

## Board of Directors reviewed business performance and approved the first half-year financial report ended June 30th, 2017:

- Important goals in market access and commercialization of Zalmoxis reached thanks to licence and distribution agreements stipulated with Megapharm for Israel and TTY for certain Asian Countries
- Pre-clinical data on CAR-CD44v6 safety profile presented which further support its therapeutic potential
- Portfolio of development and GMP production collaborations expanded by signing a development and manufacturing service agreement on a gene therapy for the treatment of Fanconi Anemia signed with Rocket Pharmaceuticals Ltd.
- Continuous improvement of Financial results:
  - Total revenues of Euro 9.8 million, of which Euro 8.9 million from sales, up by 2.9% respect to Euro 8.7 million of first half 2016
  - Operating and net results considerably improved by 21.2% and 22.2% respectively, against first half 2016
  - Positive net financial position of Euro 12.5 million

## Important results which occurred after the period:

- Commercialization and supply agreements for Zalmoxis in Europe signed with Dompé farmaceutici
- A development and manufacturing agreement in the field of allogeneic CAR T signed with Cellectis



(amounts in Euro thousand)	1 <sup>st</sup> half 2017	1 <sup>st</sup> half 2016	Variation		
	(a)	(b)	(a-b)	%	
Operating Revenues	9,819	10,221	(402)	(3.9%)	
Revenues	8,935	8,681	254	2.9%	
Other revenue	884	1,540	(656)	(42.6%)	
Operating costs	16,320	18,457 (2,137)		(11.6%)	
Operating result	(6,501)	(8,236) 1,735		21.1%	
Net financial income & charges	(21)	(143)	122	85.3%	
Result for the period	(6,522)	(8,379)	1,857	22.2%	
amounts in Euro thousand)	June 30, 2017	December, 31 2016	Variation		
	(a)	(b)	(a-b)	%	
Net financial position	12,461	19,702	(7,241)	(36.8%)	

Milan, July 27, 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 June 30<sup>th</sup>, 2017.

Riccardo Palmisano, MolMed's CEO, commented the first half 2017 business evolution as follows: "we described 2016 as the real turning point, thanks to the granting of CMA for Zalmoxis and the completion of the new facility in Bresso, two important results for the two pillars on which MolMed bases its growth prospects for the future.

During the first half semester 2017 the Company fully respected its programme of enhancing last year's results by signing several key agreements.

With regards to the main proprietary products, during the first semester of 2017, we signed contracts for the commercialization of Zalmoxis: with MegaPharm for Israel, with TTY for certain Asian Countries and, recently, a strategic agreement with Dompé farmaceutici for all member countries of the current European Economic Area (EEA) plus UK after-Brexit, and an option right for Switzerland, Turkey and Australia

Furthermore on the top level development and manufacturing for third parties front important results have been achieved: at the beginning of 2017 a development and manufacturing service agreement on a gene therapy product for the treatment of Fanconi Anemia with Rocket Pharma was concluded, a US company well-positioned in gene therapy for rare genetic disorders, while more recently a collaboration agreement was signed with Cellectis, a cutting edge innovative company listed on the French stock market and the Nasdaq, for the development and manufacturing of allogeneic CAR-T products.

Regarding future development perspectives, in the framework of proprietary products, preclinical research on proprietary immuno-gene therapy project CAR CD44v6 proceeded during the first half semester 2017, and new data has been presented to support its safety profile, providing reassurance on its potential toxicity, a key issue for the development of this technology. These data, together with those presented in December 2016 at ASH, confirm the therapeutic potential of our CAR CD44v6 in solid tumours, thereby suggesting the best



development course and its place in therapy and consequently the most appropriate path to follow to initiate human clinical trials, potentially in 2018, under the EURE-CART project.

All of these positive results, in absence of a significant improvement in the economic and financial results in the first half of 2017, would not have been sufficient to support the Company's sustainability and development prospects.

In conclusion, we are proud to confirm that in the first six months of 2017 our activities on the various fronts endorse the Company's programmes, also due to partners of excellence who believed in us and in our expertise. Thanks to a targeted strategy and a growing track record of programme delivery, MolMed is increasingly looking to implement its plans to enhance the company's assets and to ensure the company's future growth."

#### Main events occurred in the first quarter 2017

**Zalmoxis**: during the first half semester 2017 continued activities focused on the access to the European market after the initiation of the formal procedure in Italy, by filing the related dossier for pricing & reimbursement definition, in December 2016; during the first quarter the Company met with AIFA's scientific and technical commission (CTS), continued preparation of the dossier for pricing & reimbursement request to German and French Authorities and accelerated activities preparatory to negotiations in other major European countries.

With regard to the commercialization of Zalmoxis outside the European borders, on April 28th MolMed and Megapharm signed a distribution and license agreement which defines all terms and conditions for the supply and registration. In accordance with the agreement, Megapharm will distribute and market the product 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 of Zalmoxis's commercialization, on June 30th, MolMed and TTY Biopharm Company Ltd signed an exclusive license and distribution agreement which defines 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, the application of Marketing Authorization of Zalmoxis in the interested territories will be carried-out by and at the cost of TTY which will eventually perform further clinical studies, if needed to obtain regulatory approval, and will conduct all associated regulatory activities after marketing authorization, including market access and pricing & reimbursement.

On May 4th, 2017, the Italian Patent and Trademark Office granted Zalmoxis a supplementary protection certificate (SPC) on the Italian portion of the EP 1 781 789 European patent covering the product, which describes and claims the active ingredient of Zalmoxis, based on the Conditional Marketing Authorization



obtained last August in Europe. The granted SPC extends by 5 years, up to June 17th, 2030, Zalmoxis' market exclusivity in Italy.

**NGR-hTNF**: after validation of CMA request by EMA (December 23rd 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 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 European Medicines Agency (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 semester 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 Haematology Association (Madrid, 22-25 June 2017) Attilio Bondanza, Head of the Innovative Immunotherapy Unit at the Department of Immunology, Transplantation and Infectious Diseases of 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 antitumour activity of CD44v6 CAR-T cells, without incurring in unbearable 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 and to reach clinical translation, a consortium, coordinated by MolMed, of nine partners from five different EU countries was formed, including clinical, scientific and industrial groups clearly representing excellences in their fields EURE-CART project's main object is to conduct a multicentre, first-in-man Phase I/IIa clinical trial to demonstrate the safety and the efficacy of CD44v6 CAR T-cell immunotherapy in acute myeloid leukaemia and multiple myeloma.

**Development and GMP manufacturing activities**: in the first quarter of 2017 activities proceeded as scheduled with third parties (GSK, Telethon and Genenta) on therapeutics covered by existing collaborations, as well as on setting up new ones. On February 27th, 2017 MolMed and Rocket Pharmaceuticals Ltd. signed a development and manufacturing service agreement on 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.



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 and the start of the authorization process of part of the GMP Manufacturing area during the second half of 2016, validation activities continued in the first half of 2017.

#### Comments on financial results of First Half 2017

**Operating Revenues** in first half 2017 totalled Euro 9,819 thousand (Euro 10,221 thousand in first half 2016), of which Euro 8,935 thousand from sales, up by 2.9% respect to the first half of 2016 (Euro 8,681 thousand). This improvement mirrors activities planned by GlaxoSmithKline for the period and includes Euro 1,000 thousand of a milestone achieved under the terms of the agreement signed with TTY Biopharm on June, 30th, for the commercialization of Zalmoxis in certain Asian territories.

Other income, for an amount of Euro 884 thousand, includes R&D public grants (Euro 345 thousand), tax credit income on R&D activities (Euro 323 thousand) recorded pursuant to Italian Decree of May 27th, 2015, implementing Law n. 190 of 23 December 2014 ("Stability Law 2015") and tax credit income on recruitment of highly skilled people (Euro 196 thousand), recorded pursuant to Ministerial Decree of October 23rd, 2015.

In first half 2017 **operating costs** further improved by 11.6%, decreasing from Euro 18,457 thousand in the first six months of 2016 to Euro 16,320 thousand, due to the following developments:

- service costs, decreased by 35.3% from Euro 8,850 thousand in the first half 2016, to Euro 5,729 thousand in the first half 2017, when higher consultancy costs for activities preparatory to Zalmoxis' pricing & reimbursement have been more than offset by lower external development costs, due to the termination of the SUPERSIST project (October 2016) and lower development costs for one of the proprietary product;
- personnel costs, equal to Euro 6,714 thousand in the first half 2017, increased by 11.3% compared to Euro 6.031 thousand in the same period of 2016, as a result of the strengthening of the Company's operational functions and units;

The above-described trends in revenues and operating costs resulted in a 9.3% improvement of the **operating result** in the first half 2017, improved by 21.1%, from a loss of Euro 8,236 thousand to a loss of Euro 6,501 at June 30th, 2017.

For the same reasons, the **net result** clearly improved by 22.2% in first half 2017, recording a loss of Euro 6,522 thousand from a loss of Euro 8,379 thousand at June 30th, 2016.

In the first six months of 2017, **investments** amounted to Euro 741 thousand, mainly related to the construction of the operating unit in Bresso (Milan) and, to a lesser extent, to the ordinary renovation of laboratory equipment and purchase of new equipment for Zalmoxis's industrial production process, as well as to revamping and optimisation of the existing GMP facility.



The **net financial position** at June 30th, 2017 is positive for Euro 12,461 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

# MolMed and Dompé signed strategic commercialization and supply agreements for Zalmoxis in Europe

On July 26th MolMed and Dompé 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) 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 Authorization for Zalmoxis.

Concurrently with the execution of the aforementioned license and distribution 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, and Dompé will recognize a purchase price proportional to the reimbursed price of the product.

In addition to the purchase price, MolMed, on the basis of the license and distribution agreement, will receive 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 consolidated annual net sales generated in the territory covered by the agreement.

#### MolMed and Cellectis sign a collaboration agreement in the field of allogenic CAR-T

On July 27th MolMed S.p.A. and Cellectis signed a collaboration agreement under which Cellectis entrusts MolMed to develop and manufacture lentiviral vectors and genetically engineered T cells encoding for allogenic CAR-T.

#### Business outlook

In 2017, the Company, as, already stated, plans to continue the clinical, industrial and commercial development of its main proprietary investigational products in the cell and gene technology field, as well as pursue 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 a result of the collaboration with Dompé, interactions with European national health authorities will continue in order to define pricing & reimbursement of the therapy and, Phase III clinical study will be continued. Following initial feedback received on activities already implemented, the Company estimates it will be able to enter the first European market in the second half of 2017. As concerns access to the U.S. market, the Company is working with some of the most important KOL in the field of haematopoietic stem cells transplant in order to define the best strategy to gain an accelerated access from the FDA.

As for NGR-hTNF, the Company will keep on scouting for potential partners for its clinical and industrial development, reserving the right to make further submissions in the future.

With regard to the CAR CD44v6 project, based on the promising preclinical data collected in 2016 and in the first half of 2017, the grant obtained from the European Commission for the EURE-CART project, and profiting from the established development expertise within the Company, MolMed will continue investing in preclinical research and development activities, in order to valorise the unique distinguishing characteristics of the project to outline potential and place in therapy properly, and to define the development path to be followed for experimentation in humans, potentially in 2018, under the EURE-CART project.

Then, with regard to contract development and manufacturing activities, based on solid results achieved in 2016 and in the first half of 2017, the Company will keep implementing all activities aimed at providing the best service possible to current clients, and will keep scouting for new opportunities and synergies. In order to guarantee these services, as well as to support manufacturing of Zalmoxis for the market, gradual activation of the new facility in Bresso is planned in 2017.

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's (Italian securities & exchange commission) Issuers Regulation.





#### 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 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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#### **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..



# Half-year condensed financial statements at 30 June 2017 Balance sheet

(amounts in Euro thousand )	June 30, 2017	December 31, 2016
ASSETS		
Tangible assets	11,497	11,567
Goodwill	77	77
Intangible assets	491	494
Financial assets	210	211
Tax receivables	1,722	1,722
Other assets	1,250	1,500
TOTAL NON-CURRENT ASSETS	15,247	15,571
Inventories	1,520	1,067
Trade receivables and other commercial assets	6,322	5,015
Tax receivables	1,490	2,392
Other receivables and sundry assets	1,173	3,154
Other financial assets	5,007	1
Cash and cash equivalents	7,454	19,701
TOTAL CURRENT ASSETS	22,966	31,330
TOTAL ASSETS	38,213	46,901
LIABILITIES AND SHAREHOLDERS' EQUITY		-
Capital	20,313	20,313
Share premium reserve	49,347	49,347
Other reserves	542	461
Retained earnings (accumulated losses)	(47,972)	(34,096)
Profit (loss) for the period/year	(6,522)	(13,876)
TOTAL SHAREHOLDERS' EQUITY	15,708	22,149
Liabilities for pensions and employee severance indemnity (TFR)	145	146
Trade payables	1,400	1,800
Other liabilities	4,533	4,700
TOTAL NON-CURRENT LIABILITIES	6,078	6,646
Trade payables	13,144	12,526
Other liabilities	3,283	5,580
TOTAL CURRENT LIABILITIES	16,427	18,106
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	38,213	46,901



### Half-year condensed financial statements at 30 June 2017 Income statement

(amounts in Euro thousand )	1 <sup>st</sup> half 2017	1 <sup>st</sup> half 2016
Revenues	8,935	8,681
Other revenue	884	1,540
Total operating revenues	9,819	10,221
Purchases of raw materials and consumables	2,424	2,289
Costs for services	5,729	8,850
Costs for use of third-party assets	729	705
Personnel costs	6,714	6,031
Other operating costs	79	97
Amortization and depreciation	645	485
Total operating costs	16,320	18,457
Operating result	(6,501)	(8,236)
Financial income	37	82
Financial charges	(58)	(225)
Net financial income (charges)	(21)	(143)
Pre-tax result	(6,522)	(8,379)
Income taxes	_	_
Profit (loss) for the period	(6,522)	(8,379)
Statement of comprehensive income		
(amounts in Euro thousand )	1 <sup>st</sup> half 2017	1 <sup>st</sup> half 2016
Profit (loss) for the period	(6,522)	(8,379)
Other comprehensive income (not subsequently reclassified to the income statement)		
Profit (loss) actuarial	-	(1)
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)	1	(1)
Other comprehensive income (subsequently reclassified to the income statement)		
Net change in fair value of assets available for sale	-	-
Other comprehensive income, net of taxes (subsequently reclassified to the income statement)	-	-

#### FROM GENES TO THERAPY

Total comprehensive income (loss) for the period

(8,380)

(6,521)



# Half-year condensed financial statements at 30 June 2017

## Cash flow statement

(amounts in Euro thousand )		1 <sup>st</sup> half 2017	1 <sup>st</sup> half 2016
Cash and cash equivalents		19,701	11,770
Opening cash and cash equivalents	А	19,701	11,770
Cash flow from operating activities:			
Profit (loss) for the year		(6,522)	(8,379)
Amortization/Depreciation of intangible/tangible assets		645	485
Change in liabilities for pensions and employee severance indemnity		(1)	(51)
Non-cash costs for stock options		68	14
Decrease in other non current assets due to option rights		_	86
Reversal of financial income and charges		21	143
Cash flow from operating activities before changes in working capital		(5,789)	(7,703)
Changes in current assets and liabilities:			
(Increase) decrease in inventories		(453)	(294)
(Increase) decrease in trade and other receivables		1,577	3,612
Increase (decrease) in trade and other payables		619	(3,555)
Increase (decrease) in other liabilities		(2,297)	(728)
Total changes in current assets and liabilities		(554)	(965)
(Increase) decrease in non-current tax receivables		-	2,457
Increase (decrease) in other liabilities		-	(165)
Increase (decrease) in trade and non current trade payables		(400)	(400)
Increase (decrease) in other financial assets		(167)	-
Increase (decrease) in other activities		-	1
Interest paid		(2)	(65)
		(6,912)	(6,840)
Total cash flow generated (absorbed) by operating activities	В	-	-
Cash flow from investing activities:		(567)	(860)
Net (investment) divestment in tangible assets		(13)	(73)
Net (investment) in other financial assets		(5,006)	8,000
(investment) in other financial assets		1	117
Interest received		(5,335)	7,184
Total cash flow generated (absorbed) by investing activities	С	-	-
Cash flow from financing activities:		-	-
Increases in capital and share premium reserve		-	-
Shareholders' advance payment for share capital increase			-
Total cash flow generated (absorbed) by financing activities	D		-
Cash flow generated (absorbed) during the year	E=B+C+D	(12,247)	344
Closing cash and cash equivalents	A+E	7,454	12,114



## Half-year condensed financial statements at 30 June 2017

## $Statement\ of\ changes\ in\ shareholders'\ equity$

(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
Balance at Jaunary 1st 2016	19,842	45,764	223	416	(12)	(13,520)	(20,784)	31,929
Allocation of prior year result	-	-	-	-	-	(20,784)	20,784	-
Personnel costs for stock options 2012	-	-	-	14	-	-	-	14
Other variations - stock options, Plan 2012	-	-	-	(208)	-	208	-	-
Profit (loss) for the period	-	-	-	-	(1)	-	(8,379)	(8,380)
Balance at June, 30 2016	19,842	45,764	223	222	(13)	(34,096)	(8,379)	23,563

(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
Balance at Jaunary 1st 2017	20,313	49,347	223	251	(13)	(34,096)	(13,876)	22,149
Allocation of prior year result	-	-	-	-	-	(13,876)	13,876	-
Personnel costs for stock options 2016-2021	-	-	-	83	-	-	-	83
Other variations - stock options, Plan 2016-2021	-	-	-	(3)	-	-	-	- 3
Profit (loss) for the period	-	-	-	-	1	-	(6,522)	(6,521)
Balance at June, 30 2017	20,313	49,347	223	331	(12)	(47,972)	(6,522)	15,708