



The Board of Directors examined the business performance and approved the first nine months financial report ended at September 30th, 2017:

- Strong improvement in Financial results with respect to the first nine months of 2016:
 - Revenues from sales up to +22.4%
 - Operating result and result of the period improve respectively of +43.9% and +43.2%
 - o Positive net financial position of Euro 17,4 million
- Important goals in market access of Zalmoxis reached thanks to license and distribution agreements signed with Dompé farmaceutici for Europe, Megapharm for Israel and TTY Biopharm Company for certain Asian Countries; interactions progressing with national Authorities for Marketing Authorization, pricing and reimbursement
- Expansion of client portfolio for GMP production collaborations by signing new development and manufacturing service agreements with Rocket Pharma e Cellectis

Important results occurred after the financial period

Promising pre-clinical data on CAR-CD44v6 safety profile presented at the international congress "COSTEM" in Berlin



(amounts in Euro thousand)	3 rd quarter 2017	3 rd quarter 2016	01.01.2017 - 30.09.2017 (a)	01.01.2016 - 30.09.2016 (b)	Variation (a-b)	Variation %
Operating revenues	6,226	3,680	15,641	13,901	1,740	12.5%
Revenues	6,001	3,526	14,936	12,207	2,729	22.4%
Other revenues	225	154	705	1,694	(989)	(58.4%)
Operating costs	7,633	9,553	23,549	28,010	(4,461)	(15.9%)
Operating result	(1,407)	(5,873)	(7,908)	(14,109)	6,201	43.9%
Net financial income & charges	(172)	(14)	(193)	(157)	(36)	(22.9%)
Result for the period	(1,579)	(5,887)	(8,102)	(14,266)	6,165	43.2%

(amounts in Euro thousand)	September 30, 2017 (a)	December 31, 2016 (b)	Variation (a-b)	Variation %
Net Financial Position	17,423	19,702	(2,279)	(11.6%)

Milan, November 6, 2017 – The Board of Directors of MolMed S.p.A. (Milan: MLM), met today under the chairmanship of Professor Claudio Bordignon, reviewed and approved interim financial results at September 30th, 2017.

Commenting on the business performance Riccardo Palmisano, MolMed's Chief Executive Officer, said: "During the first nine months of 2017 the Company took the necessary steps to exploit the important results achieved in 2016 and continued to focus its efforts on pursuing the goals set. We are proud to say that both pillars on which MolMed's growth strategy stands - development of proprietary R&D products and high added value GMP services - have been bolstered. With regards to Zalmoxis®, based on the Conditional Marketing Authorization (CMA) granted by EMA in 2016, major distribution and marketing contracts were entered into with noteworthy partners such as Dompé, Megapharm and TTY, while market access activities continued.

Additionally, pre-clinical development activities on our immuno-gene therapy project CAR CD44v6 generated significant new and positive data regarding the safety profile of our product in in vivo models, which were presented at the 4th International Congress on Stem Cell Transplantation and Cellular Therapies - COSTEM (Berlin, October 26-29). In addition to the excellent results achieved, both in in vitro and in vivo pre-clinical models confirme a high level of efficacy against leukaemia and a series of solid tumours which express CD44v6.

On development and manufacturing services for third parties, after extending the scope of the contract with GSK and signing a collaboration agreement with Genenta in 2016, MolMed entered in 2017 in major strategic agreements with Rocket Pharma and Cellectis, active in two key areas, namely rare diseases and CAR therapies, in which cell and gene therapies concentrate their pledges to improve the life of patients with, as yet, unmet medical needs.

Finally, we are extremely pleased with the significant improvement in the financial results, which show a reduction in losses of more than 43% over 2016. This goal was achieved thanks to an increase in sales revenues, having found innovative partners synergic with our corporate strategy, but also due to substantial operating cost containment resulting from the increased focus that the Company is pursuing day after day.



All the positive results achieved so far this year seem to confirm that we have chosen the right path to ensure the future growth of MolMed and maximize the company's assets".

Main events occurred in the first nine months of 2017

Zalmoxis: during the first nine months of 2017 the Company continued activities focused on the access to the European market. Following the initiation of the formal procedure in Italy, by filing the related dossier for pricing & reimbursement definition, in December 2016, the Company met with AIFA's scientific and technical commission (CTS) and answered to the AIFA Commission for Pricing and Reimbursement clarification requests, getting ready for the upcoming negotiation. Furthermore MolMed moved forward with Dompé farmaceutici, licensee for the European area, the preparation of both the dossiers for pricing & reimbursement request to German and French Authorities and accelerated preparatory activities for negotiations in other major European countries.

With regard to the commercialization of Zalmoxis outside the European borders, in April MolMed and Megapharm Ltd. signed a distribution and license agreement defining all terms and conditions for the supply, registration, promotion and distribution of Zalmoxis in Israel. In accordance with this agreement, Megapharm will distribute and market Zalmoxis in Israel, once approved by the Israeli Ministry of Health (MOH) and included in the Israeli National Health Basket of drugs by the MOH. Furthermore, Megapharm will be responsible for conducting all regulatory activities after marketing authorisation in Israel, including market access and price & reimbursement in the Country.

In the same field, in June 2017 MolMed and TTY Biopharm Company Ltd signed an exclusive license and distribution agreement defining all terms and conditions to import, use, market, sell and/or distribute the product in Taiwan, Hong Kong, Singapore, Thailand, Philippines, Vietnam and Malaysia. Under the terms and conditions of the agreement, TTY shall be responsible for the application of Marketing Authorization of Zalmoxis in the interested territories and will perform further clinical studies if needed to obtain regulatory approval, and will conduct all regulatory activities consequent to marketing authorization, including market access and pricing & reimbursement. Additionally, TTY could promote the enrolment of patients in the TK008 phase III trial by the compassionate use of Zalmoxis. In this case, TTY will be responsible for the accrual of the clinical centers and of the interaction with the local health Authorities of the Countries involved.

Thanks to rights conferred to TTY, MolMed might receive an upfront payment, potential regulatory and sales milestone payments up to Euro 13.5 million, as well as royalty payments in the range of 10% to 20% on annual net sales generated in each country covered by the agreement.

On July 2017 MolMed and Dompé farmaceutici S.p.A. entered into a 15 year exclusive license and distribution agreement granting Dompé the exclusive right and obligation to conduct all activities aimed at promoting, marketing, exploiting, distributing and selling Zalmoxis in all member countries of the current European Economic Area (EEA), UK after Brexit included, and an option right for Australia, Switzerland and Turkey.

Under the terms and conditions of the license and distribution agreement Dompé shall also perform and/or complete market access activities and take care of negotiating pricing and reimbursement of Zalmoxis in each interested Country other than Italy. MolMed will be responsible for performing market access activities, pricing and reimbursement negotiations in Italy, maintaining the Conditional Marketing Authorization and complying with the post approval commitments imposed by EMA in order to obtain full Market Authorization for Zalmoxis.



Concurrently with the execution of the aforementioned contract, MolMed and Dompé signed a manufacturing and supply agreement pursuant to which MolMed will be responsible for production, supply and delivery of Zalmoxis to the final users in all countries, and Dompé will recognize an amount proportional to the reimbursed price of the product.

On the basis of the license and distribution agreement, MolMed might receive, in addition to the purchase price, up to euro 43.5 million, of which up to euro 12.5 million as contributions in the 2017 – 2020 timeframe, and up to euro 31 million as sales milestones, depending on annual net sales generated in each country covered by the agreement.

NGR-hTNF: after EMA validation, on December 23rd, 2016, of a CMA request filed by MolMed on December 6th, 2016, as second-line treatment for adult patients affected by malignant pleural mesothelioma with disease progressing within 6 months from end of first-line treatment, EMA started the dossier evaluation procedure and appointed, in the first quarter of 2017, Rapporteur and Co-Rapporteur in charge of the CMA procedure, and CHMP adopted the first List of Questions (LoQ), at day 120. Following the interactions in the second quarter with the EMA, during which certain issues related to the list of questions formulated in the LoQ were discussed, MolMed decided to withdraw the CMA application, having come to the conclusion that it did not have enough time to complete activities aimed at obtaining data on production and control of the product, in the timeframe granted by the CMA Competent Authority.

CAR CD44v6: During the first nine months of 2017, based on the pre-clinical data collected, which confirmed the efficacy and safety profile in leukemia and solid tumors, the pre-clinical research and development activities continued on the immune proprietary project-gene therapy CAR CD44v6 in order to enhance its specificity, accurately outline potential and place in therapy, and define the development path for trials in man

In fact, at the 22nd annual Congress of the European Hematology Association (Madrid, 22-25 June 2017) Dr. Attilio Bondanza, Head of the Innovative Immunotherapy Unit at the Department of Immunology, Transplantation and Infectious Diseases at the San Raffaele Hospital (Milan) Medical Institute, provided new safety in-vitro data on the CAR-CD44v6 during an oral session titled "Hematology-in-Focus: New strategies in cellular therapy to prevent relapse of acute leukemia".

In particular, Dr. Bondanza's data focused on the safety profile of CD44v6 CAR-T cells showing how, although expressing the CD44v6 target at detectable levels, keratinocytes are highly resistant to CAR-T cell killing. These data suggest a wide enough therapeutic window for exploiting the antitumor activity of CD44v6 CAR-T cells, without incurring in relevant skin toxicity.

Finally during the first quarter of 2017, with the kick-off meeting held in Milan on 27-28 February 2017 the EURE-CART project (EURopean Endeavour for Chimeric Antigen Receptor Therapies) got underway. To carry out this project, a consortium of nine partners from five different EU countries, coordinated by MolMed, was formed. EURE-CART project's main object is to conduct a multicenter, first-in-man Phase I/IIa clinical trial to demonstrate the safety and the efficacy of CD44v6 CAR T-cell immunotherapy in acute myeloid leukemia and multiple myeloma.

In the meetings held in June and September by the Steering Committee of EURE-CART, the progress of the project was verified in line with the planned timings.

Development and GMP manufacturing activities: in the first nine months of 2017 activities with third parties (GSK, Telethon and Genenta) on therapeutics covered by existing collaborations proceeded as



scheduled, and new ones have been sat up. On February 27th, 2017 MolMed and Rocket Pharmaceuticals Ltd. signed a development and manufacturing agreement of a gene therapy for the treatment of Fanconi Anemia. Pursuant to this agreement, MolMed will develop and manufacture the lentiviral vectors to be used for the ex vivo transduction of hematopoietic stem cells, as part of the manufacturing process of Rocket's cellular therapy products intended for clinical trials and in related research and development activities.

Furthermore on July 27th, the Company and Cellectis signed a development and manufacturing agreement in the field of allogeneic CAR T-cell products. Cellectis develops UCARTs (Universal Chimeric Antigen Receptor T-cells) that are "off-the-shelf" allogeneic CARs. Under the collaboration agreement, Cellectis entrusts MolMed to develop and manufacture lentiviral vectors and genetically engineered T cells encoding for allogenic CAR-T.

Simultaneously, the Company, during the first nine months of 2017, pursued interactions with new potential partners and clients for the development of proprietary products and high added value GMP services with the aim of further expanding the collaboration portfolio, as well as evaluating technologies and products to expand its pipeline.

Regarding the new facility located at the Open Zone in Bresso, after the authorization of the Quality Control areas, storage of materials and storage products, in July 2017 AIFA (*Agenzia Italiana del Farmaco*) granted the *Officina Farmaceutica* status authorizing the manufacturing of medicinal gene therapy products for investigational purposes, in particular T cells genetically modified with viral vectors. This authorization is valid for GMP manufacturing, for quality control activities and for the production of TK cells used in clinical trials.

Furthermore, continues the validation process for other GMP Manufacturing areas whose authorization process initiated in July 2017.

Comments on financial results of First nine months of 2017

The first nine months of 2017 totaled **Operating revenues** up by 12.5% in respect of the same period of 2016, from Euro 13,901 thousand (Euro 3,680 thousand in the third quarter) to Euro 15,641 thousand in the first nine months of 2017 (Euro 6,226 thousand in the third quarter). In particular, the **Revenues from sales**, up +22.4%, have highlighted an important positive variation thanks to revenues from Zalmoxis®, Euro 2,500 thousand, related to milestone and up-front from agreement, signed with TTY Biopharm and agreement signed with Dompé farmaceutici S.p.A..

During the first nine months of 2017, **Operating costs** decreased by 15.9%, from Euro 28,010 thousand in the first nine months of 2016 (Euro 9,553 thousand in the third quarter 2016), to Euro 23,549 thousand (Euro 7,633 thousand in the third quarter 2017) due to the following developments:

Service costs, decreased by 41.4% from Euro 13,861 thousand in the first nine months of 2016, to Euro 8,124 thousand in the first nine months of 2017, when higher consultancy costs for activities preparatory to Zalmoxis' pricing & reimbursement have been more than offset by lower external development costs, due to (i) the termination of the SUPERSIST project (October 2016), (ii) lower development costs for one of the proprietary product and (iii) lower costs for License fees and patent fees:



Personnel costs, equal to Euro 9,592 thousand in the first nine months of 2017, increased by 8.7% compared to Euro 8,828 thousand in the same period of 2016, as a result of strengthening the Company's operational functions and units, consistent with the development of the business.

Increase in revenues and decrease in operating costs, in the first nine months of 2017, was recorded a strong improvement (+43.9%) of the **Operating result**, from a loss of Euro 14,109 thousand in the first nine months of 2016 (Euro 5,873 in the third quarter) to a loss of Euro 7,908 thousand in the first nine months of 2017 (Euro 1,407 in the third quarter).

For the same reasons, the **net result** clearly improved by 43.2% in the first nine months of 2017, recording a loss of Euro 8,102 thousand (Euro 1,579 thousand in the third quarter) from a loss of Euro 14,266 thousand at September 30th, 2016 (Euro 5,887 thousand loss in the third quarter).

The **net financial position** at September 30th, 2017 is positive for Euro 17,423 thousand (Euro 19,702 thousand at December 31st, 2016) and consists solely of cash, cash equivalents and current financial receivables in the form of time deposit, with no financial debt.

Key events occurred after the period

Dr. Attilio Bondanza, Head of Innovative Immunotherapies Unit, Division of Immunology, Transplantation and Infectious Diseases, at San Raffaele Hospital Scientific Institute, at the 4th International Congress on Stem Cell Transplantation and Cellular Therapies – COSTEM - (Berlin, October 26-29, 2017), presented new relevant pre-clinical in vivo safety data on its proprietary cancer immunogen therapy project CAR-CD44v6.

Business outlook

In 2017, the Company plans to continue the clinical, industrial and commercial development of its main proprietary investigational products, the activities finalized to pursue the market access of Zalmoxis® and the expansion of collaboration agreements for development and GMP production of cell and gene therapies for third parties.

With regard to Zalmoxis, in 2017, also as result of the collaboration with Dompé, interactions with European national health authorities will continue in order to define pricing & reimbursement of the therapy and the enrolment of patients required for completing the Phase III clinical study will progress. Following initial feedback received on activities already implemented, the Company estimates it will be able to enter the first European market end 2017/beginning of 2018. With reference to the access to the U.S. market, the Company is working with several KOLs in the field of hematopoietic stem cells transplant in order to define the best strategy to gain an accelerated access approval by the FDA.

As for NGR-hTNF, the Company will continue scouting for potential partners for its clinical and industrial development, reserving the option to make further submissions to the European authorities in the future.

With regard to the CAR CD44v6 project, based on the promising preclinical data collected in term of efficacy and safety and in light of the grant obtained from the European Commission for the EURE-CART project, also taking advantage of the expertise of the Company, will continue investing in preclinical research and development activities, in order to maximize the unique characteristics of the project aiming to start the first in man study in 2018.

With regard to contract development and manufacturing activities, based on solid results achieved in 2016 and in the first nine months of 2017, the Company will keep scouting for new industrial partners and for new



service agreements.

Finally, during 2017 the gradual activation of the new facility in Bresso is planned in line with the evolution of present and future collaborations' portfolio.

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 amortization, 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; CAR-CD44v6 is 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 manufacturing of viral vectors and patient-specific genetically engineered cells. MolMed is headquartered at the San Raffaele Biotechnology Department (DIBIT) in Milan, Italy, and an operating unit at OpenZone in Bresso (Milan, Italy). 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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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, 2017 Income statement

(amounts in Euro thousand)	3 rd quarter 2017	3 rd quarter 2016	1.1.2017- 30.09.2017	1.1.2016- 30.09.2016
			(a)	(b)
Revenues	6,001	3,526	14,936	12,207
Other revenues	225	154	705	1,694
Total operating revenues	6,226	3,680	15,641	13,901
Purchases of raw materials and consumables	1,220	1,050	3,644	3,339
Costs for services	2,799	5,011	8,124	13,861
Costs for use of third-party assets	365	353	1,094	1,058
Personnel costs	2,878	2,797	9,592	8,828
Other operating costs	31	49	110	146
Amortization and depreciation	340	293	985	778
Total operating costs	7,633	9,553	23,549	28,010
Operating result	(1,407)	(5,873)	(7,908)	(14,109)
Financial income	151	68	188	150
Financial charges	(323)	(82)	(381)	(307)
Net financial income (charges)	(172)	(14)	(193)	(157)
Pre-tax result	(1,579)	(5,887)	(8,102)	(14,266)
Income taxes	-	-	-	-
Profit (loss) for the period	(1,579)	(5,887)	(8,102)	(14,266)

Statement of comprehensive income

(amounts in Euro thousand)				
	3 rd quarter	3 rd quarter	1.1.2017-	1.1.2016-
	2017	2016	30.09.2017	30.09.2016
			(a)	(b)
Profit (loss) for the period	(1,579)	(5,887)	(8,102)	(14,266)
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)				
Fari value valuation reserve	-	-	-	-
Other comprehensive income, net of taxes (subsequently				
reclassified to the income statement)	-	-	-	-
Total comprehensive income (loss) for the period	(1,580)	(5,888)	(8,103)	(14,267)



Financial statements at September 30, 2017 Net financial position

(amounts Euro thousand)	September 30, 2017	December 31, 2016	
Cash on hand	13	13	
Other cash	12,404	19,688	
Cash equivalents	-	-	
A. Total cash and cash equivalents	12,417	19,701	
B. Current financial receivables and other financial assets	5,007	1	
Finance lease payables	-	-	
Current financial Debts	-	-	
C. Current financial debt	-	-	
D. Net current financial position (A+B+C)	17,423	19,702	
Finance lease payables	-	-	
Non current financial Debts	-	-	
E. Non-current financial debt	-	-	
F. Net financial position (D+E)	17,423	19,702	