



PRESS RELEASE

MolMed: interim financial report as of September 30th 2018 approved.

Financial results confirm the first half positive trend and show a significant improvement compared to the first nine months of 2017:

- *Revenue from sales equal to Euro 19.4 million, up 30% compared to Euro 14.9 million of the same period of the previous year;*
- *Operating result and Net result respectively equal to a loss of Euro 4.6 million and Euro 4.9 million, respectively up 41.5% and 40% compared to a loss of Euro 7.9 million and Euro 8.1 million at September 30th 2017;*
- *Net financial position equal to Euro 15.8 million compared to Euro 18.1 million as of December 31st 2017.*

Milan (Italy), November 12th 2018 – The Board of Directors of MolMed S.p.A. (MLMD.MI) (the “Company”), clinical stage biotechnology company focusing on research, development, manufacturing, and clinical validation of cell & gene therapies to treat cancer and rare diseases, met today under the chairmanship of Carlo Incerti, reviewed and approved the interim financial results as of September 30th, 2018, reported on a voluntary basis¹.

Riccardo Palmisano, CEO of MolMed S.p.A., commented on the business trend: “*The interim financial report at September 30th confirms the growth trend observed in the first six months of the year, with a reduction in the loss for the period of 40% compared to the corresponding period of the previous year. This result was achieved thanks to an increase in revenues from sales of 30%, following new collaborations with innovative partners, synergistic with the company strategy, but also thanks to the containment of operating costs. The results achieved confirm the soundness of the dual-business model that has characterized the Company for some years. Today, November 12th, MolMed and Dompé reached a mutual agreement for the termination of the license and distribution agreement of Zalmoxis[®], thanks to which MolMed reacquired the marketing rights of the product for all the countries of the European Union, as well as for Switzerland, Turkey and Australia, together with all the ongoing activities to guarantee the continuity and interest of patients. Our attention will now be focused on the identification of a new partner and the advancement of the clinical study of the product, also thanks to the resources obtained with the termination of the contract, to ensure that Zalmoxis[®] could be*

¹ MolMed S.p.A. following the continuity with the practice adopted up to now and with the aim of ensuring continuity in the information to the market, communicates, on a voluntary basis, the additional periodic financial information referred to in Article 82-ter of Consob Regulation 11971/99. Please note that the Legislative Decree 25/2016, implementing the Directive 2013/50 / EU, eliminated the obligation to publish the interim management report, previously envisaged by paragraph 5 of art. 154-ter of Legislative Decree 58/1998.



PRESS RELEASE

available to patients as quickly as possible. At the same time the activities for the development of the proprietary pipeline continued, starting from CART CD44v6: as soon as we receive the regulatory authorizations for the start of the clinical phase, after the application already filed, we will begin the first human tests to verify the safety and efficacy of therapy in blood cancers (AML and MM)”.

Key financial results as of September 30th 2018

(amounts in Euro thousand)

	3rd quarter 2018	3rd quarter 2017	01.01.2018 - 30.09.2018 (a)	01.01.2017 - 30.09.2017 (b)	Variation	
					(a-b)	%
Operating Revenues	7,300	6,226	20,012	15,641	4,371	27.9%
Revenues	7,202	6,001	19,436	14,936	4,500	30.1%
Other revenue	98	225	576	705	(129)	(18.3%)
Operating costs	(9,077)	(7,633)	(24,640)	(23,549)	(1,091)	4.6%
Operating result	(1,777)	(1,407)	(4,628)	(7,908)	3,280	(41.5%)
Net financial income & charges	(11)	(172)	(245)	(193)	(52)	26.9%
Result for the period	(1,788)	(1,579)	(4,873)	(8,102)	3,229	(39.9%)

Operating revenues, as of September 30th 2018, are equal to Euro 20,012 thousands, up 27.9% compared to the first nine months of 2017 (Euro 15,641 thousands), thanks to **Revenue from sales** equal to Euro 19,436 thousands, up 30.1% compared to the first nine months of 2017 (Euro 14,936 thousands), including:

- Revenues from development and manufacturing activities for third parties equal to Euro 16,213 thousands, including Euro 679 thousands from *milestone*, up 30.4% (Euro 12,436 thousands in the same period of the previous year);
- Revenues from Zalmoxis® equal to Euro 3,223 thousands, deriving from (i) *milestone* from the licence and distribution agreement signed on July 26th 2017 with Dompé farmaceutici S.p.A. for a total amount of Euro 3,000 thousands and (ii) from the sale of the product under AIFA funding scheme for a total amount of Euro 223 thousands.

As announced today, November 12th, 2018, and reported in the paragraph “Key events occurred after September 30th 2018”, the Company and Dompé mutually terminated the license and distribution agreement for Zalmoxis®. According to the agreement, MolMed reacquired the marketing rights of the product for all the countries of the European Union, as well as for Switzerland, Turkey and Australia and receives from Dompé 100% of the deferred contribution contractually foreseen for the year 2018, amounting Euro 3,000 thousands.

The increase in Revenue from sales is partially offset by the reduced weight of the **Other Revenue** amount, totalling Euro 576 thousand (Euro 705 thousand in the first nine months of 2017), due to a decrease in R&D public grants.

Operating costs totalling Euro 24,640 thousands, slightly increased compared to the first nine months of 2017 (Euro 23,549 thousands), mainly due to the following changes:

- higher costs from purchases of raw materials and consumables, totalling Euro 4,261 thousands (Euro 3,644 as of September 30th 2017), mainly due to an increase in R&D activities and in the Development of the pipeline proprietary products;
- higher personnel costs, totalling Euro 9,887 thousands (Euro 9,592 thousands as of September 30th 2017). This increase, equal to Euro 295 thousands, and is attributable to the one-off compensation to be paid to Prof. Bordignon, for an amount of Euro 800 thousand, following the termination of the



PRESS RELEASE

employment relationship with the Company, which took place on September 24th 2018, pursuant to the non-competition agreement provided for in his contract. This amount will be paid in monthly instalments for the 24-month duration of the agreement, and not in a lump sum as provided for and illustrated in the Remuneration Report, and is partially offset by lower personnel costs deriving from the absorption at the higher level of the roles of General Manager and Director of Strategic Affairs;

- a small increase in depreciation and amortization of tangible assets, totalling Euro 1,130 thousands (Euro 985 thousands as of September 30th 2017) following the start of the amortization period of the assets relating to the new Bresso facility purchased during the 2017 financial year.

The **Operating Results** of the first nine months of the 2018 is equal to a loss of Euro 4,628 thousands and, compared with a loss of Euro 7,908 thousands in the same period of the previous year, shows a positive increase of +41.5%. The increase is mainly due to higher Operating revenues in 2018, more than proportional increased compared to Operating costs (+27.9% vs. +4.6%).

Net Financial Income and Charges show a negative result equal to Euro 245 thousands (Euro 193 thousands as of September 30th 2017), with a decrease of Euro 52 thousands compared to the same period of the previous year, as a consequence of a decrease in Financial income, totalling Euro 39 thousands (Euro 188 thousands as of September 30th 2017) following a decrease in exchange income, together with a decrease in financial charges, equal to Euro 284 thousands (Euro 381 thousands as of September 30th 2017), due to lower fees paid in relation to the utilization of the last tranche of the Standby Equity Facility (SEF).

As a consequence of the above mentioned changes, **Net Result** in the first nine months of 2018, shows a loss of Euro 4,873 thousands, considerably improved (+39.9%) compared to a loss of Euro 8,102 thousands, reported in the same period of the previous year.

During the first nine months of 2018, **investments** amounted to Euro 999 thousands, for the set-up of new premises for the production and the purchase and renewal of manufacturing process equipment, as well as the renewal and optimization of the existing GMP system.

Net financial position as of September 30th 2018 is equal to Euro 15,757 thousands (Euro 18,111 thousands as of September 31st 2017) and consists solely of cash and cash equivalents and current financial receivables represented by corporate bond "available for sale", with no financial debt.

Key events occurred in the first nine months of 2018

January 15th: Zalmoxis® price & reimbursement dossier filed in Germany, making Zalmoxis® prescribable and reimbursable as of January 15th in one of the largest European market.

February 8th: Dompé exercises the option right to undertake the market access and commercialization activities for Zalmoxis® in Switzerland, Turkey and Australia.

February 15th: AIFA Determina on reimbursement regime and market price for the proprietary cell therapy Zalmoxis® published on the Official Gazette. The Determina will be effective from the fifteenth day subsequent to its publication on the Official Gazette.

April 12th: MolMed and Orchard Therapeutics announce the beginning of their collaboration in the field of gene therapy for rare diseases.



PRESS RELEASE

May 4th: signed a five-year Master Service Agreement and a related first Project Agreement with Boston Children's Hospital, for the supply of lentiviral vectors to be used for clinical application in rare diseases.

May 17th: full results of NGR-hTNF trial in mesothelioma published by the leading research journal The Lancet Oncology. The study has shown the efficacy of NGR-hTNF in the treatment of mesothelioma, an asbestos-related tumour, with particular reference to patients with a very dismal, refractory or chemo resistant prognosis

May 24th and 25th: 5th and last tranche of the share capital increase reserved to Société Générale ("SEF") requested and completed.

May 30th: further data on the safety profile of MolMed's proprietary product CAR-T CD44v6 resulted from a study conducted by San Raffaele Hospital, published by the prestigious journal Nature Medicine.

May 31st: announced the execution of a binding term sheet with Glycostem for the development and manufacturing of allogeneic CAR-NK therapies.

June 4th: new and relevant data on the therapeutic potential of NGR-hTNF in brain lymphomas presented at the American Society of Clinical Oncology di Chicago (ASCO): an independent study showed multiple complete or partial regression of lymphoma in patients treated with NGR-hTNF in combination with standard chemotherapy.

June 22nd: extended the collaboration in the field of gene therapy for rare diseases with Orchard Therapeutics to Orchard pipeline products for the treatment of MPS IIIA and IIIB.

June 28th: signed a three-year Master Agreement for the development of new CARs targeting novel tumour antigens with AbCheck.

July 13th: signed a new, three-year agreement for the development and supply of lentiviral vectors for clinical use within GSK project in the oncology field. The agreement renews the historic collaboration, this time in the oncology field, between MolMed and GSK, following the sale by GSK of its previous contract with MolMed, concerning products for rare diseases, to Orchard Therapeutics.

July 27th: the European Commission informed MolMed on the Renewal of the Conditional Marketing Authorization of Zalmoxis®. On the same date the Company was also informed by EMA of the positive opinion for MolMed procedure to request the addition of Bresso facility as a production and batch control and release site for Zalmoxis®.

September 11th: Salvatore Calabrese appointed Chief Financial Officer.

September 24th: Carlo Incerti succeeded to Claudio Bordignon as Chairman of the Company's Board. Salvatore Calabrese appointed Officer Responsible for the preparation of corporate financial reports. The Board of Directors called Shareholders' Meeting on October 25th 2018 to resolve on the appointment of a new Board Member or number of the Board member's reduction and on the proposal of capital increase, within the limit of 10%, with the exclusion of the option rights.

September 29th: MolMed participates at the first annual meeting of the International Academy for Clinical Hematology ("IACH"), explaining the therapeutic potential of Zalmoxis® in haploidentical transplantation and of CAR T CD44v6 in blood tumours.

In the first nine months of 2018, the preclinical development and manufacturing processes related to the



PRESS RELEASE

retroviral vector coding for CAR CD44v6 and of CAR T cells were also completed. In the third quarter the authorization process of the clinical trial has started in various European countries, starting from Italy, where the documentation was submitted to AIFA on October 10th and is currently under evaluation.

Furthermore, in the first nine months of 2018, following a number of submissions of authorization packages relating to the GMP Manufacturing area, which occurred between the end of 2017 and the beginning of 2018, authorization was granted by the competent authorities for Stream 1 (approximately 600 square meters) of the GMP Manufacturing area at new Bresso Facility for the production of viral vectors and genetically modified cells related to therapies for both clinical research and market purposes.

Key events occurred after September, 30th 2018

October 17th: results from a new study on CAR T CD44v6 in in-vivo experimental models of lung carcinoma and melanoma confirming the high therapeutic potential of MolMed's therapy also in solid tumors presented at the ESGCT.

October 25th: the Shareholders meeting resolved to delegate to the Board of Directors the power to increase the share capital with the exclusion of the pre-emption right, within 24 months, up to 10%. The Shareholders meeting also resolved to reduce the number of the members of the Board of Directors from eleven to ten.

In accordance with Consob resolution 16839 of 19/03/2009, the Company, as part of a review of the existing structure costs, has sent to Mediobanca - Banca di Credito Finanziario S.p.A., the withdrawal from the mandate of Liquidity Provider, and at the same time the corporate broking contract. Mediobanca will cease operating as liquidity provider for MolMed on February 12th, 2019.

November 12th: MolMed and Dompé mutually terminated the license and distribution agreement for Zalmoxis[®], signed on July 27th 2017: according to the termination agreement, MolMed gains back the product marketing rights to re-start its commercial development and receives from Dompé 100% of the deferred contribution contractually foreseen for the year 2018, amounting Euro 3,000 thousands.

Business Outlook

With regard to the proprietary pipeline, the Company foresees to proceed with the clinical study of Phase III (TK-008) aimed at confirming the safety and therapeutic efficacy of Zalmoxis[®] in association with haploidentical transplant, in terms of disease-free survival and overall survival, compared to controls submitted only to haploidentical transplant, by the enrolment of new patients. With reference to the terms of resolution of the licence and distribution agreement with Dompé, in order to ensure the continuity of the ongoing activities, Dompé will support MolMed in the transition phase that is expected to be completed by early 2019. Furthermore, the resources corresponded by Dompé will allow MolMed to finance the continuation of the current clinical trial, during the search for a new partner with which to restart the commercial development of the product in the shortest possible time.

With regard to CAR CD44v6 project, the advancement of all preliminary activities, completed in the first nine months of 2018, makes the Company confident in the possibility of starting the clinical trial on humans with the activation of the first Phase I / II clinical study in blood tumors (AML) and MM) by the end of the first quarter of 2019. It is also envisaged the continuation of the authorization process of the clinical trial, started in the third



PRESS RELEASE

quarter in various European countries, and started from Italy where the documentation was submitted to AIFA on October 10th and is currently under evaluation. Preliminary studies to submit the application for the authorization for human testing of CAR T CD44v6 on solid tumors are also near to completion.

In the upcoming months, the new product portfolio of CAR platform will also be developed, with the continuation of development activities already started, after the signing in the second quarter of the agreements with Glycostem and AbCheck s.r.o., and aimed at expanding the proprietary pipeline in the onco-hematological area. The new CARs, both autologous and allogeneic, will be developed on new therapeutic targets, also thanks to the introduction of innovative technological platforms, through the search for new partnerships and new opportunities aimed at strengthening internal pre-clinical research capabilities.

Lastly, during the fourth quarter of 2018, the gradual activation of the new Bresso facility is expected to continue, in line with the evolution of the existing and future collaborations portfolio. Also on the basis of the new available areas, the business development activity will be increased, to extend the collaborations in progress and make new alliances in the development and manufacturing of cell & gene therapy products for third parties.

The official manager responsible for preparing the Company's financial reports, Salvatore Calabrese, 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 available on the Company website www.molmed.com



PRESS RELEASE

About MolMed

MolMed S.p.A. is a clinical stage biotech company focused on research, development, manufacturing and clinical validation of innovative anticancer therapies. MolMed's product portfolio includes proprietary anti-tumor therapies in both clinical and preclinical development: Zalmoxis® (TK) is a cell therapy based on donor T cells genetically engineered to enable bone marrow transplants from partially compatible donors for patients with high-risk hematological malignancies, eliminating post-transplant immunosuppression prophylaxis and inducing a rapid immune reconstitution. Zalmoxis® received Orphan Drug Designation and is currently in Phase III in a high-risk population of acute leukemia patients, but has already obtained a Conditional Marketing Authorization by the European Commission in the second half of 2016 as well as reimbursement conditions in Italy at the end of 2017 and in Germany at the beginning of 2018. Still focusing on this cell & gene technology, the company is developing a new CAR pipeline based on Chimeric Antigen Receptor; the most advanced product, the CAR-T CD44v6, currently in advanced preclinical development, and is potentially effective both for some hematological malignancies and several solid epithelial tumors. Following the authorization request submitted to European Regulatory Agencies, MolMed plans to commence during the first half of 2019, human clinical trials in the AML and MM indications. In addition, the Company is developing a new CAR pipeline, both autologous and allogeneic, the last one based on NK (Natural Killer) cells. is also the first company in Europe to have obtained the GMP manufacturing authorization for cell & gene therapies for its proprietary products (Zalmoxis®) as well as for third parties and/or in partnership (Strimvelis, an Orchard gene therapy for the ADA-SCID). With reference to GMP development and manufacturing activities for third parties, MolMed signed numerous partnership agreements with leading European and US companies. MolMed, founded in 1996 as an academic spin-off of the San Raffaele Scientific Institute, is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana since March 2008. MolMed is headquartered and based in Milan, at the San Raffaele Biotechnology Department (DIBIT) and has an operating unit at OpenZone in Bresso.

For further information:

Ilaria Candotti

Investor Relations & Communication Manager

MolMed S.p.A.

+39 02 21277.205

+39 02 21277.325

investor.relations@molmed.com

Marcella Ruggiero

Press agent

SEC Relazioni Pubbliche e Istituzionali s.r.l.

+39 02 6249991

+39 335 214241

ruggiero@secrp.com

Attachments

- Income Statement and Statements of Comprehensive Income as of September 30th 2018
- Net Financial Position as of September 30th 2018

Income Statement ended September 30th 2018

<i>(amounts in Euro thousand)</i>	3rd quarter 2018	3rd quarter 2017	01.01.2018- 30.09.2018	01.01.2017- 30.09.2017
Revenues	7,202	6,001	19,436	14,936
Other revenue	98	225	576	705
Total operating revenues	7,300	6,226	20,012	15,641
Purchases of raw materials and consumables	(1,409)	(1,220)	(4,261)	(3,644)
Costs for services	(3,209)	(2,799)	(8,173)	(8,124)
Costs for use of third-party assets	(365)	(365)	(1,126)	(1,094)
Personnel costs	(3,671)	(2,878)	(9,887)	(9,592)
Other operating costs	(32)	(31)	(63)	(110)
Amortization and depreciation	(391)	(340)	(1,130)	(985)
Total operating costs	(9,077)	(7,633)	(24,640)	(23,549)
Operating result	(1,777)	(1,407)	(4,628)	(7,908)
Financial income	13	151	39	188
Financial charges	(24)	(323)	(284)	(381)
Net financial income (charges)	(11)	(172)	(245)	(193)
Pre-tax result	(1,788)	(1,579)	(4,873)	(8,102)
Income taxes	-	-	-	-
Profit (loss) for the period	(1,788)	(1,579)	(4,873)	(8,102)

Statements of Comprehensive Income ended September 30th2018

<i>(amounts in Euro thousand)</i>	3rd quarter 2018	3rd quarter 2017	01.01.2018- 30.09.2018	01.01.2017- 30.09.2017
Profit (loss) for the period	(1,788)	(1,579)	(4,873)	(8,102)
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	(1,787)	(1,580)	(4,872)	(8,103)



PRESS RELEASE

Net Financial Position as of September 30th 2018

(amounts Euro thousand)

	September 30, 2018	December 31, 2017
Cash on hand	9	12
Other cash	14,779	13,093
Cash equivalents	-	-
A. Total cash and cash equivalents	14,788	13,105
B. Current financial receivables and other financial assets	969	5,006
Finance lease payables	-	-
Current financial Debts	-	-
C. Current financial debt	-	-
D. Net current financial position (A+B+C)	15,757	18,111
Finance lease payables	-	-
Non current financial Debts	-	-
E. Non-current financial debt	-	-
F. Net financial position (D+E)	15,757	18,111