

# Interim financial report at 30 September 2018

English translation for convenience

#### FROM GENES TO THERAPY



# From genes...

Our mission: focusing on innovative cell and gene therapies that can meet the therapeutic needs in the treatment of tumors and rare diseases, by combining scientific and research excellence with a clear and strong industrial project

...to therapy



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## General corporate information

Registered office: Via Olgettina, 58 – 20132 MILAN (Italy)

Operating unit: OpenZone, Via Meucci, 3 - 20091 Bresso (Milan), Italy

 Tax Number:
 11887610159

 VAT no.:
 IT 11887610159

 Milan Company Register:
 no. 11887610159

REA (economic and administrative index): 1506630

Share capital: Euro 21,819,020.83 fully paid

Ticker Borsa Italiana: MLM

ISIN: IT0001080248

Ticker Reuters: MLMD.MI
Ticker Bloomberg: MLM IM

LEI code 815600342FDC0C3F6E10

Outstanding shares: 463,450,672

(100% ordinary shares with no par value)

#### **DISCLAIMER**

This document may contain forward-looking statements that reflect the current views of the Company on future events based on information available as of today's date. Forecasts and estimates are generally identified by words such as "possible", "should", "forecast", "expected", "estimated", "believe", "intend", "plan" "objective" or by the negative form of these expressions or other variations thereof or by the use of comparable terminology. Although the Company believes that its expectations are based on reasonable assumptions, these forwardlooking statements are subject to numerous risks and uncertainties that are beyond Managers' control, including scientific, business, economic and financial factors, which could cause actual results to differ materially from those projected in the forward-looking statements.

The Company assumes no obligation to publicly update and revise forecasts and estimates following the availability of new information, future events or other factors, without prejudice to compliance with applicable laws. All subsequent forecasts and estimates, whether oral or written, attributable to the Company or any persons acting on its behalf, are expressly qualified, in their entirety, by these cautionary statements.

This document does not constitute an offer or invitation to subscribe for or purchase any securities of MolMed S.p.A.





# Corporate bodies

President Carlo Incerti

Chief Executive Officer Riccardo Palmisano
Directors Alberto Luigi Carletti

Laura Iris Ferro, independent

Sabina Grossi

Mario Masciocchi, independent

Alfredo Messina

Elizabeth Robinson, *independent* Raffaella Ruggiero, *independent* Didier Trono, *independent* 

The Board of Directors was appointed by the Shareholders' Meeting of April 18th, 2016, and shall remain in office until the Shareholders' Meeting called to approve the Financial Statements of December 31st, 2018.

Riccardo Palmisano also serves as "Director in charge of the internal control and risk management system".

## **Board of Statutory Auditors**

Chairman Riccardo Perotta
Standing auditors Flavia Daunia Minutillo

Enrico Scio

Deputy Auditors Alessia Bastiani

Giuliana Maria Converti

The Board of Statutory Auditors was appointed by the Shareholders' Meeting of April 18th, 2016, and shall remain office until the Shareholders' Meeting called to approve the Financial Statements of December 31st, 2018.

#### Control and Risks Committee \*

Chairman Mario Masciocchi, independent

Members Sabina Grossi

Elizabeth Robinson, independent

## Remuneration and Nomination Committee

Chairman Raffaella Ruggiero, *independent*Members Laura Iris Ferro, *independent*Didier Trono, *independent* 

#### External Auditing Firm

EY S.p.A.

<sup>\*</sup> Also carries out the function of Committee for Transactions with Related Parties



## Scientific Advisory Board

MolMed's Scientific Advisory Board (SAB), chaired by Professor Claudio Bordignon, is an independent advisory body - typical of companies in which the quality of projects is determined by the value of their scientific content - which plays a role of guidance in the research and development of new therapeutic strategies, and gives an external objective assessment of the results obtained.

MolMed's Scientific Advisory Board offers a unique combination of knowledge and experience, provided by leading international scientists. Its membership includes:

- Claudio Bordignon, Chairman and Founder Founding member of the Scientific Advisory Board of the European Research Council; Honorary Professor of haematology at the University Vita-Salute San Raffaele in Milan (Italy);
- Malcolm K. Brenner, Director of the Centre for Cell and Gene Therapy at the Baylor College of Medicine, Houston, Texas, USA; Professor of Medicine and Paediatrics at Fayez S. Sarofim (Baylor College of Medicine), Houston, Texas, USA.
- Gianpietro Dotti, member of the UNC Lineberger Comprehensive Cancer Centre, Professor of the Department of Microbiology and Immunology at the University North Carolina School of Medicine, North Carolina, USA;
- Mohamad Mohty, Professor of Haematology in the Faculty of Medicine of the Pierre and Marie Curie University, Paris, France and Director of Haematology and Cell Therapy at the Saint-Antoine Hospital, Paris, France;
- Miguel-Angel Perales, Oncologist and Vice-Director of the Bone-marrow Transplant Service and Director of the Adult Bone Marrow Transplantation Fellowship Program at the Memorial Sloan Kettering Cancer Centre, NY, USA.

The professional profiles of the members of the Scientific Advisory Board are available on the Company's website (www.MolMed.com).



# Interim report on operations at September 30th, 2018

# Summary of income results

(amounts in Euro thousand)	3 <sup>rd</sup> quarter 2018	3 <sup>rd</sup> quarter 2017	01.01.2018 - 30.09.2018	01.01.2017 - 30.09.2017	Vari	ation
			(a)	(b)	(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%)

### *Investments*

(amounts in Euro thousand)	01.01.2018- 30.09.2018 (a)		Variazione (a-b)	Variazion e %
Investments	999	1,587	(588)	(37.0%)

# Net financial position

(amounts in Euro thousand)	thousand) September 30, 2018 (a)		Variation (a-b)	Variation %	
Net Financial Position	15,757	18,111	(2,354)	(13.00%)	

# Average number of employees

	01.01.2018-	01.01.2018-	01.01.2017-
	30.09.2018	30.06.2018	31.12.2017
Average number of employees	196	195	185



# 1. A history of excellence

MolMed is a medical biotechnology company, focused on research, development and clinical validation of novel gene and cell therapies to treat tumors and rare diseases, by combining scientific and research excellence with a clear and solid industrial project.

Created in 1996 as a spin-off of the San Raffaele Scientific Institute of Milan, dedicated to research, development and production in the field of gene and cell therapy, applied to both rare genetic diseases and hematologic neoplasms, over the years MolMed has developed a dual business model, where R&D activities for its own products are placed alongside GMP development and production services on behalf of third parties. Among the leading companies in Europe to boast laboratories authorised for the GMP production of gene and cell therapies, and the first and only facility authorised in Europe for ex vivo cell&gene production for the market, MolMed is now a consolidated company, both in the area of research and development of its products and for GMP services on behalf of third parties, like CDMO (Contract Development & Manufacturing Organisation), a sector in which it boasts major international partnerships and double-digit growth in revenues, also thanks to the new Bresso facility. As regards proprietary products, MolMed is able to internally carry out all the functions typical of a biotechnology company, from basic research, to development, production, up to clinical approval, to regulatory activities and negotiation of the price and reimbursement of its therapies, and is one of the first companies in the world to have obtained the marketing authorisation for a gene-cell therapy which is the result of immune system engineering.

The current proprietary product portfolio of MolMed includes three therapies:

Zalmoxis® (TK), a cell therapy that allows the transplants of haematopoietic stem cells from donors partially compatible with patients with high-risk haematological malignancies, eliminating post-transplant immunosuppression, currently at Phase III of clinical trials, but has already received the Conditional Marketing Authorisation – CMA from the European Commission. Based on the CMA of 2016, Zalmoxis® was the object of licence agreements for all EU countries, as well as Switzerland, Israel, Turkey, Australia and a number of South-East Asian countries. At the start of 2018, it received reimbursement in the two main markets for bone marrow transplants, Italy and Germany, while access, price and reimbursement activities are continuing in the other national markets;

CAR-CD44v6, an original immune gene therapy project, potentially effective for haematological neoplasms and some solid tumours, currently at the last phase of pre-clinical development, which demonstrated a high level of effectiveness and safety in experimental animal models;

NGR-hTNF, a therapeutic agent for treating several solid tumours which displays anti-tumour activity through its specific binding to blood vessels feeding the tumour and to the concentration of immune system cells into the tumour mass, involved a large program of advanced clinical development (phases II and III), which involved more than 1,000 patients.

MolMed also conducts cell&gene therapy projects in collaboration with third parties, offering resources and expertise in support of development and production for pre-clinical and clinical studies (Phase I-III) and for commercial use. These projects include the development and the validation of the manufacturing process as well as its control strategy, and the cGMP production of clinical and commercial-grade viral vectors and genetically modified cells. Thanks to its consolidated leadership in this sector, in the last few years, MolMed has entered into close agreements with some of the major players in the gene and cell therapy sector, including Fondazione Telethon, GlaxoSmithKline (GSK), Orchard Therapeutics, Genenta Science, Rocket Pharma, Boston Children Hospital and Cellectis, for the provision of development, manufacturing and technology transfer services for the clinical application of gene therapies based on viral vector cell transduction. In





particular, according to the agreements signed in 2011 and 2013, MolMed worked on the development and validation of the production process, the analytical methods and the supply process for the compassionate use of Strimvelis<sup>™</sup> (autologous CD34+ cells transduced to express the gene encoding for ADA) of GSK, an exvivo gene therapy based on stem cells, for the treatment of patients with an extremely rare disease called ADA-SCID (Severe Combined Immunodeficiency due to Adenosine Deaminase deficiency) that obtained the EMA marketing authorisation in 2016. Following a successful collaboration process, based on the agreement signed with GSK in March 2015, and thanks to the AIFA authorisation of the manufacturing facility at DIBIT (Department of Biotechnologies at the San Raffaele Hospital) and the price & reimbursement guaranteed by AIFA to GSK, MolMed manufactures Strimvelis<sup>™</sup> for the market.

In fact, MolMed has had the status of "Pharmaceutical Company" (Officina farmaceutica) since 2003 for its GMP facility located at DIBIT and carries out all activities in compliance with the guidelines on best practices for the production of genetically modified patient-specific cells and of active pharmaceutical ingredients. Thanks to the additional authorisation received from AIFA on December 1st, 2015, MolMed is the only Pharmaceutical Company authorised to manufacture gene therapies for the market.

In 2013, MolMed started a major project aimed at expanding its manufacturing capacity, which led to the construction of a second manufacturing facility at the Open Zone science park in the Municipality of Bresso (Milan). In July 2017, the AIFA granted this new facility the status of "Pharmaceutical Company" for the manufacturing of gene therapy experimental drugs. On completion of the AIFA authorisation process for other areas of GMP Manufacturing, MolMed will have trebled its production capacity, adding the rooms and areas built in Bresso to those already operating at San Raffaele Hospital.

MolMed is a public company listed since March 2008, on the Mercato Telematico Azionario (MTA - screen-based equity market) managed by Borsa Italiana (Ticker Reuters: MLMD.MI).



## 2. Report on operations

## 2.1 Summary of main activities in the first nine months of 2018

#### Zalmoxis® (TK)

Following the obtainment, in December 2017, of the price and reimbursement from AIFA in Italy, on February 14th, 2018, the Company announced the publication, in Official Journal of the Italian Republic, of Determination no. 139/2018 of January 29th, 2018, regarding the system of reimbursement and price of Zalmoxis®, indicated as an extra treatment in the haploidentical transplantation of hematopoietic stem cells (HSCT) in adult patients with high-risk hematologic neoplasms. The Determination took effect on March 1st, fifteen days after the publication. The supply of Zalmoxis® based on the agreement with AIFA makes provision for an ex factory reimbursement price (excluding VAT) of Euro 149,000 per infusion, before legal reductions, including a flat reimbursement per patient and a revenue protection clause for the first 24 months.

On January 16th, 2018, the company also announced that Dompé farmaceutici S.p.A. ("Dompé"), licence holder of Zalmoxis® for Europe, filed the AMNOG dossier (Gesetz zur Neuordnung des Arzneimittelmarkt) at the Joint Federal Institution (Gemeinsamer-Bundesausschuss G-BA) relating to the product. Following this filing and the simultaneous publication of the sale price of LauerTaxe®, as of January 15th Zalmoxis® can be prescribed and reimbursed in Germany at a proposed sale price of Euro 163,900 per infusion (ex-factory price excluding VAT). The approved treatment is 1 or more infusions, until immune reconstitution is achieved, with a maximum of 4 allowed. These sale conditions are valid for 12 months, during which, in application of the AMNOG model, and as indicated on the G-BA site, an evaluation will be conducted on the additional benefit of the new therapy in patients in order to negotiate the final price on this basis.

Contrary to the provisions, sales have still not commenced either in Italy or Germany due to the difficulties encountered in the initial phases of product marketing. This situation is currently being carefully examined by MolMed in order to evaluate the appropriate actions to be taken, also in relation to certain disagreements that have arisen regarding to fulfilment of the obligations of the marketing contract stipulated with Dompé, whose outcomes are not foreseeable at present.

In February, Dompé also exercised the option for the development and marketing of Zalmoxis® in Switzerland, Turkey and Australia set out in the strategic agreement for the marketing and supply of MolMed's proprietary therapy signed with the Company. Exercising of the option allows Dompé to launch the activities involving access to the market in the listed areas, including the activities targeted at obtaining the marketing authorisation and obtainment of the price and reimbursement from the reference regulatory authorities, therefore expanding the potential reference market for Zalmoxis®.

MolMed is proceeding with Phase III studies. In particular, the Phase III study is targeted at confirming the safety and effectiveness of Zalmoxis® in combination with haploidentical transplantation, in terms of disease-free survival and overall survival, versus control subjects undergoing haploidentical transplantation only. As regards the US market, the Company is working with the American transplantation community and the reference American scientific company to identify the most suitable strategy for obtaining accelerated access from the FDA.

In May the inspection visit at the Olgettina facility by TFDA (the Regulatory Agency of Taiwan) was also passed successfully, in collaboration with AIFA (joint inspection), targeted at the production of Zalmoxis® for its future marketing in Taiwan.



#### CAR CD44v6

With regards to the CAR CD44v6 project, based on the promising pre-clinical data collected in 2016 and 2017 and the grant obtained from the European Commission for the EURE-CART project, MolMed is continuing to invest in research and development activities, in order to increase the value of the special and unique characteristics of the product, demonstrating its effectiveness and safety and accurately defining its therapeutic positioning, thanks to the start of the first clinical human trial, planned for the end of 2018.

In particular, the first half saw the launch and the conclusion of the phases of development of the processes for the GMP manufacturing of the coding retroviral vector for CAR CD44v6 and CAR T cells. At the same time, experiments commenced and continued involving the transduction on T cells from patients affected by multiple myeloma in order to optimise the process that will be applied during the clinical trial.

At pre-clinical level, effectiveness and safety experiments were conducted, to be presented to the regulatory authorities together with the results of the bio-distribution study commenced on March 20th and completed after around 85 days of observation.

The final version of the clinical protocol was finally drafted, which was shared and validated with members of the EURE-CART Consortium, alongside the Steering Committee on June 28th. At the end of May, Nature Medicine, one of the most prestigious magazines in the international scientific committee, also published additional data relating to the safety profile of CAR-CD44v6, which emerged from a study conducted by researchers at the IRCCS San Raffaele Hospital of Milan on the safety of immunotherapy based on CAR-T cells in the treatment of tumours, highlighting their scope and potential repercussions in making CAR-T lymphocytes therapy much safer and manageable.

The study, which used CAR-Ts, including CAR-T CD44v6 of MolMed and CAR-T CD19 (already approved by the FDA), actually demonstrated the effectiveness of a strategy for controlling the main side effects observed up until now in these types of therapies, i.e. cytokine release syndrome (CRS) and neurotoxicity, which requires the administration of anakinra, a drug now marketed for the prevention and treatment of arthritis.

#### *New products (CAR pipeline)*

In the second quarter, MolMed strengthened new strategic agreements to expand and construct a solid CAR pipeline of original products, both autologous and allogenic, capable of fighting liquid and solid tumours. In particular, on May 31st, MolMed signed a binding term sheet with the Dutch biotech firm Glycostem for the development and production of CAR-NK allogenic therapies, focused on the clinical development of off-the-shelf allogenic cell immunotherapies based on NK (Natural Killer) cells. The agreement will allow MolMed to expand its oncological pipeline by entering the promising field of allogenic therapies. The agreement is expected to be finalised by September 30th, 2018, subject to the positive outcome of the due diligence conducted by MolMed. Based on the contract, Glycostem and MolMed will collaborate exclusively in the development and production of genetically modified NK cells to recognise three different tumour antigens: Glycostem will be responsible for GMP production and the release of the finished product and MolMed will have the exclusive rights to use the end product, after payment of the associated upfront fees, milestones and royalties.

On June 28th, MolMed announced that it had signed a 3-year Master Agreement with AbCheck s.r.o., a Czech company focused on the research and optimisation of high-quality antibodies for the development of innovative CARs targeted at new tumour antigens, with both liquid and solid tumours as the therapeutic target. Based on the agreement, AbCheck will use its proprietary platform for the research, selection, optimisation and



production of different human single-chain variable fragments (scFvs) capable of specifically recognising each potential target chosen by MolMed. The ScFvs are fragments of the CAR that, by recognising and binding with the tumour antigens, give said CAR unique qualities.

The new scFvs optimised and created by AbCheck, will allow MolMed to expand its pipeline both in relation to the platform of autologous CAR-T, and as regards the future creation of allogenic CAR-NK.

#### NGR-hTNF

In the second quarter of 2018, as confirmation of the clinical effectiveness of NGR-hTNF, the complete results of the phase III study in mesothelioma were published in a prestigious oncological journal - *The Lancet Oncology* - and the preliminary data of a phase II study in patients with primary brain lymphoma, were presented at the annual convention of the American Society of Clinical Oncology (ASCO). The results of this study highlighted the ability of NGR-hTNF to permeabilise the vessels that feed the tumour mass and increase the effectiveness of the combined chemotherapy administered in these patients resistant or refractory to the standard therapies. Thanks to the excellent effectiveness and tolerability results the therapy demonstrated in clinical trials on more than 1,000 patients, the Company confirms its strategy to search for potential partners for the clinical and industrial development of the product, reserving the right to go ahead with new applications for marketing authorisations in the future.

#### Development and GMP production

Development and production activities continued in the first half of 2018, which MolMed is managing on behalf of third parties, as part of the pathologies forming the object of the partnerships and collaborations in place with GSK, Orchard Therapeutics, Telethon/TIGET, Genenta, Rocket Pharmaceutical, Cellectis and Boston Children's Hospital.

The company is also continuing to look for new partners and customers and to carry out feasibility studies with the aim of further increasing the number of collaborations, both as regards the production of viral vectors and genetically modified cells.

In particular, on April 12th, MolMed announced the start of a collaboration with Orchard Therapeutics, a UK biotech company, in the gene therapy for rare diseases sector, deriving from the latter's acquisition of the GSK portfolio of therapies for rare diseases, with the objective of reinforcing its position of global leader in gene therapies for rare diseases.

Orchard Therapeutics' replacement of GSK in the contract ensures the continuity of the development of programmes and of patient access to all the therapies developed previously and produced for GSK: Strimvelis, the first ex-vivo autologous gene therapy for the treatment of children suffering from ADA-SCID immunodeficiency, approved by EMA in 2016, the two advanced clinical experimental programmes for registration purposes relating to metachromatic leukodystrophy (MLD), and Wiskott Aldrich Syndrome (WAS), and a programme at the clinical development phase on beta thalassemia. On June 22nd, Orchard Therapeutics extended the agreement to two additional therapeutic indications, entrusting to MolMed some activities connected with the production of ex-vivo autologous gene therapies for two additional indications: Mucopolysaccharidosis type IIIA ("MPSIIIA") and Mucopolysaccharidosis type IIIB ("MPS-IIIB").

On May 4th, MolMed also signed a 5-year Master Service Agreement, together with the first associated Project Agreement, with the Boston Children's Hospital, for the production of lentiviral vectors to be used in clinical applications for rare diseases. The Boston Children's Hospital is one of the most important paediatric institutions in the world in the treatment of complex pathologies, which has strong affiliations including the one



with the Harvard Medical School.

In the first half of 2018, as a result of various submissions of authorisation packages relating to the GMP Manufacturing area, which took place between the end of 2017 and the start of 2018, the authorisation was granted by the competent authorities of the GMP Manufacturing area relating to Stream 1 (around 600 sq. metres) of the new Bresso Facility for the production of viral vectors and genetically modified cells relating to therapies for clinical research purposes.

## 2.2 Other events occurred during the first six months of 2018

On June 29th, the Executive Officer responsible for preparing company financial reports resigned, effective from September 30th, 2018, to take up a new career. In order to ensure business continuity and a smooth transition, Mr. Andrea Quaglino will retain his roles and responsibilities as Chief Financial Officer and Executive Officer responsible for preparing the company financial reports of MolMed S.p.A., until his successor is appointed, for which the selection process has already started.

# 3. Other information

## Grants and other financial support

In its particular area of activity, MolMed takes advantage of the benefits resulting from European, national or regional subsidised loans intended to support and encourage innovation.

From January 2017, MolMed has been a strategic partner and coordinator of EURE-CART (EURopean Endeavour for Chimeric Antigen Receptor Therapies), a project co-financed by the European Union as part of the funds intended for new therapies for chronic diseases (including tumors) of the research and innovation framework programme "Horizon 2020". The role of project coordinator and Sponsor of Phases I/II of the Project was assigned to MolMed given that, as recognised by the competent Commission «MolMed Spa is uniquely endowed in the EU with the know-how and experience necessary to meet this ambitious objective, as demonstrated by its unparalleled track record»

It was assigned a grant of Euro 5,903 thousand in December 2016; MolMed holds a share of the total amount of Euro 1,995 thousand, which will cover a large part of the R&D costs for a period of 48 months. In December 2016, the first portion of the financing (pre-financing) was disbursed for an amount of roughly 50% of the grant awarded.

# 4. Comments on performance and financial highlights

(amounts in Euro thousand)	3 <sup>rd</sup> quarter 2018	3 <sup>rd</sup> quarter 2017	01.01.2018 - 30.09.2018	01.01.2017 - 30.09.2017	Vari	ation
			(a)	(b)	(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%)



## 4.1 First nine months of 2018

#### Operating revenues

Operating revenues amounted to 20,012 thousand Euro in the first nine months of 2018, compared to 15,641 thousand Euro in the prior-year period. They are broken down as follows:

- Sales totaling 19,436 thousand Euro, increasing by 30.1% compared to the prior-year period, and consisting of:
  - 16,213 thousand Euro revenues arising from development and production activities on behalf of third parties (including 679 thousand Euro for milestones) and increasing by 30.4% compared to prior-year period (12,436 thousand Euro);
  - 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, of witch 2,000 thousand Euro not yet collected, and (ii) from the sale of the product under AIFA funding scheme for a total amount of Euro 223 thousands.
    - On November 12<sup>th</sup>, 2018, as reported below in the paragraph *6. Significant events after the reporting period*, the Company and Dompé mutually terminated the license and distribution agreement for Zalmoxis<sup>®</sup>. 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.
- Other income of 576 thousand Euro, compared to 705 thousand Euro in the prior-year period, mainly relating to research and development grants the Company received based on its participation in publicsector subsidized projects.

#### **Operating costs**

Operating costs amounted to 24,640 thousand Euro in the first nine months of 2018, increasing by 1,091 thousand Euro (+4.6%) compared to the prior-year period (23,549 thousand Euro).

This net change is primarily due to:

- an increase in costs for the purchase of raw materials and consumables, mainly due to growing research and development activities and to the development of products in the pipeline;
- a change in personnel costs due to lower costs incurred after cancellation of the roles of General Manager and Head of Strategic Affairs, which were offset by the recognition in 3Q of a one-off compensation to be paid to Mr. Bordignon who left the Company on September 24, 2018 and pursuant to the 24-month non-competition agreement signed on January 26, 2017 (for further information, reference should be made to the **Notes** of this Report);
- an increase in the depreciation of property, plant and equipment after the beginning of the depreciation period for the assets purchased in 2017 and relating to the new facility in Bresso.



#### **Operating result**

Operating result for the first nine months of 2018 improved by 41.5% compared to the prior-year period. The operating loss amounted to 4,628 thousand Euro, down by 3,280 thousand Euro from the 7,908 thousand Euro loss recognized in the first nine months of 2017. This improvement is mainly attributable to the more-than-proportional increase in operating revenues in the first nine months of 2018 compared to the increase in operating costs (+27.9% vs +4.6%).

It should be noted that, based on the Company's operations and the objective characteristics of the trials performed, research and development costs are fully expensed as incurred. MolMed's financials are peculiar to the business model of biotech companies developing new therapeutic products that have not reached a balanced income and financial position yet. At this stage significant costs must be borne, in relation to the testing and development of investigational new drugs, and return is expected in forthcoming years.

#### Net financial income and charges

The Company's financial activities generated a negative result of 245 thousand Euro, deteriorating by 52 thousand Euro compared to the prior-year period. Financial income decreased by 149 thousand Euro (-79.3%), mainly due to a reduction in unrealized foreign exchange profits. Financial charges decreased by 97 thousand Euro (-25.5%) mainly due to 2018 fees on Standby Equity Facility (SEF) installments compared to the amounts recognized in the prior-year period (for further details, reference should be made to the **Notes** of this Report).

#### Profit (loss) for the period

As a result of the above, the Company recognized a loss of 4,873 thousand Euro in the first nine months of 2018 compared to a loss of 8,102 thousand Euro recognized in the prior-year period, thus achieving a net improvement (+39.9%).

#### 4.2 Third quarter of 2018

Operating revenues amounted to 7,300 thousand Euro in the third quarter of 2018, compared to 6,226 thousand Euro in the third quarter of 2017, thus increasing by 1,074 thousand Euro (or +17.0%). Such revenues are broken down as follows:

- Sales totaling 7,202 thousand Euro, increasing by 20.0% compared to the prior-year period, and consisting of:
  - 6,202 thousand Euro revenues arising from development and production activities on behalf of third parties (including 254 thousand Euro for milestones) and increasing by 3.4% compared to prior-year period (6,001 thousand Euro);
  - 1,000 thousand Euro revenues, not yet collected, relating to Zalmoxis<sup>®</sup>, arising from the product license and distribution agreement entered into between MolMed and Dompé on July 26, 2017.
- Other income of 98 thousand Euro, mainly relating to research and development grants the Company received based on its participation in public-sector subsidized projects.





Operating costs amounted to 9,077 thousand Euro in the third quarter of 2018, increasing by 1,444 thousand Euro (or +18.9%) from the 7,633 thousand Euro recognized in the third quarter of 2017. This change is primarily due to:

- an increase in costs for the purchase of raw materials and consumables to the tune of 189 thousand Euro (+15.5%), mainly due to growing research and development activities on behalf of third parties and to the development of products in the pipeline;
- an increase in costs for services (410 thousand Euro, +14.6%), mainly due to the combined effect of the increase in the facility management and maintenance costs and in the outsourced production and development costs on the one hand and the decrease in business development costs on the other;
- an increase in personnel costs to the tune of 793 thousand Euro (+27.6%) due to the one-off compensation to be paid to Mr. Bordignon who left the Company on September 24, 2018 and pursuant to the 24-month non-competition agreement signed on January 26, 2017 (for further information, reference should be made to the Notes).

In the third quarter of 2018, the Company's financial activities generated a negative result of 11 thousand Euro, strongly improving compared to the prior-year period, which included the fees paid following subscription for shares, as provided for by the SEF agreement entered into with Société Générale, in August and September 2017 (two installments).

The Company recognized a loss of 1,788 thousand Euro for the third quarter of 2018, slightly deteriorating (-13.3%) compared to the loss of 1,579 thousand Euro recognized in the same period of 2017. The increase in the loss for the period is mainly due to the one-off compensation in favor of Mr. Bordignon. If the Company had not recognized this extraordinary item, the loss for the period would have amounted to 833 thousand Euro—a strong improvement compared to the prior-year period.



# 5. Performance and financial highlights

## *5.1 Financial statements*

### *5.1.1 Income statement*

(amounts in Euro thousand)	Note	3 <sup>rd</sup> quarter 2018	3 <sup>rd</sup> quarter 2017	01.01.2018- 30.09.2018	01.01.2017- 30.09.2017	Variation (a-b)	Variation %
Revenues		7,202	6,001	19,436	14,936	4,500	30.1%
Other revenue		98	225	576	705	(129)	(18.3%)
Total operating revenues	1	7,300	6,226	20,012	15,641	4,371	27.9%
Purchases of raw materials and consumables	2	(1,409)	(1,220)	(4,261)	(3,644)	(617)	16.9%
Costs for services	3	(3,209)	(2,799)	(8,173)	(8,124)	(49)	0.6%
Costs for use of third-party assets	4	(365)	(365)	(1,126)	(1,094)	(32)	2.9%
Personnel costs	5	(3,671)	(2,878)	(9,887)	(9,592)	(295)	3.1%
Other operating costs	6	(32)	(31)	(63)	(110)	47	(42.7%)
Amortization and depreciation	7	(391)	(340)	(1,130)	(985)	(145)	14.7%
Total 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%)
Financial income		13	151	39	188	(149)	(79.3%)
Financial charges		(24)	(323)	(284)	(381)	97	(25.5%)
Net financial income (charges)	8	(11)	(172)	(245)	(193)	(52)	26.9%
Pre-tax result		(1,788)	(1,579)	(4,873)	(8,102)	3,229	(39.9%)
Income taxes		-	-	-	-	-	-
Profit (loss) for the period	-	(1,788)	(1,579)	(4,873)	(8,102)	3,229	(39.9%)

# 5.1.2 Statement of comprehensive income

(amounts in Euro thousand)	3 <sup>rd</sup> quarter 2018	3 <sup>rd</sup> quarter 2017	01.01.2018- 30.09.2018	01.01.2017- 30.09.2017	Variation (a-b)	Variation %
Profit (loss) for the period	(1,788)	(1,579)	(4,873)	(8,102)	3,229	(39.9%)
Other comprehensive income (not subsequently reclassified to the income statement)						
Profit (loss) actuarial	1	(1)	1	- 1	2	(200.0%)
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)	1	(1)	1	- 1	2	(200.0%)
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	(1,787)	(1,580)	(4,872)	(8,103)	3,231	(39.9%)



## 5.1.3 Net financial position

(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

#### 5.2 Notes

#### Accounting standards and basis of measurement

MolMed's Interim Management Report at September 30, 2018 has been prepared in compliance with the International Financial Reporting Standards ("IFRSs") issued by the International Accounting Standards Board ("IASB") and endorsed by the European Union, as well as pursuant to Legislative Decree 58/1998, as subsequently amended. This Interim Management Report has also been prepared in compliance with the Consob Issuers' Regulations and subsequent communications. The accounting standards applied are the same as those used to prepare the annual financial statements at December 31, 2017.

Income figures concern the quarter ended September 30, 2018 as well as the first nine months of the annual period ending December 31, 2018. They are compared with those recognized in the prior-year period. Figures relating to the statement of financial position and the net financial position are compared with those recognized at December 31, 2017.

The amounts indicated in this Interim Management Report are expressed in thousands of Euro, unless otherwise stated. The Euro is the Company's functional currency.

This Interim Management Report has not been audited.

#### Note 1 - Sales

(amounts in Euro thousand)	1.1.2018- 30.09.2018 (a)	1.1.2017- 30.09.2017 (b)	Variation (a-b)	Variation %
Revenues (from activities from third parties)	16,213	12,436	3,777	30.4%
Other income	3,223	2,500	723	28.9%
Total operating revenues	19,436	14,936	4,500	30.1%

Sales totaled 19,436 thousand Euro in the first nine months of 2018, compared to 14,936 thousand Euro in the prior-year period. They are broken down as follows:

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- 16,213 thousand Euro revenues arising from activities on behalf of third parties (including 679 thousand Euro for milestones) and increasing by 30.4% compared to the prior-year period (12,436 thousand Euro);
- 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, of witch 2,000 thousand Euro not yet collected, and (ii) from the sale of the product under AIFA funding scheme for a total amount of Euro 223 thousands.
  On November 12th, 2018, as reported below in the paragraph 6. Significant events after the reporting period, 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.

#### Note 2 – Other income

At September 30, 2018, other income, recognized as part of operating revenues and amounting to 576 thousand Euro (compared to 705 thousand Euro in the first nine months of 2017), mainly consists of research and development grants the Company received based on its participation in public-sector subsidized projects.

#### Note 3 – Purchases of raw materials and consumables

Costs for raw materials and consumables, which largely consist of materials and reagents used in production and development activities, rose from 3,644 thousand Euro at the end of the first nine months of 2017 to 4,261 thousand Euro at the end of the first nine months of 2018. The 617 thousand Euro increase in the aforementioned costs (+16.9%) is mainly due to growing research activities and to the development of products in the pipeline.



#### *Note 4 – Costs for services*

The breakdown of this item at September 30, 2018 and September 30, 2017 is as follows:

(amounts Euro thousand)	1.1.2017- 30.09.2018	1.1.2017- 30.09.2017	Variation	Variation
	(a)	(b)	(a-b)	%
Outsourced development costs	2,270	1,885	385	20.4%
Consultancy and technical fees	509	462	47	10.2%
License and patents consultancy fees	442	464	(22)	(4.7%)
Maintenance	814	648	166	25.6%
Transport and storage of laboratory materials	403	420	(17)	(4.0%)
Utilities	1,070	1,094	(24)	(2.2%)
Directors and statutory auditors' fees	291	314	(23)	(7.3%)
Audit	60	57	3	5.3%
Legal, administrative and managerial fees	482	404	78	19.3%
Listing consultancy fees and other listing costs	97	56	41	73.2%
Supervisory board fees	71	88	(17)	(19.3%)
Communications agency fees	178	885	(707)	(79.9%)
IT assistance and other IT costs	327	249	78	31.3%
Other general and administrative costs	700	559	141	25.2%
Ttravel, staff training and othe personnel costs	459	539	(80)	(14.8%)
Total costs for services	8,173	8,124	49	0.6%

Costs for services slightly increased from 8,124 thousand Euro at September 30, 2017 to 8,173 thousand Euro at September 30, 2018. Almost unchanged compared to the prior-year period (+0.6%), this item is broken down as follows:

- outsourced development costs, increasing from 1,885 thousand Euro at September 30, 2017 to 2,270 thousand Euro at September 30, 2018, due to an extended pipeline;
- maintenance costs, increasing from 648 thousand Euro in the first nine months of 2017 to 814 thousand Euro in the first nine months of 2018, after revamping of both facilities;
- business development costs, decreasing from 885 thousand Euro in the first nine months of 2017 to 178 thousand Euro in the first nine months of 2018, mainly due to pricing and reimbursement advisory services in relation to Zalmoxis<sup>®</sup> ended in 2017;
- general and administrative costs, rising by 141 thousand Euro (+25.2%) from 559 thousand Euro at September 30, 2017 to 700 thousand Euro at September 30, 2018, due to insurance adjustments recognized in the period.



#### *Note 5 – Costs for use of third-party assets*

Costs for use of third-party assets, amounting to 1,126 thousand Euro in the first nine months of 2018, are broadly in line with those recognized in the prior-year period (1,094 thousand Euro, +2.9%).

#### *Note 6 – Personnel costs*

Personnel costs slightly increased compared to the prior-year period (+3.1%), from 9,592 thousand Euro for the first nine months of 2017 to 9,887 thousand Euro for the first nine months of 2018. The change in these costs is mainly due to the saving arising from the cancellation of the roles of General Manager and Head of Strategic Affairs in 2017, offset by the recognition in 3Q of a one-off gross compensation of 800 thousand Euro in favor of Mr. Bordignon who left the Company and resigned from his office as Chairman of the Board of Directors on September 24, 2018.

The one-off amount has to be paid based on the Board of Director's resolution dated April 18, 2016. On that occasion, the Board resolved to pay Mr. Bordignon 800 thousand Euro, gross of taxes, as compensation for the 24-month non-competition obligation after the end of his term of office for whatever reason. Such amount has to be paid in a lump sum at the end of his term of office and should it not be renewed. A penalty shall apply if the obligation is not fulfilled.

It should be noted that Mr. Bordignon will not receive any further compensation relating to company bonuses for 2018. Furthermore, the Company Stock Options he held should be considered as expired.

The remuneration component arising from stock option plans refer to plans with Company shares as underlying securities and is represented by the notional cost recognized as a separate component of equity (see **Note 12**).

At September 30, 2018, the actual number of employees was 202, while in the first nine months of 2018, the average number of employees was 196 (195 in the first half of 2018 and 185 in 2017).

#### *Note 7 – Amortization, depreciation and impairment*

Amortization, depreciation and impairment totaled 1,130 thousand Euro in the first nine months of 2018. They increased by 145 thousand Euro compared to the prior-year period (985 thousand Euro) following the beginning of the amortization/depreciation period for the assets purchased in 2017 and relating to the new facility in Bresso. Investments in the period of 999 thousand Euro were primarily made to bring new production facilities online following the acquisition of new customers; they were also mainly incurred for routine replacement of laboratory equipment, where necessary, for the purchase of new equipment used in the production process, as well as for maintenance and improvement work on the existing GMP facility.

#### *Note 8 – Financial income and charges*

The Company's financial activities generated a negative result of 245 thousand Euro, deteriorating by 52 thousand Euro compared to the prior-year period.

Financial income of 39 thousand Euro sharply decreased by 74.9%, due to a reduction in unrealized foreign exchange profits.



Financial charges decreased by 25.5% (-97 thousand Euro), due to lower fees paid in the period in relation to SEF installments.

## *Note 9 – Net financial position*

The net financial position was positive to the tune of 15,757 thousand Euro at September 30, 2018. It only consists of cash and cash equivalents and current financial receivables (available-for-sale corporate bonds), since no financial debt was recognized.

#### *Note 10 - Changes in equity*

The changes in the Company's equity for the first nine months of 2018 are shown in the following table:

(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 January 1st 2018	21,514	58,976	223	396	(13)	- 47,966	(8,497)	24,633
Allocation of prior year result						(8,497)	8,497	
Personnel costs for stock options 2016-2021				89				89
Other variation for stock options 2016-20121				(260)		260		
Capital increase dedicated to SG	305	2,803						3,108
Profit (loss) for the period					1		(4,873)	(4,872)
Balance at September, 30 <sup>th</sup> 2018	21,819	61,779	223	225	(12)	(56,203)	(4,873)	22,958

In compliance with the SEF – Standby Equity Facility agreement entered into with Société Générale on October 6, 2016, subscription for shares resulting from the dedicated capital increase, excluding SG's pre-emption rights, was made in the first half of 2018, on May 25 (fifth and last installment).

After the capital increase, a total number of 6,488,279 shares were issued for an overall amount of 3,108 thousand Euro, of which 305 thousand Euro credited to the capital account and 2,803 thousand Euro to the share premium account.

#### *Note 11 – Transactions with related parties*

The Company has a current and deposit account with Banca Mediolanum S.p.A. Transactions are regulated at arm's length.

#### *Note 12 – Share-based payments*

The following table shows a breakdown of the options granted and held at September 30, 2018:

Name surname and position held		Type of Stock Options assigned	Options held at 31.12.2017	Options expired in the first nine months of 2018	Options exercied in the first nine months of 2018	Options assigned in the first first nine months of 2018	Options held at 30.09.2018	Strike price
	President of Board of							
Claudio Bordignon	Directors	2016-2021 Plan	1,896,528	1,896,528	-	-	-	-
Riccardo Palmisano	CEO	2016-2021 Plan	2,275,834	-	-	-	2,275,834	0.3878
Executives		2016-2021 Plan	4,109,145	-	-	-	4,109,145	0.3878
Managers responsible for unity		2016-2021 Plan	758,610	126,435	-	-	632,175	0.3878
Collaborators		2016-2021 Plan	316,088	-	-	-	316,088	0.3878
		Total	9,356,205	2,022,963	-	-	7,333,242	



It should be noted that the stock options previously held by Mr. Bordignon should be considered as expired starting from the date he resigned from his office as Chairman of the Board of Directors, as previously mentioned in **Note 6**.

Further information on share-based payments are provided in the Notes to the Financial Statements for the year ended December 31, 2017 and in the Notes to the Interim Financial Statements for the period ended June 30, 2018 to which reference should be made.

# 6. Significant events after the reporting period

## 7. 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 quarter in various European countries, and started from Italy where the documentation was submitted to AIFA on October 10<sup>th</sup> 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.



# Right to depart from disclosure requirements in the event of significant transactions

During the Board of Directors' meeting of November 12, 2012, based on the amendments to Articles 70 and 71 of the Issuers' Regulations introduced by Consob resolution 18214 dated May 9, 2012, the Company resolved to depart from the disclosure requirement as described in paragraph 6 of Article 70 and paragraph 1 of Article 71, respectively, disclosing this decision in the financial reports published pursuant to Article 154-ter of the Consolidated Law.

# Statement pursuant to the provisions of Article 154-bis, paragraph 2, of Legislative Decree no. 58/98

In compliance with the provisions of Article 154-bis, part IV, title III, chapter II, section V-bis of Legislative Decree no. 58 of February 24, 1998, the Executive Officer responsible for preparing MolMed's financial reports hereby states that the financial disclosure contained in this document is consistent with the entries in accounting books and record.

Milan, Novembre 12, 2018

[Signed by]

Carlo Incerti
Chairman of the Board of Directors

[Signed by]

Salvatore Calabrese Executive Officer responsible for preparing company financial reports