financial Reporting Manager of MolMed S.p.A., Enrico Cappelli, 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 November 3, 2005 - are illustrated below:*

- *Operating result: defined as the difference between revenues and other income, and costs for materials, costs of services received, costs for use of third-party assets, personnel costs and amortisation, depreciation & writedowns. It represents the profit before financial flows and taxes;*
- *Net Financial Position: is the algebraic sum of cash and 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 14.5.1999 as subsequently amended.*

## **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.*

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## **About MolMed**

MolMed S.p.A. is a biotechnology company focused on research, development and clinical validation of novel antitumour therapies. MolMed's pipeline includes two novel therapeutics in clinical development: TK, a cell-based therapy enabling bone marrow transplants from partially compatible donors, in Phase III in high-risk acute leukaemias; NGR-hTNF, a novel vascular targeting agent (VTA), in Phase II in six different indications: colorectal, lung (small-cell and non-small-cell), liver and ovarian cancers, and malignant pleural mesothelioma. MolMed is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy. The company's shares (Milan:MLM) are listed on the Milan Stock Exchange, at the Standard segment (class I) of the MTA managed by Borsa Italiana.

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## Financial Statements as of September 30, 2009

### Income statement

(amounts in thousands of Euro)	3 <sup>rd</sup> Quarter 2009	3 <sup>rd</sup> Quarter 2008	1.1.2008- 30.9.2009 (a)	1.1.2008- 30.9.2008 (b)	Change	
					(a-b)	%
Revenues	714	430	1.882	949	933	98,2%
Other income	287	1.881	1.998	2.274	(276)	(12,1%)
<b>Total operating revenues</b>	<b>1.001</b>	<b>2.311</b>	<b>3.880</b>	<b>3.223</b>	<b>657</b>	<b>20,4%</b>
Purchases of raw and consumable materials	(462)	(438)	(1.594)	(1.465)	(129)	8,8%
Costs for services	(2.990)	(2.510)	(7.332)	(7.644)	312	(4,1%)
Use of 3rd party assets	(339)	(319)	(1.007)	(945)	(62)	6,6%
Personnel costs	(1.739)	(1.628)	(5.634)	(5.412)	(222)	4,1%
Other operating costs	(24)	(39)	(166)	(167)	1	(0,5%)
Amortisation, depreciation and writedowns	(447)	(424)	(1.322)	(1.233)	(89)	7,2%
<b>Total operating costs</b>	<b>(6.001)</b>	<b>(5.358)</b>	<b>(17.055)</b>	<b>(16.865)</b>	<b>(190)</b>	<b>1,1%</b>
<b>Operating profit (loss)</b>	<b>(5.000)</b>	<b>(3.047)</b>	<b>(13.175)</b>	<b>(13.641)</b>	<b>466</b>	<b>(3,4%)</b>
Financial income	148	504	633	1.239	(606)	(48,9%)
Financial charges	(33)	(20)	(131)	(32)	(99)	312,5%
<b>Net financial income (charges)</b>	<b>115</b>	<b>484</b>	<b>502</b>	<b>1.207</b>	<b>(705)</b>	<b>(58,4%)</b>
<b>Profit (loss) before taxation</b>	<b>(4.885)</b>	<b>(2.563)</b>	<b>(12.673)</b>	<b>(12.435)</b>	<b>(238)</b>	<b>1,9%</b>
Income taxes	-	-	-	-	-	-
<b>Net profit (loss) for the period</b>	<b>(4.885)</b>	<b>(2.563)</b>	<b>(12.673)</b>	<b>(12.435)</b>	<b>(238)</b>	<b>1,9%</b>

### Statement of Comprehensive Income

(amounts in thousands of Euro)	3 <sup>rd</sup> Quarter 2009	3 <sup>rd</sup> Quarter 2008	1.1.2008- 30.9.2009 (a)	1.1.2008- 30.9.2008 (b)	Change	
					(a-b)	%
<b>Profit (loss) for the period</b>	<b>(4.885)</b>	<b>(2.563)</b>	<b>(12.673)</b>	<b>(12.435)</b>	<b>(238)</b>	<b>1,9%</b>
<b>Other components of comprehensive income</b>						
available for sale financial assets	(55)	-	(58)	-	(58)	(100,0%)
Income tax related to components of other	-	-	-	-	-	0,0%
<b>Total other comprehensive income (after tax)</b>	<b>(55)</b>	<b>-</b>	<b>(58)</b>	<b>-</b>	<b>(58)</b>	<b>(100,0%)</b>
<b>Total comprehensive income (loss) for the period</b>	<b>(4.940)</b>	<b>(2.563)</b>	<b>(12.731)</b>	<b>(12.435)</b>	<b>(296)</b>	<b>2,4%</b>

## Net financial position

(amounts in thousands of Euro)	September 30, 2009 (a)	June 30, 2009 (b)	December 31, 2008	Change	
				(a-b)	%
Cash and cash equivalents	3.075	6.719	15.611	(3.644)	(54,2%)
<b>A. Cash and cash equivalents</b>	<b>3.075</b>	<b>6.719</b>	<b>15.611</b>	<b>(3.644)</b>	<b>(54,2%)</b>
<b>B. Current financial receivables and other financial assets</b>	<b>20.489</b>	<b>20.676</b>	<b>19.927</b>	<b>(187)</b>	<b>(0,9%)</b>
Finance lease payables	(85)	(82)	(43)	(3)	3,7%
<b>C. Current financial debt</b>	<b>(85)</b>	<b>(82)</b>	<b>(43)</b>	<b>(3)</b>	<b>3,7%</b>
<b>D. Net current financial position (A+B+C)</b>	<b>23.479</b>	<b>27.313</b>	<b>35.495</b>	<b>(3.834)</b>	<b>(14,0%)</b>
Finance lease payables	(356)	(378)	(214)	22	(5,8%)
<b>E. Non current net financial position</b>	<b>(356)</b>	<b>(378)</b>	<b>(214)</b>	<b>22</b>	<b>(5,8%)</b>
<b>F. Net financial position (D+E)</b>	<b>23.123</b>	<b>26.935</b>	<b>35.281</b>	<b>(3.812)</b>	<b>(14,2%)</b>