

## MolMed Board of Directors approves the draft financial statements for year 2009

- Main R&D achievements in 2009: positive results of its anticancer drug NGR-hTNF in several Phase II trials, in particular in mesothelioma, thus providing the rationale for advancing the compound to the next clinical Phase; start of a randomised Phase II trial in non-small cell lung cancer; protocol amendment of the Phase III trial of TK therapy for high-risk leukaemias
- Positive net financial position of € 19.6 million, consisting of cash, cash equivalents and current financial assets
- Operating costs of € 22.5 million, in line with the previous year despite progress of MolMed's strategic projects
- Total loss of € 17.2 million, comparable with FY 2008 result, reflecting the business model of a biotech company focused on R&D activities and whose economic rewards are postponed to future years
- In 2010, MolMed plans to further advance the development of its investigational therapies NGR-hTNF and TK

Milan (Italy), 15 March 2010 - The Board of Directors of MolMed S.p.A. (Milan:MLM), chaired by Professor Claudio Bordignon, today reviewed and approved the draft year-end financial statements as at 31 December 2009.

### FINANCIAL HIGHLIGHTS

(amounts in thousands of €)	FY 2009	FY 2008	Change	Change %
Revenues and other income	4,712	3,963	749	18.9
Operating costs	(22,519)	(23,073)	554	(2.4)
Operating result	(17,807)	(19,110)	1,303	(6.8)
Net financial income (loss)	638	1,664	(1,026)	(61.7)
Result for the year	(17,169)	(17,446)	277	(1.6)

  

	December 31, 2009	December 31, 2008	Change	Change %
Net financial position	19,567	35,281	15,714	(44.5)

### HIGHLIGHTS OF DEVELOPMENT ACTIVITIES IN YEAR 2009

Key achievements were obtained in the development of the investigational anticancer drug NGR-hTNF for the treatment of solid tumours:

- Results of clinical trials of NGR-hTNF, presented in September at ECCO-ESMO 2009 and in June at ASCO 2009:
  1. **top-line results of Phase II trial as monotherapy in malignant pleural mesothelioma (NGR010)**, where NGR-hTNF was administered in chemo-pretreated patients, either every three weeks or every week. Results showed a disease control rate of 46% with a median duration of 4.7 months, and a median overall survival of over one year (12.1 months). The

comparison of progression-free survival between the tri-weekly and the weekly cohort showed a clear advantage of treatment intensification;

2. **top-line results of Phase II trial as monotherapy in primary liver cancer (NGR008)**, 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;
  3. **first results of 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;
  4. **long-term follow up data for Phase II trial as monotherapy in colorectal cancer (NGR006)**, where 1.5-year and 2-year survival rates are of 33% and 25%, respectively;
  5. **top-line results of Phase I trial in combination with cisplatin (NGR004)**, showing the safety of the combination therapy and promising clinical activity.
- Start of 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) - as first-line treatment for non-small cell lung cancer (NGR014), following the positive outcome of Phase I in combination with cisplatin;
  - Progress of patient recruitment in Phase II trials of NGR-hTNF in combination with doxorubicin - in small-cell lung cancer (NGR007) and in ovarian cancer (NGR012), respectively - and in 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 completed in Phase II trial in combination with Xelox in colorectal cancer (NGR005);
  - Publication by the European Journal of Cancer (Eur J Cancer 2010 Jan;46(1):198-206) of the results of a Phase I trial of low-dose NGR-hTNF as monotherapy (NGR002), completed in 2006 and allowing to choose the optimal biologic dose currently used in Phase II trials. Publication by the British Journal of Cancer (BJC 2009; 101(2), 219-224) of 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;
  - Grant of two novel European patents on NGR-hTNF: 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);
  - Orphan Drug designation for primary liver cancer, also following the results of Phase II trial NGR008, granted by the FDA in October and by the European Commission in November.

Concerning TK, MolMed's cell-based therapy in Phase III for high-risk leukaemias, progress made in 2009 includes:

- Approval by the Italian Drug Agency (AIFA) of an amendment to the clinical protocol of Phase III trial (TK008), now involving a study population of 152 patients, with a randomisation ratio (TK vs no TK) of 3:1; the key objectives of the trial are overall survival and reduction of transplant-related mortality;
- Expansion of 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 a Phase II trial (TK007) by The Lancet Oncology (2009 May 1;10:489-50). The trial, conducted on adult patients affected by high risk leukaemias receiving bone marrow transplants from partially compatible family donors, showed that TK therapy allows add-backs of donor T cells, that promote a rapid and wide immune reconstitution, reducing transplant-related mortality and leading to long-term survival;
- Positive outcome for MolMed of the patent suit filed by LTK Farma s.a.s. and Université Pierre et Marie Curie for the alleged infringement of their European patent because of TK clinical development activities. The patent suit had been included among the "risk factors" in MolMed's

IPO Offering Circular issued on February 15, 2008 (see pages 25, 96-97, 198, 237 and 276 of the Offering Circular), and mentioned as possible “contingent liability” in subsequent annual financial statements and interim financial reports;

- Completion of the feasibility study for TK manufacturing process in a fully-automated closed system.

### Outlook for 2010

In 2010, MolMed plans to keep its focus on the development of the investigational therapies NGR-hTNF and TK, particularly by:

- Advancing clinical development of NGR-hTNF, with the start of Phase III in mesothelioma, and randomisation of Phase II trials in other indications;
- Expanding Phase III trial of TK to other clinical centres in Europe and in the US, and obtaining first results by the end of the year.

## SUMMARY ON FINANCIAL RESULTS

### Revenues and other income

In FY 2009, MolMed reported operating revenues of € 4.712 million, an increase of 18.9% compared to € 3.963 million in FY 2008.

This increase resulted from the combined effect of a slight reduction in revenues, from € 2.435 million in FY 2008 to € 2.413 million in FY 2009, with an increase in other income, from € 1.528 million in FY 2008 to € 2.299 million in FY 2009.

The decrease in revenues is partly due to the recording, in FY 2008, of a quota of revenues from out-licensing agreements that had been previously postponed to future fiscal years; such decrease has however been substantially compensated by additional revenues from service activities to third parties.

The increase of other income is mainly due to the recording in FY 2009 of a benefit in the form of tax credit for R&D costs incurred in years 2008 and 2009. The benefit accrued amounts to € 1.085 million for year 2008 and to € 959 thousand for year 2009. Accounting of this fiscal benefit in support of innovation, introduced by the Italian Fiscal Bill 2007 for the period 2007-2009, was executed after obtaining clearance from the Italian fiscal authority (*Agenzia delle Entrate*), following the application submitted according to the provisions in force.

### Operating costs

In 2009, operating costs totalled € 22.519 million, down 2.4% compared to FY 2008:

- costs for raw materials and consumables, consisting essentially of materials and reagents used in R&D activities, increased consistently with the increase in activities related to the development of MolMed’s investigational new therapies and to services performed for third parties. Said costs amount to € 1.977 million, up 5.9% compared to FY 2008;
- service costs decreased by 6.1% compared to FY 2008, mainly because this item included in 2008 costs related to the listing of the Company on the Milan Stock Exchange;
- costs for use of third-party assets grew from € 1.266 million in FY 2008 to € 1.344 million in 2009, up 6.2% because of the lease of new premises for office facilities at the *Centro Direzionale* in Milano 2 - Segrate (Milan);
- staff costs decreased by 2,2%, from € 7.937 million in FY 2008 to € 7.760 million in 2009, because of a reduction in the number of employees from 91 in 2008 to 84 in 2009.

## Financial income and charges

Financial income reached € 638 thousand in 2009 compared with € 1.664 million in 2008. The decrease is linked, on one hand, to the progressive reduction of financial resources available due to the absorption of liquidity related to ordinary activities, and, on the other hand, to a strong reduction in interest rates, related to general macro-economic conditions.

## Full year result

The result for year 2009 shows a loss of € 17.169 million, compared with a loss of € 17.446 in FY 2008. In this regard, it should be noted that in the slide on financial data in MolMed company presentations, because of a clerical error the figure related to the result of the year for FY 2008 was replaced by the figure related to the operating result of FY 2008 (€ 19,110 million).

## Net financial position

Net financial position, from € 35.281 million as at December 31, 2008, to € 19.567 million as at December 31, 2009, is linked to the absorption of liquidity related to the Company's ordinary activities.

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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.*

*The report on Corporate Governance, the draft FY 2009 financial statements, the Board of Statutory Auditors' Report and the independent auditor's reports will be made available to the public at the company's headquarters and at Borsa Italiana SpA via the NIS circuit, as well as on the company website ([www.molmed.com](http://www.molmed.com)), in accordance with legal provisions.*

*The following statements related to Financial Statements as at December 31, 2009, are provided in attachment to this press release:*

- *Balance sheet*
- *Income statement*
- *Statement of comprehensive income*
- *Cash flow statement*
- *Statement of Changes in Shareholders' Equity*

*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 Profit: 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 & 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.*

*The audit is still underway, and the Audit Report on the Financial Statements as of December 31, 2009 will be issued by the Independent Auditors on a date subsequent to the publication date of this press release.*

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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 14.5.1999 as subsequently amended.*

#### **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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#### **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 December 31, 2009

### Balance sheet

(amounts in thousands of Euro)	December 31, 2009	December 31, 2008
<b>ASSETS</b>		
Tangible assets	2.189	2.367
Goodwill	77	77
Intangible assets	1.188	2.178
Financial assets	13	13
Tax receivables	3.568	3.589
Other assets	2.669	3.185
<b>TOTAL NON CURRENT ASSETS</b>	<b>9.704</b>	<b>11.409</b>
Inventories	304	357
Accounts receivable and other commercial assets	1.456	2.389
Tax receivables	2.381	1.051
Other receivables and sundry assets	1.167	954
Other financial assets	15.679	19.927
Cash and cash equivalents	4.308	15.611
<b>TOTAL CURRENT ASSETS</b>	<b>25.295</b>	<b>40.289</b>
<b>TOTAL ASSETS</b>	<b>34.999</b>	<b>51.698</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Share capital	21.679	21.638
Share premium reserve	21.815	45.463
Other reserves	2.121	1.889
Retained earnings (accumulated losses)	194	(6.322)
Net profit (loss) for the year	(17.169)	(17.446)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>28.640</b>	<b>45.222</b>
Liabilities for pensions and employee leaving indemnity	220	284
Accounts payable	38	188
Finance lease payables	333	214
Other liabilities	269	-
<b>TOTAL NON CURRENT LIABILITIES</b>	<b>860</b>	<b>686</b>
Accounts payable	4.152	4.693
Other liabilities	1.260	1.054
Finance lease payables	87	43
<b>TOTAL CURRENT LIABILITIES</b>	<b>5.499</b>	<b>5.790</b>
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>	<b>34.999</b>	<b>51.698</b>

## Financial statements at December 31, 2009

### Income statement

(amounts in thousands of Euro)	Year 2009	Year 2008
Revenues	2,413	2,435
Other income	2,299	1,528
<b>Total operating revenues</b>	<b>4,712</b>	<b>3,963</b>
Purchases of raw and consumable materials	(1,977)	(1,867)
Costs for services	(9,385)	(9,995)
Use of 3rd party assets	(1,344)	(1,266)
Personnel costs	(7,760)	(7,937)
Other operating costs	(215)	(225)
Amortization, depreciation and writedowns	(1,838)	(1,783)
<b>Total operating costs</b>	<b>(22,519)</b>	<b>(23,073)</b>
<b>Operating profit (loss)</b>	<b>(17,807)</b>	<b>(19,110)</b>
Financial income	797	1,707
Financial charges	(159)	(43)
<b>Net financial income (charges)</b>	<b>638</b>	<b>1,664</b>
<b>Profit (loss) before taxation</b>	<b>(17,169)</b>	<b>(17,446)</b>
Income taxes	-	-
<b>Net profit (loss) for the year</b>	<b>(17,169)</b>	<b>(17,446)</b>

(amounts in thousands of Euro)	Year 2009	Year 2008
Basic profit/(loss) per share	(0.1643)	(0.1743)
Diluted/(profit)/loss per share	-	-

## Financial statements at December 31, 2009

### Statement of comprehensive income

(amounts in thousands of Euro)	Year 2009	Year 2008
<b>Profit (loss) for the year</b>	<b>(17,169)</b>	<b>(17,446)</b>
<b>Other components of comprehensive income</b>		
Gains/(losses) on <i>fair value</i> of available for sale financial assets	(163)	7
Income tax related to components of other comprehensive income	-	-
<b>Total other comprehensive income (after tax)</b>	<b>(163)</b>	<b>7</b>
<b>Total comprehensive income (loss) for the year</b>	<b>(17,332)</b>	<b>(17,439)</b>

## Financial statements at December 31, 2009

### Cash flow statement

(amounts in thousands of Euro)		Year 2009	Year 2008
Cash and cash equivalents		15,611	5,591
<b>Opening cash and cash equivalents</b>	<b>A</b>	<b>15,611</b>	<b>5,591</b>
<b>Cash flow from operating activities:</b>			
Net profit (loss) for the year		(17,169)	(17,446)
Amortization/Depreciation of intangible/tangible assets		1,838	1,783
Change in liabilities for pensions and employee leaving indemnity		(75)	15
Share based payments		590	709
Decrease in other assets for option right	(*)	516	430
Reversal of financial income and charges		(638)	(1,544)
Reversal of taxes		-	-
<b>Cash flow from operating activities before changes in working capital</b>		<b>(14,938)</b>	<b>(16,053)</b>
<b>Changes in current assets and liabilities</b>			
(Increase) decrease in inventories		53	(157)
(Increase) decrease in accounts receivable and other receivables	(*)	(610)	405
Increase (decrease) in accounts payable and other payables	(*)	(541)	(352)
Increase (decrease) in other liabilities		206	(4,131)
<b>Total changes in current assets and liabilities</b>		<b>(892)</b>	<b>(4,235)</b>
(Increase) decrease in non current tax receivables		14	(1,738)
Increase (decrease) in non current accounts payable		(150)	(288)
Increase (decrease) in other liabilities		269	516
Interest paid		(133)	(27)
Taxes paid		-	-
<b>Total cash flow from operating activities</b>	<b>B</b>	<b>(15,830)</b>	<b>(21,825)</b>
<b>Cash flow from investing activities</b>			
Net investment (divestment) in tangible assets		(581)	(957)
Net investment (divestment) in intangible assets		(89)	(45)
Net investment (divestment) in other financial assets		3,857	(19,853)
Interest received		1,017	1,570
<b>Total cash flow from investing activities</b>	<b>C</b>	<b>4,204</b>	<b>(19,285)</b>
<b>Cash flow from financing activities</b>			
Increases in share capital and share premium reserve		160	56,152
Other changes in shareholders' equity - deduction of listing costs		-	(5,279)
Change in finance lease payables		163	257
<b>Total cash flow from financing activities</b>	<b>D</b>	<b>323</b>	<b>51,130</b>
<b>Cash flow generated (absorbed) during the year</b>	<b>E=B+C+D</b>	<b>(11,303)</b>	<b>10,020</b>
<b>Closing cash and cash equivalents</b>	<b>A+E</b>	<b>4,308</b>	<b>15,611</b>

(\*) of which with related parties (as required by Consob resolution n.15519 of July 27, 2006)

(amounts in thousands of Euro)	Year 2009	Year 2008
(Increase) decrease in accounts receivable and other receivables	928	560
(Increase) decrease in non current other assets	516	430
Increase (decrease) in accounts payable and other payables	(553)	(384)

## Financial statements at December 31, 2009

### Statement of Changes in Shareholders' Equity

(amounts in thousands of Euro)	Share Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Reserve fair value valuation	Retained earnings and (losses carried forward)	Profit (loss) for the year	Total shareholders' equity
<b>Balance as at January 1, 2007</b>	22,487	10,502	-	1,024	7	-	(9,910)	(10,697)	13,413
Payment of remainder of share capital increase	193	-	-	-	-	-	-	-	193
Allocation of prior year loss	-	(10,502)	-	-	-	-	(195)	10,697	-
Payment for future share capital increases	-	-	9,301	-	-	-	-	-	9,301
Payment for share capital increases	3,436	6,591	(9,301)	-	-	-	-	-	726
Reduction in share capital and coverage of losses	(9,888)	(6,591)	9,606	-	-	-	6,873	-	-
Personnel costs for stock options	-	-	-	128	-	-	-	-	128
Actuarial valuation	-	-	-	-	14	-	-	-	14
Comprehensive income (loss) for the year	-	-	-	-	-	-	-	(12,696)	(12,696)
<b>Balance as at December 31, 2007</b>	16,228	-	9,606	1,152	21	-	(3,232)	(12,696)	11,080

(amounts in thousands of Euro)	Share Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Reserve fair value valuation	Retained earnings and (losses carried forward)	Profit (loss) for the year	Total shareholders' equity
<b>Balance as at January 1, 2008</b>	16,228	-	9,606	1,152	21	-	(3,232)	(12,696)	11,080
Allocation of prior year loss	-	-	(9,606)	-	-	-	(3,090)	12,696	-
Share capital increase	5,410	50,742	-	-	-	-	-	-	56,152
Deduction of listing costs	-	(5,279)	-	-	-	-	-	-	(5,279)
Change in stock options plans	-	-	-	709	-	-	-	-	709
Comprehensive income (loss) for the year	-	-	-	-	-	7	-	(17,446)	(17,439)
<b>Balance as at December 31, 2008</b>	21,638	45,463	-	1,861	21	7	(6,322)	(17,446)	45,222

(amounts in thousands of Euro)	Share Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Reserve fair value valuation	Retained earnings and (losses carried forward)	Profit (loss) for the year	Total shareholders' equity
<b>Balance at January 1, 2009</b>	21,638	45,463	-	1,861	21	7	(6,322)	(17,446)	45,222
Allocation of prior year loss	-	(23,768)	-	-	-	-	6,322	17,446	-
Stock options subscription	41	119	-	194	-	-	194	-	160
Change in stock options plans	-	-	-	590	-	-	-	-	590
Comprehensive income (loss) for the year	-	-	-	-	-	(163)	-	(17,169)	(17,332)
<b>Balance as at December 31, 2009</b>	21,679	21,815	-	2,257	21	(156)	194	(17,169)	28,640