

The Financial Statement have been translated from those issued in Italy, from the Italian into English language solely for the convenience of international readers



Management Report at September 30th, 2019

FROM GENES TO THERAPY

MOLMED S.p.A.

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Share Capital € 21,819,020.83 fully paid – REA no. 1506630 – Milan Companies Register, Tax and VAT no. 11887610159



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, with a clear and solid industrial project based on research, development and production excellence

...to therapy



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General company information

Registered Office:	Via Olgettina, 58 – 20132 MILAN (MI)
Operating Unit:	Open Zone, Via Meucci, 3 - 20091 Bresso (MI), Italy
Tax Number:	11887610159
VAT Number:	IT 11887610159
Milan Companies Register:	no. 11887610159
REA (economic and administrative index):	1506630
Share Capital:	€ 21,819,020.83, fully paid
Borsa Italiana Ticker Symbol:	MLM
ISIN:	IT0001080248
Reuters Ticker Symbol:	MLMD.MI
Bloomberg Ticker Symbol:	MLM IM
LEI Code:	815600342FDC0C3F6E10
Outstanding shares: (100% ordinary shares with no par value)	463,450,672

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 forward-looking 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

Board of Directors

Chairperson	Carlo Incerti
CEO	Riccardo Palmisano
Directors	Alberto Luigi Carletti
	Laura Iris Ferro, <i>independent</i>
	Sabina Grossi
	Mario Masciocchi, <i>independent</i>
	Alfredo Messina
	Elizabeth Robinson, <i>independent</i>
	Raffaella Ruggiero, <i>independent</i>

The Board of Directors, appointed by the Shareholders' Meeting held on April 30th, 2019, will remain in office until the Shareholders' Meeting convened to approve the Financial Statements at December 31st, 2021. Riccardo Palmisano is the "Director responsible for the internal control and risk management system".

Board of Statutory Auditors

Chairperson	Riccardo Perotta
Statutory Auditors	Flavia Daunia Minutillo
	Michele Milano
Substitute Statutory Auditors	Alessia Bastiani
	Giuliana Maria Converti
	Tommaso Casale

The Board of Statutory Auditors, appointed by the Shareholders' Meeting held on April 30th, 2019, will remain in office until the Shareholders' Meeting convened to approve the Financial Statements at December 31st, 2021.

Control and Risk Management Committee *

Chairperson	Mario Masciocchi, <i>independent</i>
Members	Sabina Grossi
	Elizabeth Robinson, <i>independent</i>

* It also acts as the Committee responsible for transactions with related parties.

Remuneration and Nomination Committee

Chairperson	Raffaella Ruggiero, <i>independent</i>
Members	Laura Iris Ferro, <i>independent</i>
	Sabina Grossi

Scientific Advisory Board**

Chairperson	Claudio Bordignon
Members	Malcolm K. Brenner
	Gianpietro Dotti
	Mohamad Mohty
	Miguel-Angel Perales

Advisory independent body that provides scientific advisory support to the Company's research and development programs. For further detail please refer to www.molmed.com

External Auditors

EY S.p.A.



Management Report at September 30th, 2019

Introduction

The Transparency II Directive (Directive 2013/50/EU) and the relevant national regulation transposing it into Italian law have abolished the requirement to prepare interim management statements, deferring the decision on whether to introduce additional quarterly reporting requirements to Consob (Italy's market regulator). MolMed decided to voluntarily approve the Management Report at September 30th, 2019 consistently with past practice and in line with Italian and international best practices, reserving the right to reconsider this decision.

Key performance highlights

(amounts in Euro thousand)	3 rd quarter 2019	3 rd quarter 2018	Variation	Variation %	1.1.2019- 30.09.2019	1.1.2018- 30.09.2018	Variation	Variation %
Revenues from sales	8,507	7,202	1,305	18%	24,820	19,436	5,384	28%
Revenues for service to third parties	8,507	6,202	2,305	37%	24,820	16,213	8,607	53%
Revenues from Zalmoxis®	-	1,000	(1,000)	(100%)	-	3,223	(3,223)	(100%)
Operating Revenues	8,511	7,300	1,211	17%	24,886	20,012	4,874	24%
Total operating costs net of depr. and amort.	(8,100)	(8,686)	586	(7%)	(24,696)	(23,510)	(1,186)	5%
EBITDA⁽¹⁾	412	(1,386)	1,797	(130%)	190	(3,498)	3,688	(105%)
Amortization and depreciation	(855)	(391)	(464)	119%	(2,532)	(1,130)	(1,402)	124%
EBIT⁽²⁾	(444)	(1,777)	1,333	(75%)	(2,341)	(4,628)	2,286	(49%)
Financial result	(32)	(11)	(21)	189%	(57)	(245)	188	(77%)
Pre-tax result	(475)	(1,788)	1,313	(73%)	(2,398)	(4,873)	2,475	(51%)
Tax	(11)	-	-	100%	(11)	-	(11)	100%
Profit (loss) for the period	(486)	(1,788)	1,313	(73%)	(2,409)	(4,873)	2,464	(51%)

¹ The gross operating margin (EBITDA) represents the difference between net revenues and operating costs before non-monetary costs such as amortization and depreciation of current and non current assets

² EBIT: defined as the difference between revenues and other income and costs related to the consumption of materials, the cost for services, the cost for the use of third-party assets, the cost of personnel and depreciation, amortization and write-downs. Represents the margin realized before financial management and taxes

EBITDA for the first nine months of 2019 present an income of 190 thousand Euro, compared to a loss of 3,498 thousand Euro in the prior-year period, up 3,688 thousand Euro or +105%. The net increase was partly attributable to the adoption of IFRS 16 “Leases” as of January 1st, 2019, which caused the Company to reclassify 1,014 thousand Euro in lease costs and recognize a 944 thousand Euro in depreciation as well as an additional 89 thousand Euro in financial expenses. Excluding the impact of the new accounting standard, EBITDA would still have improved by 2,674 thousand Euro or +76%. This was the result of (i) growing sales revenues from services rendered to third parties, following the increase in revenue from contracts with long-standing customers, and (ii) the curbing of non-recurring costs. As a percentage of sales revenues, operating costs were down from 127% in the first nine months of 2018 to 110% in the first nine months of 2019.

EBIT for the first nine months of 2019 present a loss of 2,341 thousand Euro, compared to a loss of 4,628 thousand Euro in the prior-year period, up 2,286 thousand Euro (or +49%). The change was attributable to the more than proportional increase in sales revenues (+28%) relative to operating costs (+11%) thanks to rising sales revenues from services rendered to third parties and greater profit margins.

Net Result of the first nine months of 2019 present a loss of 2,409 thousand Euro, reduced by more than 50% compared to a loss of 4,873 thousand Euro as of September 30th 2018.



EBITDA for the third quarter of 2019 present an income of 412 thousand Euro, compared to a loss of 1,386 thousand Euro in the prior-year period, up 1,797 thousand Euro (or +130%). This result accounts for the adoption of IFRS 16 as of January 1st, 2019. Excluding the impact of IFRS 16, EBITDA would still have improved by 1,403 thousand Euro or +105%. This was the result of growing sales revenues from services rendered to third parties, following the increase in revenue from contracts with long-standing customers, and the curbing of non-recurring costs. As a percentage of sales revenues, operating costs were down from 126% in the third quarter of 2018 to 105% in the third quarter of 2019.

EBIT for the third quarter of 2019 present a loss of 444 thousand Euro, compared to a loss of 1,777 thousand Euro in the prior-year period, up 1,333 thousand Euro (or +75%). The change was attributable to the more than proportional increase in sales revenues (+18%) as well as a 1% decline in operating costs.

Net Result of the third quarter 2019 present a loss of 486 thousand Euro, in respect of a loss of 1,788 thousand Euro for the same period of previous year.

Net financial position

<i>(amounts in Euro thousand)</i>	September 30, 2019	December, 31 2018
Net financial position - IFRS 16 included	2,590	16,466
IFRS 16 application - current	1,200	-
IFRS 16 application - non current	7,628	-
Net financial position IFRS 16 not included	11,418	16,466

Investments

<i>(amounts in Euro thousands)</i>	01.01.2019- 30.09.2019 (a)	01.01.2018- 30.09.2018 (b)	Variation (a-b)	Variation %
Investments	845	1,384	(539)	(38.9%)



1. A history of excellence in R&D and cell & gene manufacturing

MolMed (“the Company”) is listed on the MTA (*Mercato Telematico Azionario*) managed by Borsa Italiana (Reuters Ticker Symbol: MLMD.MI). It is a biotechnology company focused on research, development, clinical validation and manufacturing of innovative cell and gene therapies for the treatment of tumors and rare diseases.

In the last few years MolMed has relied on distinctive competences in the field of gene and cellular therapies, acquired by working on its products, to develop a business model that has supported R&D activities on proprietary products, a development and production service activity GMP (Good Manufacturing Practices) for third parties. This last business has grown and consolidated in recent years, achieving double-digit revenue growth following the expansion of the customer portfolio, bringing the company close to break-even.

Among the first realities in Europe to boast of GMP-authorized laboratories for gene therapy and ex-vivo cell phones for trade, MolMed has become a solid company both in the CDMO (Contract Development & Manufacturing Organization) area, where it boasts important international partnerships, and in the R&D area for proprietary products, focusing on CAR (Chimeric Antigen Receptor) therapies for the treatment of tumors.

1.1 Proprietary pipeline

Zalmoxis® (TK)

On June 27th, 2019, based on the findings of an interim analysis, which had not been planned and the Company voluntarily conducted as part of a review of the product’s place in therapy involving the first 90 patients participating in the TK008 clinical trial, the Company communicated its decision to suspend the enrollment of new patients because of, even though they were not conclusive and did not reveal any changes in the product’s safety profile, the findings of the interim analysis did not show an advantage of the arm treated with Zalmoxis® compared to the control arm treated with the standard of care with respect to the primary endpoint of the study, i.e. disease free survival.

In fact, the adoption of the so-called Baltimore Protocol by Bone Marrow Transplantation Centers as a standard of care has improved the survival of patients suffering from high-risk blood cancers undergoing haploidentical transplantation, i.e. from a partially compatible donor, thus reducing the advantage brought by the use of Zalmoxis® in a less and less used transplantation procedure, namely the T cell-depletion.

In light of these data, the Company has decided to withdraw for commercial reasons the Conditional Marketing Authorization (CMA) issued by the European Commission in 2016 and not to further invest in a product that the evolution of clinical practices makes it no longer up-to-date with reference to its therapeutic impact.

Pipeline CAR

CAR-T CD44v6

CAR-T CD44v6 is an immuno-gene therapy, potentially effective in certain hematological malignancies and a number of solid tumors. It has demonstrated a hopeful degree of efficacy and safety in experimental animal models. CAR-T CD44v6 is the first CAR that targets the CD44v6 antigen and thanks to the inclusion in the construct of the MolMed proprietary suicide gene has a potentially high safety profile. The product has entered the clinical trial phase and the multicenter phase I / II study in patients with acute myeloid leukemia (AML) and



multiple myeloma (MM) is part of the European project EURE-CART Horizon 2020, of which MolMed is coordinator and sponsors.

The lack of harmonized European authorization procedures for the conduct of clinical studies in gene and cell therapies, the time required for the finalization of clinical trial contracts and the need to accredit and validate laboratories that are responsible for patient screening, have led to a series of delays in the beginning of the enrollment of the clinical trial. To date, the Italian and Czech authorities have approved the start of the clinical trial, while Germany and Spain have expressed a negative opinion.

Currently the study is active in two Italian centers of excellence (Ospedale San Raffaele in Milan, coordinator of the clinical study and Ospedale Pediatrico Bambin Gesù in Rome) where the patient enrollment has started, and consists of two phases: a first phase involving adult patients with AML and MM, aimed at identifying the Maximum Tolerated Dose (MTD) among the dose levels foreseen by the clinical protocol, and a second phase, which will include also pediatric patients, with the primary objective to evaluate the therapeutic activity of CAR-T cells in each pathology in a larger number of patients.

Regarding the intention of the Company to submit a similar application for a clinical trial authorization for CAR-T CD44v6 in relation to solid tumors, only after the publication of the early efficacy and safety findings expected from the first phase of the dose escalation study in patients with liquid tumors, involving 18 to 30 patients with three dose levels (BOIN Adaptive Design). CD44v6 is an original antigen that has never been targeted as part of CAR-T therapies and is expressed by only certain hematological tumors such as myeloma and leukemia, but also several solid tumors—including big killers such as adenocarcinomas of the pancreas, head, and neck, as well as others.

On May 24th, 2019, the European Patent Office (EPO) announced its decision to grant patent EP3194434 titled “Chimeric Antigen Receptors” for an innovative structural component applicable to CAR technology and already used in the proprietary product CAR-T CD44v6. The patent will be valid through 2035, granting market exclusivity in all countries where it will be validated, up to a maximum of 38 countries that are signatories to the European Patent Convention. The Company has filed equivalent patent applications in the United States, Japan, and other major emerging markets.

Autologous CAR T and allogeneic CAR NK

The Company has entered into strategic agreements with the aim of expanding its cancer CAR pipeline, potentially capable of treating liquid and solid tumors with new original targets. The research project involves developing both autologous CAR T and new allogeneic CAR therapies that, unlike the former, use cells from healthy donors to produce therapies for different patients, leading to significant estimated manufacturing cost savings.

In 2019, the Company continued working together with AbCheck and Glycostem under the strategic agreements entered into during 2018. In particular, the agreement signed with the Dutch biotech company Glycostem focuses on the co-development of off-the-shelf allogeneic cell immunotherapies based on natural killer (NK) cells. Based on the agreement, MolMed and Glycostem cooperate in the development and manufacturing of NK cells that are genetically modified to recognize tumor antigens. Glycostem is responsible for GMP manufacturing and the release of the finished product, while MolMed has exclusive rights to use any final product in return for relevant upfront, milestone and royalty payments following achievement of relevant



objectives.

During the year, the Company has also continued to cooperate with AbCheck s.r.o.—a Czech company focusing on the research and optimization of high quality antibodies—to develop innovative autologous CARs for new tumor antigens. According to the agreement, AbCheck will use its proprietary platform for the research, selection, optimization and manufacturing of various human single-chain variable fragments (scFvs) which are capable of specifically recognizing every potential target chosen by MolMed. The scFvs are CAR fragments which confer specificity to the CAR itself by recognizing and binding to tumor antigens. MolMed is currently focused on a specific autologous CAR-T, characterized by originality, freedom to operate from the point of view of the intellectual property and potential on both liquid and solid tumors and on in vitro and in vivo functional screening tests animal aimed at assessing the possible therapeutic efficacy of previously selected CAR-Ts.

In light of the state of progress of early-stage research projects, the management with the support of some members of the Scientific Advisory Board has defined milestones and scientific outcomes necessary for the definition of future investment choices on autologous and allogeneic CARs, whose results are expected in the first quarter of 2020. In particular, attention has focused on assessing the progress of collaborations with third parties, also evaluating the hypothesis of internalization of some processes now conducted outside the Company.

Decision not to confirm a request of financing within the innovation fund of the MiSE

With reference to the request of financing within the innovation fund of the MiSE, submitted by the Company to the authorities in February 2019 and, concerning the financing of MolMed's R&D expenses in the CAR field, in light of the delays in the start of the phase I/II clinical trial in AML and MM and on the enrollment of patients and obtaining safety and efficacy data that will arise from the phase I/II clinical trial in AML and MM, whose outcomes are needed before commencing the clinical trial in solid tumors as well for the commencement of some other projects comprised in the request of financing, the Company evaluated carefully its demand of funding.

Taking into account that main part of these research activities would fall outside the three-year envisaged by the innovation grant, the Company decided not to confirm the funding request, reserving the right to submit again the request at a later stage.

NGRhTNF

In light of the ever increasing focus and specialization of MolMed in the cell & gene area, the upcoming expiration of patent protection and the results of the maintenance study on mesothelioma (NGR019), which confirm the non-superiority compared to the control arm, already observed in patients treated in second line in the same pathology (study NGR015, concluded in 2014), the Company confirms the decision not to continue to invest in the product.

1.2 GMP development and manufacturing activities on behalf of third parties

In recent years, MolMed has continued growing its development and manufacturing activities on behalf of third parties in the cell and gene therapy field, leveraging the experience acquired by working on its own products. Today, it provides both vectors and genetically engineered cells to international customers for clinical trial and commercial purposes.

Thanks to its recognized and growing leadership in this field, MolMed has entered into several agreements



with major players, expanding its customer base from two to seven over the last 4 years. MolMed's customers are leading international players, including universities and non-profit entities, such as the Telethon Foundation and the Boston Children's Hospital, as well as major research companies such as GlaxoSmithKline (NYSE: GSK), Orchard Therapeutics (Nasdaq: ORTX), Rocket Pharma (Nasdaq: RCKT), Cellestis (Nasdaq: CLLS) and Genenta Science, which are provided with development, manufacturing and technology transfer services for clinical application of gene therapies based on cell transduction with viral vectors.

In order to support these activities, the Company has also been developing an important project aimed at expanding its production capacity through the completion of a second facility in the Open Zone scientific park in Bresso (Milan). In July 2017, AIFA (*Agenzia Italiana del Farmaco* – Italian Medicines Agency) granted this new facility the status of "Qualified Manufacturing Site" for the manufacturing of investigational gene therapies. After various authorization packages relating to the GMP manufacturing area of the Bresso site were submitted, authorization was granted in 2018 by the relevant authorities relating to the GMP manufacturing area with reference to Stream 1 of the new facility. When the expansion of Stream 2 of the new facility and the relevant AIFA authorization processes for all GMP manufacturing areas are complete, MolMed's production capacity will be tripled, considering both the spaces of the new manufacturing site and those already operational at the San Raffaele Hospital.

On March 7th, 2019, the Company renewed and extended its partnership agreement in the field of oncology, signed in March 2016 with Genenta Science, a biotechnology company that has now begun the experimental clinically developing of a new immunotherapy approach based on the modification of autologous hematopoietic stem cells.

On March 13th, 2019, the Company renewed and extended to three new therapeutic indications the activities related to the manufacturing of lentiviral vectors within the framework of the partnership started in February 2017 with Rocket Pharmaceuticals Ltd (Nasdaq: RCKT), a US company specialized in the development of innovative therapies for the treatment of rare genetic diseases.



2. Performance and financial highlights

Accounting standards and basis of measurement

MolMed's Management Report for the period ended September 30th, 2019 has been prepared in accordance 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 Italian Legislative Decree 58/1998, as subsequently amended. This Management Report has also been prepared in compliance with the Consob Issuers' Regulations no. 11917/98 and subsequent communications.

On January 1st, 2019, the standard IFRS 16 became effective. The new standard provides a new definition of lease and applies a control model (right of use) to distinguish between a lease and a service contract based on the following: identification of the asset, the right to substitute it, the right to obtain substantially all of the economic benefits from the use of the identified asset and the right to direct the use of the underlying asset. The adoption of the new accounting standard resulted in a different accounting for leases, recognizing a "right-of-use asset" and the relevant lease liability in the statement of financial position; meanwhile, in the income statement, lease expenses have been replaced by the depreciation of the right-of-use asset and the borrowing costs relevant to the period.

The right-of-use asset is recognized at cost, which is measured at the commencement of the lease term and includes: the amount of the initial measurement of the lease liability, any lease payments made before the commencement date, less any lease incentives received, any initial direct costs incurred by the lessee, and an estimate of the costs to be incurred in dismantling the asset and restoring the site on which it was located, where applicable. After initial recognition, the right-of-use asset is measured at cost.

The liability is measured at the commencement of the lease term and corresponds to the present value of the overall net payments to be made. After initial recognition, the lease liability is adjusted, without accounting for cases where specific reasons require remeasuring the liability, for interest and the lease payments made.

The adoption of this new accounting standard caused significant changes in the net financial position following the inclusion of the leased premises under fixed assets and of the lease payments payable over the lease term under current and non-current financial payables.

Except for the above, the accounting standards applied are the same as those used to prepare the Financial Statements at December 31st, 2018.

Income figures concern the quarter ended September 30th, 2019 as well as the first nine months of the period ending December 31st, 2019. 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 31st, 2018.

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

This Management Report has not been audited.



2.1 Financial statements

2.1.1 Income statement – first nine months of 2019

<i>(amounts in Euro thousand)</i>					
	Note	1.1.2019- 30.09.2019 (a)	1.1.2018- 30.09.2018 (b)	Variation (a-b)	%
Revenues	1	24,820	19,436	5,384	28%
Other revenue	2	66	576	(510)	(89%)
Total operating revenues		24,886	20,012	4,874	24%
Purchases of raw materials and consumables	3	(5,418)	(4,261)	(1,157)	27%
Costs for services	4	(8,983)	(8,173)	(810)	10%
Costs for use of third-party assets	5	(94)	(1,126)	1,032	(92%)
Personnel costs	6	(10,081)	(9,887)	(194)	2%
Other operating costs		(120)	(63)	(57)	90%
Amortization and depreciation	7	(2,532)	(1,130)	(1,402)	124%
Total operating costs		(27,228)	(24,640)	(2,588)	11%
Operating result		(2,341)	(4,628)	2,286	(49%)
Financial income		70	39	31	80%
Financial charges		(127)	(284)	157	(55%)
Net financial income (charges)	8	(57)	(245)	188	(77%)
Pre-tax result		(2,398)	(4,873)	2,475	(51%)
Income taxes	9	(11)	-	(11)	100%
Profit (loss) for the period	10	(2,409)	(4,873)	2,464	(51%)

2.1.2 Statement of comprehensive income – first nine months of 2019

<i>(amounts Euro thousand)</i>				
	1.1.2019- 30.09.2019 (a)	1.1.2018- 30.09.2018 (b)	Variation (a-b)	%
Profit (loss) for the period	(2,409)	(4,873)	2,463	(51%)
Other comprehensive income (not subsequently reclassified to the income statement)				
Profit (loss) actuarial	-	1	(1)	(100%)
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)	-	1	(1)	(100%)
Other comprehensive income, net of taxes (subsequently reclassified to the income statement)	-	-	-	-
Total comprehensive income (loss) for the period	(2,409)	(4,872)	2,462	(51%)



2.1.3 Net financial position at September 30th, 2019

<i>(amounts Euro thousand)</i>	September 30, 2019	December 31, 2018
Cash on hand	7	8
Other cash	10,402	15,499
Cash equivalents	-	-
A. Total cash and cash equivalents	10,409	15,507
B. Current financial receivables and other financial assets	1,009	959
Finance lease payables	(1,200)	-
Current financial Debts	-	-
C. Current financial debt	(1,200)	-
D. Net current financial position (A+B+C)	10,218	16,466
Finance lease payables	(7,628)	-
Non current financial Debts	-	-
E. Non-current financial debt	(7,628)	-
F. Net financial position (D+E)	2,590	16,466
G. IFRS16 effects - current	1,200	-
H. IFRS16 effects - non current	7,628	-
I. Net financial position - NO IFRS 16 effects	11,418	16,466

The net financial position includes cash and cash equivalents, current financial receivables consisting of corporate bonds, and current and non-current liabilities arising from the recognition of finance leases pursuant to IFRS 16. The adoption of the new IFRS 16 generated a deterioration in the net financial position. Net of the effects arising from the adoption of the above-mentioned standard, the net financial position would have amounted to 11,418 thousand at September 30th, 2019, compared to 16,466 thousand Euro at December 31st, 2018.

Note 1 – Sales revenues

<i>(amounts Euro thousand)</i>	1.1.2019- 30.09.2019	1.1.2018- 30.09.2018	Variation	%
	(a)	(b)	(a-b)	
Revenues from development and manufacturing activities	24,820	16,213	8,607	53%
Revenues from Zalmoxis [®]	-	3,223	(3,223)	100%
Total operating revenues	24,820	19,436	5,384	28%

In the first nine months of 2019, operating revenues amounted to 24,820 thousand Euro, based on recognition at a point in time, increasing by 5,384 thousand Euro or 28% when compared to the prior-year period. Such increase is attributable to the expansion of the customer base and to the growing volume of services rendered to loyal customers, that generated an increase of 8,607 thousand Euro or +53% in revenues from development and manufacturing activities to third parties, from 16,213 thousand Euro at September 30th, 2018 to 24,820 thousand Euro at September 30th, 2019. Such change was partially offset by the shortfall in revenues from Zalmoxis[®] following the termination of the licensing and distribution agreement with Dompé Farmaceutici



S.p.A. which had contributed 3,223 thousand Euro in the prior-year period—of which 3,000 thousand Euro as deferred contribution and 223 thousand Euro thanks to the sale of the product under AIFA Fund' s rules.

Operating revenues in the first nine months of 2019 are broken down as follows: 4.4% in Italy (compared to 5.2% in the first nine months of 2018), 85.6% in EU countries (compared to 80.5% in the first nine months of 2018) and 9.9% in non-EU countries (compared to 14.3% in the first nine months of 2018).

Note 2 – Other income

In the first nine months of 2019, other income, recognized as part of operating revenues, amounted to 66 thousand Euro compared to 576 thousand Euro in the first nine months of 2018. This item 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

This item is broken down as follows:

<i>(amounts Euro thousand)</i>	1.1.2019- 30.09.2019	1.1.2018- 30.09.2018	Variation	%
	(a)	(b)	(a-b)	
Processing materials	1,578	1,404	174	12%
Reagents	2,871	2,214	657	30%
General laboratory materials	969	643	326	51%
Total purchases of raw materials and consumables	5,418	4,261	1,157	27%

Costs for raw materials and consumables, which consist of materials and reagents used in manufacturing and development activities, rose from 4,261 thousand Euro in the first nine months of 2018 to 5,418 thousand Euro in the first nine months of 2019. The 1,157 thousand Euro or +27% change is mainly due to growing purchases and consumption following the increase in revenues from services and manufacturing activities to third parties.



Note 4 – Costs for services

This item is broken down as follows:

<i>(amounts Euro thousand)</i>	1.1.2019- 30.09.2019	1.1.2018- 30.09.2018	Variation	%
	(a)	(b)	(a-b)	
Outsourced development costs	2,911	2,270	641	28%
Consultancy and technical fees	735	509	226	44%
License and patents consultancy fees	341	442	(101)	(23%)
Maintenance	816	814	2	0%
Transport and storage of laboratory materials	397	403	(6)	(2%)
Utilities	1,124	1,070	54	5%
Directors and statutory auditors' fees	291	291	(0)	(0%)
Audit	60	60	(0)	(1%)
Legal, administrative and managerial fees	524	482	42	9%
Listing consultancy fees and other listing costs	56	97	(41)	(42%)
Supervisory board fees	99	71	28	40%
Communications agency fees	144	178	(34)	(19%)
IT assistance and other IT costs	384	327	57	17%
Other general and administrative costs	613	700	(87)	(12%)
Travel, staff training and othe personnel costs	488	459	29	6%
	8,983	8,173	810	10%

Costs for services rose from 8,173 thousand Euro at September 30th, 2018 to 8,983 thousand Euro at September 30th, 2019. The 810 thousand Euro or +10% increase in the period is mainly attributable to the following main changes:

- higher outsourced development costs, increasing by 641 thousand Euro (or +28%, from 2,270 thousand Euro at September 30th, 2018 to 2,911 thousand Euro at September 30th, 2019, following the increase in outsourced research and development activities aimed at developing the proprietary pipeline and services and manufacturing activities on behalf of third parties;
- higher costs for consultancy and technical fees, increasing by 226 thousand Euro or +44%, from 509 thousand Euro at September 30th, 2018 to 735 thousand Euro at September 30th, 2019, following the increase in clinical and regulatory consultancy services requested in relation to Zalmoxis[®] and CART and in technical consultancy services in relation to the facility maintenance;
- lower costs for license fees and patents, decreasing by 101 thousand Euro or -23%, from 442 thousand Euro in the first nine months of 2018 to 341 thousand Euro in the first nine months of 2019, since patents relating to the proprietary product NGR-hTNF were not renewed.

Note 5 – Costs for use of third-party assets

Costs for use of third-party assets decreased from 1,126 thousand Euro at September 30th, 2018 to 94 thousand Euro at September 30th, 2019. The 1,032 thousand Euro or -92% decrease was mainly due to the



adoption of IFRS 16 as of January 1st, 2019, which generated a reclassification of lease expenses of 1,014 thousand Euro and the recognition of depreciation and financial charges.

Note 6 – Personnel costs

<i>(amounts Euro thousand)</i>	1.1.2019- 30.09.2019	1.1.2018- 30.09.2018	Variation	%
	(a)	(b)	(a-b)	
Wages and salaries	7,514	7,531	(17)	(0%)
Social security contributions	2,117	1,863	254	14%
Defined contribution plans	427	384	43	11%
Stock option costs	-	89	(89)	(100%)
Other personnel costs	23	20	3	12%
Total personnel costs	10,081	9,887	194	2%

At September 30th, 2019, personnel costs showed an increase of 194 thousand Euro or +2% compared to the prior-year period, from 9,887 thousand Euro in the first nine months of 2018 to 10,081 thousand Euro in the first nine months of 2019. This change is attributable to the combined effect of the increase in wages and salaries following the hiring of new staff, and the recognition in the third quarter 2018 of the 800 thousand Euro one-off amount, gross of taxes, awarded to Mr. Bordignon after resigning from his role as Chairman of the Board of Directors, as compensation for the 24-month non-competition obligation after the end of his term of office.

Personnel costs include the fixed fees paid to the Chairman and the Chief Executive Officer and their relevant variable bonuses for 2019 connected to the achievement of corporate performance objectives. Such amounts refer to the agreements entered into with the Company by virtue of the tasks they perform within the framework of the powers granted by the Shareholders' Meeting and the Board of Directors on April 30th, 2019 and following the appointment of corporate bodies on the same date.

During the first nine months of 2019, the average number of employees was 216 compared to 196 in the first nine months of 2018. At September 30th, 2019, the actual number of employees was 217.

Note 7 – Amortization, depreciation and write-downs

<i>(amounts Euro thousand)</i>	1.1.2019- 30.09.2019	1.1.2018- 30.09.2018	Variation	%
	(a)	(b)	(a-b)	
Amortization of intangible assets	128	113	15	13%
Depreciation of tangible assets	2,112	1,016	1,095	108%
Write-downs	292	-	292	100%
Total amortization, depreciation & write-downs	2,532	1,130	1,402	124%

This item amounted to 2,532 thousand Euro in the first nine months of 2019, increasing by 1,402 thousand Euro compared to the prior-year period (1,130 thousand Euro). Such change is mainly due to:

- the recognition of depreciation on leased assets for 944 thousand Euro, after the adoption of the new IFRS 16 as of January 1st, 2019;



- the write-downs of tax receivables of 200 thousand Euro, previously recognized as part of non-current tax receivables;
- the write-downs of patents and trademarks relating to TK and Zalmoxis® of 92 thousand Euro after the Conditional Marketing Authorization was withdrawn on October 10th, 2019, as explained in the following paragraphs.

Note 8 – Financial income and expenses

In the first nine months of 2019, the Company's financial activities generated a negative result of 57 thousand Euro, improving by 188 thousand Euro on the prior-year period.

This change is mainly attributable to the decrease in financial expenses. At September 30th, 2018, they included the fees paid in May 2018 following subscription for shares as provided for by the SEF agreement entered into with Société Générale (fifth and last installment of 155 thousand Euro). This item includes interest expense for leases of 89 thousand Euro arising from the adoption of the new IFRS 16.

Note 9 – Income taxes

At September 30th, 2019, an amount of 11 thousand Euro was recognized for IRAP purposes.

Note 10 – Profit (loss) for the period

The Company recognized a loss of 2,409 thousand Euro in the first nine months of 2019 compared to a loss of 4,873 thousand Euro in the prior-year period, thus achieving a net improvement (+51%).



Note 11– Changes in equity

The changes in equity for the first nine months of 2019 are shown in the following table:

<i>(amounts in Euro thousand)</i>	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 December 31, 2018	21,819	61,754	223	(11)	-	(56,067)	(4,123)	23,595
IFRS 16 first adoption								
Balance at January 1st 2019	21,819	61,754	223	(11)	-	(56,067)	(4,123)	23,595
Allocation of prior year result	-	-	-	-	-	(4,123)	4,123	-
Profit (loss) for the period	-	-	-	-	-	-	(2,409)	(2,409)
Balance at September, 30th 2019	21,819	61,754	223	(11)	-	(60,190)	(2,409)	21,186

* MolMed has decided to apply IFRS 16 prospectively from January 2019, therefore without restatement of the comparative data

Note 12 – Transactions with related parties

At September 30th, 2019, no transaction with related parties were recorded.

Note 13 – Share-based payments

At the date of this Report, no stock option plans were available.



2.2 Financial statements – third quarter of 2019

2.2.1 Income statement – third quarter of 2019

<i>(amounts in Euro thousand)</i>					
	Note	3 rd quarter 2019	3 rd quarter 2018	Variation	%
		(a)	(b)	(a-b)	
Revenues	14	8,507	7,202	1,305	18%
Other revenue	15	4	98	(94)	(96%)
Total operating revenues		8,511	7,300	1,211	17%
Purchases of raw materials and consumables	16	(1,713)	(1,409)	(304)	22%
Costs for services	17	(3,117)	(3,209)	92	(3%)
Costs for use of third-party assets	18	(24)	(365)	341	(93%)
Personnel costs	19	(3,211)	(3,671)	460	(13%)
Other operating costs		(34)	(32)	(2)	6%
Amortization and depreciation	20	(855)	(391)	(464)	119%
Total operating costs		(8,955)	(9,077)	122	(1%)
Operating result		(444)	(1,777)	1,333	(75%)
Financial income		19	13	6	47%
Financial charges		(51)	(24)	(27)	112%
Net financial income (charges)	21	(32)	(11)	(21)	189%
Pre-tax result		(476)	(1,788)	1,312	(73%)
Income taxes	22	(11)	-	(11)	100%
Profit (loss) for the period	23	(487)	(1,788)	1,301	(73%)

2.2.2 Statement of comprehensive income – third quarter of 2019

<i>(amounts in Euro thousand)</i>					
		3 rd quarter 2019	3 rd quarter 2018	Variazione	%
		(a)	(b)	(a-b)	
Profit (loss) for the period		(487)	(1,788)	1,300	(73%)
Other comprehensive income (not subsequently reclassified to the income statement)					
Profit (loss) actuarial		-	1	(1)	(100%)
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)		-	1	(1)	(100%)
Other comprehensive income, net of taxes (subsequently reclassified to the income statement)		-	-	-	-
Total comprehensive income (loss) for the period		(487)	(1,787)	1,299	(73%)



Note 14 – Operating revenues

<i>(amounts Euro thousand)</i>	3 rd quarter 2019 (a)	3 rd quarter 2018 (b)	Variation (a-b)	%
Revenues from development and manufacturing activities	8,507	6,202	2,305	37%
Revenues from Zalmoxis [®]	-	1,000	(1,000)	100%
Total operating revenues	8,507	7,202	1,305	18%

Operating revenues amounted to 8,507 thousand Euro in the third quarter of 2019, increasing by 1,305 thousand Euro or +18% when compared to the prior-year period. Such change is mainly due to: (i) the increase in revenues from activities to third parties, growing by 2,305 thousand Euro or +37% from 6,202 thousand Euro at September 30th, 2018 to 8,507 thousand Euro at September 30th, 2019 and (ii) the decrease in revenues relating to Zalmoxis after the termination by mutual consent of the license and distribution agreement entered into with Dompé Farmaceutici S.p.A. which accounted for 1,000 thousand Euro in the third quarter of 2018 as deferred contribution.

Note 15 – Other income

Other income amounted to 4 thousand Euro in the third quarter of 2019 compared to 98 thousand Euro in the third quarter of 2018. This item mainly consists of research and development grants the Company received based on its participation in public-sector subsidized projects.

Note 16 – Purchases of raw materials and consumables

This item is broken down as follows:

<i>(amounts Euro thousand)</i>	3 rd quarter 2019 (a)	3 rd quarter 2018 (b)	Variation (a-b)	%
Processing materials	487	418	69	17%
Reagents	898	706	192	27%
General laboratory materials	328	285	43	15%
Total purchases of raw materials and consumables	1,713	1,409	304	22%

Costs for raw materials and consumables, which consist of materials and reagents used in manufacturing and development activities, rose by 304 thousand Euro or +22% in the third quarter of 2019, compared to the prior-year period, and they amounted to 1,713 thousand Euro. The change recognized in the third quarter reflects the growth trend of purchases and consumption in the first nine months of 2019 associated with the increase in revenues from services and manufacturing activities on behalf of third parties.



Note 17 – Costs for services

This item is broken down as follows:

<i>(amounts Euro thousand)</i>	3rd quarter 2019 (a)	3rd quarter 2018 (b)	Variation (a-b)	%
Outsourced development costs	1,096	921	175	19%
Consultancy and technical fees	219	122	97	80%
License and patents consultancy fees	75	200	(125)	(63%)
Maintenance	280	366	(86)	(23%)
Transport and storage of laboratory materials	121	174	(53)	(30%)
Utilities	562	507	55	11%
Directors and statutory auditors' fees	100	106	(6)	(6%)
Audit	19	17	2	12%
Legal, administrative and managerial fees	287	246	41	17%
Listing consultancy fees and other listing costs	18	55	(37)	(67%)
Supervisory board fees	38	25	13	52%
Communications agency fees	26	40	(14)	(35%)
IT assistance and other IT costs	129	144	(15)	(10%)
Other general and administrative costs	76	160	(84)	(53%)
Travel, staff training and other personnel costs	71	126	(55)	(44%)
Total cost of service	3,117	3,209	(92)	(3%)

Costs for services relating to the third quarter of 2019 amounted to 3,117 thousand Euro; they slightly decreased by 92 thousand Euro or-3% compared to the prior-year period 3,209 thousand Euro. The main changes were as follows:

- higher outsourced development costs, increasing from 921 thousand Euro in the third quarter of 2018 to 1,096 thousand Euro in the third quarter of 2019, due to the increase in services and manufacturing activities on behalf of third parties;
- higher costs for consultancy and technical fees, growing from 122 thousand Euro in the third quarter of 2018 to 219 thousand Euro in the third quarter of 2019, following the increase in clinical and regulatory consultancy services requested in relation to Zalmoxis® and CAR and in technical consultancy services in relation to the facility maintenance;
- lower costs for license fees and patents, decreasing from 200 thousand Euro in the third quarter of 2018 to 75 thousand Euro in the third quarter of 2019, since patents relating to the proprietary product NGR-hTNF were not renewed;
- lower maintenance costs, decreasing from 366 thousand Euro in the third quarter of 2018 to 280 thousand Euro in the third quarter of 2019, due to maintenance work carried out at the facility located in Milan, via Olgettina, in the prior-year period.



Note 18 – Costs for use of third-party assets

Costs for use of third-party assets recognized in the third quarter of 2019 amounted to 24 thousand Euro, decreasing by 341 thousand Euro or -93% compared to the prior-year period. Such change was mainly due to the adoption of new IFRS 16 which generated the reclassification of lease expenses of 319 thousand Euro and the recognition of depreciation and financial expenses.

Note 19 – Personnel costs

(amounts Euro thousand)	3 rd quarter 2019 (a)	3 rd quarter 2018 (b)	Variation (a-b)	%
Wages and salaries	2,372	2,878	(506)	(18%)
Social security contributions	660	618	42	7%
Defined contribution plans	171	154	17	11%
Stock option costs	0	14	(14)	(100%)
Other personnel costs	8	7	1	14%
Total personnel costs	3,211	3,671	(460)	(13%)

Personnel costs in the third quarter of 2019 decreased by 460 thousand Euro or -13% compared to the prior-year period, from 3,671 thousand Euro at September 30th, 2018 to 3,211 thousand Euro at September 30th, 2019. This change is attributable to the combined effect of the increase in wages and salaries following the hiring of new staff, and the recognition in the third quarter 2018 of the 800 thousand Euro one-off amount, gross of taxes, awarded to Mr. Bordignon after resigning from his role as Chairman of the Board of Directors, as compensation for the 24-month non-competition obligation after the end of his term of office.

Personnel costs include the fixed fees paid to the Chairman and the Chief Executive Officer and their relevant variable bonuses for 2019 connected to the achievement of corporate performance objectives. Such amounts refer to the agreements entered into with the Company by virtue of the tasks they perform within the framework of the powers granted by the Shareholders' Meeting and the Board of Directors on April 30th, 2019 and following the appointment of corporate bodies on the same date.

Note 20 – Amortization, depreciation and write-downs

(amounts Euro thousand)	3 rd quarter 2019 (a)	3 rd quarter (b)	Variation (a-b)	%
Amortization of intangible assets	42	39	3	8%
Depreciation of tangible assets	721	352	369	105%
Write-downs	92	-	92	100%
Total amortization, depreciation & write-downs	855	391	464	119%

Amortization, depreciation and write-downs in the third quarter of 2019 increased by 464 thousand Euro or +119% compared to the prior-year period, from 391 thousand Euro in the third quarter of 2018 to 855 thousand Euro in the third quarter of 2019. Such increase is mainly attributable to the recognition of depreciation on leased assets of 319 thousand Euro, after the adoption of the new IFRS 16 as of January 1st, 2019. In the third quarter of 2019, patents and trademarks relating to TK and Zalmoxis® were impaired for 92 thousand Euro

The Financial Statement have been translated from those issued in Italy, from the Italian into English language solely for the convenience of international readers



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after the Conditional Marketing Authorization was withdrawn on October 10th, 2019, as explained in the following paragraphs.



Note 21 – Financial income and expenses

In the third quarter of 2019, the Company's financial activities generated a negative result of 32 thousand Euro, compared to 11 thousand Euro in the prior-year period. Such change was mainly due to the effects arising from the adoption of new IFRS 16 (44 thousand Euro in the third quarter of 2019).

Note 22 – Income taxes

At September 30th, 2019, an amount of 11 thousand Euro was recognized for IRAP purposes.

Note 23 – Profit (loss) for the period

The Company recognized a loss of 487 thousand Euro in the third quarter of 2019 compared to a loss of 1,788 thousand Euro in the prior-year period, thus achieving a significant improvement (+73%).



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

During the Board of Directors' meeting of November 12th, 2012, based on the amendments to Articles 70 and 71 of the Issuers' Regulations introduced by Consob Resolution no. 18214 of May 9th, 2012, the Company resolved to depart from the disclosure requirements as described in paragraph 6 and paragraph 1, respectively, and communicated this decision in the financial reports published pursuant to Article 154-ter of the Consolidated Law.

4. Significant events after the reporting period

As announced on October 10th, 2019, the Company has decided to withdraw the Conditional Marketing Authorization for Zalmoxis because of commercial reasons. This decision was taken based on the overall results of the interim analysis voluntarily conducted as part of the review of the product's commercial development plan as well as talks with the EMA. In accordance with IAS 10 "Events after the Reporting Period", following the withdrawal of the Conditional Marketing Authorization, at September 30th, 2019, the Company wrote down the value of patents and trademarks associated with TK and Zalmoxis® by 92 thousand Euro.

5. Business outlook

In light of two fundamental analysis, one internal related to the performance of the two areas of MolMed's dual-business model and one external, concerning the global scenario of cell & gene therapies, the Company has identified the following strategic guidelines for its business development.

The excellence matured in the cell & gene field by working on proprietary projects has proved to be key in developing a GMP services business for third parties, which in recent years has performed excellent results, in terms of both turnover and margin. At the same time, the growing demand for production capacity of viral vectors and genetically engineered cells, has led to an increase of clients, with constantly growing service requests from both current and new potential customers.

At the same time global investments in advanced therapies have significantly increased from 2016 to 2018 and more than 1,000 clinical trials are currently undergoing at a global level, of which over 50% are in oncology. The combination of these elements leads to an imbalance between supply and demand in the development and manufacturing of viral vectors and genetically modified cells, thus increasing the demand and consequently the value of companies able to offer these services with high quality standards.

Also in light of Zalmoxis® CMA withdrawal, the Company will be able to allocate both the manufacturing areas and human resources previously dedicated to the production of TK cells to expand the offer of its own CDMO. At the same time, the Company aims to expand the quantity and scale of the offered services, in order to maintain the competitiveness that brought to the growth highlighted in this quarter.

The Company will continue the research activity on proprietary products, but will focus on CAR therapies, with particular regard to the clinical development of CAR-T CD44v6 in liquid tumors (AML and MM). Following the



regulatory authorizations of Italy and Czech Republic, and the negative opinions of Germany and Spain, the opportunity to expand the number of clinical centers in the authorized countries in order to increase the patient enrollment opportunities will be assessed within the Eure-CarT project.

The submission of the application to commence a clinical trial with CD44v6 CAR-T in solid tumors will be subject to the safety and efficacy results of the aforementioned phase I/II trial in liquid tumors.

Finally, with regard to the development of the early stage pipeline, started with the agreement with Glycostem and AbCheck in 2018, the Company has established scientific milestones to assess the advancement of the projects and their potential to advance to the clinic stage, with results expected by the first quarter of 2020.

It has also to be noted that, given the Company's high dependence on the current external partners in the development of the early stage CAR pipeline, their suitability as well as the potential internalization of some activities is going to be assessed in the upcoming months.

6. Statement pursuant to the provisions of Article 154-bis, paragraph 2, of Legislative Decree 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 24th, 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 records.

Milan, November 11th, 2019

[Signed by]

Carlo Incerti
Chairman of the Board of Directors

[Signed by]

Salvatore Calabrese
Executive Officer responsible for preparing
company financial reports