

MolMed: positive financial results in the first nine months of 2016 and achievement of key milestones for the future growth of the Company

MolMed's Board of Directors examined the business performance and approved the results at September 30, 2016:

- *August 18, 2016: grant of conditional marketing authorisation for Zalmoxis® by the European Commission*
- *September 1st, 2016: expansion of the strategic agreement signed in 2015 with GSK: minimum expected revenues of € 48 million, increased from previous € 34 million*
- *Total revenues increased by 34.7% and revenues from activities for third parties increased by 23.5% compared to the first nine months of 2015*
- *Operating results and net results improved by more than 13% compared to the first nine months of 2015*
- *Positive net financial position of € 14.6 million (€ 29.9 million at December 31, 2015)*

The Board awarded the options under the Stock Options Plan 2016-2021 approved today by the Shareholders' Meeting

| <i>(amounts in Euro thousand)</i> | 3 rd quarter 2016 | 3 rd quarter 2015 | 01.01.2016 - 30.09.2016 (a) | 01.01.2015 - 30.09.2015 (b) | Variation (a-b) | Variation % |
|---|---------------------------------|---------------------------------|-----------------------------------|-----------------------------------|--------------------|----------------|
| Operating revenues | 3,680 | 3,147 | 13,901 | 10,321 | 3,580 | 34.7% |
| <i>Revenues from activities for third parties</i> | 3,526 | 2,999 | 12,207 | 9,887 | 2,320 | 23.5% |
| Operating costs | 9,553 | 8,291 | 28,010 | 26,564 | 1,446 | 5.4% |
| Operating result | (5,873) | (5,144) | (14,109) | (16,243) | 2,134 | 13.1% |
| Net financial income & charges | (14) | (123) | (157) | (232) | 75 | 32.3% |
| Result for the period | (5,887) | (5,267) | (14,266) | (16,475) | 2,209 | 13.4% |

| <i>(amounts in Euro thousand)</i> | September 30, 2016 (a) | December 31, 2015 (b) | Variation (a- b) | Variation % |
|-----------------------------------|------------------------------|-----------------------------|---------------------|----------------|
| Net Financial Position | 14,569 | 29,938 | (15,369) | (51.34%) |

FROM GENES TO THERAPY

MOLMED S.p.A.

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Milan (Italy), November 7, 2016 – The Board of Directors of MolMed S.p.A. (Milan: MLM), met today under the chairmanship of Professor Claudio Bordignon, reviewed and approved the interim financial report at September 30, 2016.

Riccardo Palmisano, MolMed's CEO, commented the business evolution of the period as follows: *"We are pleased we can communicate rapidly growing revenues also for the first nine months of 2016, a period in which we saw key events for the life and future growth of MolMed come true. In fact, the developments occurred in the period represent real milestones for the Company, and have further consolidated our position in the field of gene and cell therapy: the conditional marketing authorisation granted by the European Commission for Zalmoxis is both a confirmation of MolMed's excellence in research and development, and a turning point in the life of the Company. On the other hand, the review of the service agreement signed with GSK further strengthens the second pillar of MolMed's growth strategy, i.e. high added value development and production services.*

In addition to these concrete results, research and development activities pursued in the first nine months of 2016 contributed in defining the strategic guidelines by which MolMed intends to exploit the maximum value of its assets for the Company's growth. In particular, we invested and keep investing in preclinical activities on the CAR CD44v6 project, in order to better define the potential of this highly innovative product, identify its appropriate place in therapy and define a development plan to initiate clinical trials in humans. In parallel, following progress made in the optimisation of the manufacturing process and the positive outcome of non-binding consultations with EMA in June, we are moving forward, as planned, with the preliminary activities needed to start the regulatory process aimed at obtaining a conditional marketing authorisation also for NGR-hTNF."

Comment on main events occurred in the first nine months of 2016

Regarding the product portfolio, a major milestone in the history of the Company has been reached with the conditional marketing authorisation granted by the European Commission for **Zalmoxis** on August 18, 2016: MolMed will be able to anticipate the marketing of Zalmoxis in the 28 EU Member States and throughout the European Economic Area, speeding up the access to this innovative therapy for adult patients affected by high-risk haematological malignancies for whom there was no therapeutic solution. An extraordinary achievement for patients, the Company and its shareholders: a real turning point, that the Company will seek to make the most of, with the strong support of the available clinical data, recently presented at the 1st International EBMT transplant Course held in Barcellona, and adding to the recognised expertise in research, development and manufacturing the necessary marketing activities. Therefore, in order to speed up patients' access to this innovative therapy, yet in the first half-year 2016 - with the support of a consulting firm - the Company conducted a market analysis instrumental to the definition of the dossier that will support price & reimbursement negotiations with individual EU Member States authorities, with whom the first interactions started in the third quarter of 2016. Following initial feedbacks, the Company believes it will be able to enter the first market in Europe by the first half-year 2017. As for the choice of the marketing strategy among different still viable options, in the third quarter the Company kept evaluating the interest - expressed by some potential partners yet after the positive opinion of EMA's CHMP in June - in in-licensing Zalmoxis for its commercialisation in Europe. As to the access to the U.S. market, following the successful experience with European authorities, MolMed's management is considering to start activities required for an accelerated access request to the FDA.

Still about its product portfolio in cell and gene therapy, in the first nine months of 2016 MolMed pursued research and development activities on the **CAR CD44v6** project acquired in 2015.

Also for **NGR-hTNF**, very significant results for the future of the product: were achieved in the first nine months of 2016: in fact, the manufacturing process was optimised and, once validated, will be used for the production for the market.

The first nine months of 2016 also brought confirmation of the excellence that MolMed can claim in development and GMP manufacturing activities; in this area, MolMed is the first example of biotech company able to manage in-house the entire cycle - from discovery to development, up to manufacturing - that leads to an *ex vivo* cell or gene therapy product: **revenues generated from manufacturing for third parties** again recorded strong growth and, thanks to the expansion and strengthening of the portfolio of industrial collaborations achieved during the period, they will feature also in the near future a solid support for research and development activities, vital for the Company's sustainability. Indeed, in the first nine months of 2016 a new agreement was signed with Genenta Science, as well as a review agreed with GSK of the contract signed with the same in 2015, thanks to which minimum expected revenues increased from €34 million to €48 million. In addition, the authorisation granted by the European Commission to Strimvelis™ - gene therapy for the treatment of children affected by ADA-SCID, owned by GSK – should also be remembered among the goals achieved, both because MolMed has greatly contributed to its development, and because it will be its exclusive manufacturer. Given these developments, the importance of the strategic choice made in the recent past becomes apparent, i.e. to invest in the expansion of the production capacity by setting up a second facility at the Open Zone Science Park in Bresso, whose authorisation process by the Italian healthcare authority AIFA was initiated in 2016.

Comment on financial results at September 30, 2016

In the first nine months of 2016, the Company recorded **total revenues** for Euro 13,901 thousand (Euro 3,680 thousand in the third quarter 2016), increased by 34.7% compared to the corresponding period in 2015 (Euro 3,147 thousand in the third quarter 2015). This result was mainly driven by intensified development and GMP production activities for third parties, which recorded revenues for Euro 12,207 thousand, up by 23.5% because of the activities carried out for GlaxoSmithKline and for new customers.

Other income, for an amount of Euro 1,694 thousand in the first nine months of 2016, includes R&D financial grants awarded through the participation of the Company to public grant awards (Euro 1,288 thousand), and tax credit income (Euro 406 thousand) recorded pursuant to the Italian Decree of 27 May 2015 implementing Law n. 190 of 23 December 2014 ("Stability Law 2015").

Operating costs for the first nine months of 2016 totalled Euro 28,010 thousand (Euro 9,553 thousand in the third quarter 2016), slightly increased compared to Euro 26,564 thousand recorded in the same period of the previous year (Euro 8,291 thousand in the third quarter 2015), and due to the following activities:

- *service costs*, equal to Euro 13,861 thousand, decreased by 7.1% compared to the same period of the previous year (when the costs related to the purchase of the CAR CD44v6 were incurred), and mainly including external development costs and costs related to 2016 license and patent fees, triggered by reaching specific milestones in Zalmoxis's development following the grant of conditional marketing authorisation and recorded in the third quarter 2016;
- *raw material and consumables costs*, grown from Euro 2,771 thousand at September 30, 2015 to Euro 3,339 thousand at September 30, 2016, as a result of the intensification of development and GMP production activities for third parties;

- *personnel costs*, equal to Euro 8,828 thousand in the first nine months of 2016, increased compared to Euro 7,356 thousand in the same period of 2015, as a result of the strengthening of the Company's operating functions and units;
- *amortisation and depreciation*, equal to Euro 778 thousand at September 30, 2016, increased compared to Euro 410 thousand in the same period of 2015 due to the start of the amortisation period at full capacity of the assets related to the Bresso facility.

In the first nine months of 2016 **investments** amounted to Euro 1,587 thousand, mainly related to the construction of the operating unit in Bresso (Milan) and, to a lesser extent, to the ordinary renewal of laboratory equipment and the purchasing of new equipment for Zalmoxis's industrial production process, as well as to revamping and optimisation of the existing GMP facility.

As to the first nine months of 2016, the strong growth in revenues, combined to the above-described trend of operating costs, resulted into an improvement by 13.1% of the **operating result**, equal to a loss of Euro 14,109 thousand at September 30, 2016 (Euro 5,873 thousand in the third quarter 2016), compared to a loss of Euro 16,243 thousand in the same period of 2015 (Euro 5,144 thousand in the third quarter 2015).

For the same reasons, also the **net result** improved considerably, with a decreased loss of Euro 14,266 thousand in the first nine months of 2016 (Euro 5,887 thousand in the third quarter 2016) compared to the loss of Euro 16,475 thousand recorded in the same period of 2015 (Euro 5,267 thousand in the third quarter of 2015).

The **net financial position** at September 30, 2016 is positive for Euro 14,569 thousand (Euro 29,938 thousand at December 31, 2015) and only consists of cash and cash equivalents and current financial receivables in the form of time deposit, with no financial debt.

Significant events occurred after closure of the period

Today, the Shareholders' Meeting called to resolve upon the agenda proposed by the Board of Directors on October 6, 2016:

- approved a stock option plan for MolMed ordinary shares, named "Stock Options Plan 2016-2021", reserved to MolMed's executive directors, executives with strategic responsibilities, employees and collaborators, and resolved to increase the share capital against payment and in divisible form, excluding option rights pursuant to art. 2441, paragraphs 5 and 8, of the Italian Civil Code, up to a maximum nominal amount of Euro 595,250.46, by issuance, even in more tranches, of maximum 12,643,520 MolMed ordinary shares with no par value, for the purpose of the Plan;
- resolved to grant the Board of Directors, pursuant to Article 2443 of the Italian Civil Code, the power to increase the share capital against payment and in divisible form, excluding option rights pursuant to Article 2441, fourth paragraph, second sentence of the Italian Civil Code, by issuance, even in more tranches, of maximum 42,000,000 ordinary shares with no par value, to be reserved to *Société Générale* under terms and conditions specified in the Standby Equity Facility agreement subscribed by the Board of Directors on October 6, 2016;
- approved the adoption of a new text of the Articles of Association in order to make them more organic and linear, adapt them to the law and regulatory provisions in force, introduce some changes in the Company's governance structure and, finally, introduce some clarification of terminology in the corporate purpose.

Business outlook

Considering the events occurred in the first nine months of 2016, the Company plans to continue clinical and industrial development of its main investigational products, as well as preparatory market access activities for its products, and to continue investments aimed at significantly increasing the production capacity dedicated to the development and production of cell and gene therapy products, both proprietary and for third parties.

With regard to proprietary products, following The European Commission's grant of a conditional marketing authorisation for Zalmoxis, the Company will intensify preparatory market access activities (both directly and through distributors/dealers), also carrying on negotiations with some potential partners started in the third quarter.

As for NGR-hTNF, following the optimisation of the manufacturing process, necessary in order to carry on with its validation for the market, and the outcome of the non-binding consultations held in June with the European regulatory authorities, added to the clinical data obtained so far, the evolutionary trends in the specific clinical area at international level, and taking into account potential industrial partners' feedback, in 2016 activities will continue as follows: the opportunity to start the submission process of a conditional marketing authorisation request with the EMA (European Medicines Agency) and of an Accelerated Approval request with the U.S. FDA (Food and Drug Administration) for the second-line treatment of pleural mesothelioma in patients with poor prognosis will be concretely evaluated; at the same time, on the basis of a reviewed place in therapy and the analysis of potential industrial partners' feedback, the search for an industrial partner for further product development will be re-focused, and priority will be given to those therapeutic indications considered more promising on the basis of results already obtained from randomised Phase II trials and of specific unmet therapeutic needs as indicated by clinicians and the market.

The Company also intends to carry on investing on research and pre-clinical development activities related to the CAR project, in order to highlight the distinctive specificity of this asset acquired in 2015, taking advantage of its established in-house development expertise.

With regard to contract development and manufacturing activities, supported by results obtained so far, the Company will carry on the search aimed at identifying new industrial partners and signing new service contracts.

Finally, following interactions with AIFA throughout the course of the first nine months of 2016, the first AIFA authorisations for manufacturing activities in the new facility in Bresso may be obtained by the end of the year.

* * *

The Board of Directors, implementing the powers granted today by the Shareholders' Meeting, awarded part of the options of the "Stock Options Plan 2016-2021", at a subscription price for each share of Euro 0.3878, equal to the average of the official closing prices recorded by MolMed ordinary shares on the main segment (MTA) of the Italian stock exchange in the six months before the options' award date.

The options' award to Executive Directors and to executives with strategic responsibilities was resolved upon proposal of the Remuneration and Nomination Committee, which met today.

In particular, the Board of Directors awarded options to the Chairman of the Board Claudio Bordignon, to the CEO Riccardo Palmisano, to the two executives with strategic responsibilities, including the general manager Gian Paolo Maria Rizzardi, to other executives and to some unit heads and strategic collaborators of the Company.

For details of the Plan, please refer to the dedicated Information Document - drafted pursuant to art. 114-bis of the Italian Consolidated Law Finance of finance (CLF) and of Article 84-bis of Consob resolution 11971 of

May 14, 1999 (Issuers' Regulation) – already available to the public at the Company's registered office and on MolMed's website (www.molmed.com).

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 prophylaxis, currently in Phase III in high-risk acute leukaemia and granted a Conditional Marketing Authorisation by the European Commission; NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the cancer and to the concentration of immune system cells into the tumour mass, currently investigated in a broad clinical programme, involving more than 1000 treated patients; CAR-CD44v6, an immune 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 is headquartered at the San Raffaele Biotechnology Department (DIBIT) in Milan, Italy, and a local unit 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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PRESS RELEASE

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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, 2016

Income statement

(amounts in Euro thousand)

| | 3 rd quarter 2016 | 3 rd quarter 2015 | 1.1.2016- 30.09.2016 | 1.1.2015- 30.09.2015 |
|--|---------------------------------|---------------------------------|-------------------------|-------------------------|
| Revenues | 3,526 | 2,999 | 12,207 | 9,887 |
| Other revenue | 154 | 148 | 1,694 | 434 |
| Total operating revenues | 3,680 | 3,147 | 13,901 | 10,321 |
| Purchases of raw materials and consumables | 1,050 | 855 | 3,339 | 2,771 |
| Costs for services | 5,011 | 4,514 | 13,861 | 14,922 |
| Costs for use of third-party assets | 353 | 372 | 1,058 | 1,054 |
| Personnel costs | 2,797 | 2,402 | 8,828 | 7,356 |
| Other operating costs | 49 | 38 | 146 | 93 |
| Amortization and depreciation | 293 | 110 | 778 | 368 |
| Total operating costs | 9,553 | 8,291 | 28,010 | 26,564 |
| Operating result | (5,873) | (5,144) | (14,109) | (16,243) |
| Financial income | 68 | 13 | 150 | 60 |
| Financial charges | (82) | (136) | (307) | (292) |
| Net financial income (charges) | (14) | (123) | (157) | (232) |
| Pre-tax result | (5,887) | (5,267) | (14,266) | (16,475) |
| Income taxes | - | - | - | - |
| Profit (loss) for the period | (5,887) | (5,267) | (14,266) | (16,475) |

Statement of comprehensive income

(amounts in Euro thousand)

| | 3 rd quarter 2016 | 3 rd quarter 2015 | 1.1.2016 - 30.09.2016 | 1.1.2015 - 30.09.2015 |
|---|---------------------------------|---------------------------------|--------------------------|--------------------------|
| Profit (loss) for the period | (5,887) | (5,267) | (14,266) | (16,475) |
| Other comprehensive income (not subsequently reclassified to the income statement) | | | | |
| Profit (loss) actuarial | (1) | 1 | (1) | 1 |
| Other comprehensive income, net of taxes (not subsequently reclassified to the income statement) | (1) | 1 | (1) | 1 |
| Other comprehensive income (subsequently reclassified to the income statement) | | | | |
| Fair value valuation reserve | - | - | - | - |
| Other comprehensive income, net of taxes (subsequently reclassified to the income statement) | - | - | - | - |
| Total comprehensive income (loss) for the period | (5,888) | (5,266) | (14,267) | (16,474) |

Financial statements at September 30, 2016

Net financial position

| <i>(amounts Euro thousand)</i> | September 30, 2016 | December 31, 2015 |
|--|-------------------------------|------------------------------|
| Cash on hand | 14 | 14 |
| Other cash | 9,550 | 11,756 |
| Cash equivalents | - | - |
| A. Total cash and cash equivalents | 9,564 | 11,770 |
| B. Current financial receivables and other financial assets | 5,005 | 18,168 |
| Finance lease payables | - | - |
| Current financial Debts | - | - |
| C. Current financial debt | - | - |
| D. Net current financial position (A+B+C) | 14,569 | 29,938 |
| Finance lease payables | - | - |
| Non current financial Debts | - | - |
| E. Non-current financial debt | - | - |
| F. Net financial position (D+E) | 14,569 | 29,938 |