

Board of Directors approved interim results for the nine months ended September 30th 2019:

Revenues from sales up by 53% and positive EBITDA thanks to the growth of services to third parties.

- *Revenues from services to third parties amounting to Euro 24.8 million, up by 53% compared to September 30th 2018 (Euro 16.2 million)*
- *Positive EBITDA⁽¹⁾ amounting Euro 0.2 million compared to the negative results of Euro 3.5 million as of September 30th 2018*
- *Net Result equal to a loss of Euro 2.4 million, reduced by more than 50% compared to a loss Euro 4.9 million as of September 30th 2018*

Milan, November 11th 2019 – The Board of Directors of MolMed S.p.A. (MLMD.MI) (the “Company”), a biotechnology company focused on research, development, production and clinical validation of gene and cell therapies for the treatment of cancer and rare diseases, met today under the chairmanship of Mr. Carlo Incerti, reviewed and approved the interim financial results for the nine months ended September 30th 2019, reported on a voluntary basis.

Key financial results for the nine months ended September 30th 2019

<i>(Euro thousands)</i>	3 rd quarter 2019	3 rd quarter 2018	Change	Change %	1.1.2019-30.09.2019	1.1.2018-30.09.2018	Change	Change %
Revenues from sales	8,507	7,202	1,305	18%	24,820	19,436	5,384	28%
<i>Revenues for service from third parties</i>	<i>8,507</i>	<i>6,202</i>	<i>2,305</i>	<i>37%</i>	<i>24,820</i>	<i>16,213</i>	<i>8,607</i>	<i>53%</i>
<i>Revenues from Zalmoxis®</i>	<i>-</i>	<i>1,000</i>	<i>(1,000)</i>	<i>(100%)</i>	<i>-</i>	<i>3,223</i>	<i>(3,223)</i>	<i>(100%)</i>
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	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	(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)	-	-	100%
Profit (loss) for the period	(486)	(1,788)	1,313	(73%)	(2,409)	(4,873)	2,475	(51%)

¹ EBITDA: Earnings Before Interest Taxes Depreciation and Amortization.



Revenues from sales amounted to Euro 24,820 thousands (Euro 19,436 thousands at September 30th 2018) with an increase of 28% compared to the same period of the previous year: this result was achieved thanks to both the expansion of the customer portfolio, in particular with the acquisition of the GSK oncology project, and the increase in services offered to existing customers for newly acquired projects.

Considering the recognition of Revenues from sales related to Zalmoxis® for Euro 3,223 thousands in the same period of the previous year, the growth in Revenues from third party activities amounted to 53%, with an increase in the 3rd quarter of 37% compared to the third quarter of 2018.

Operating costs net of amortization and depreciation amounted to Euro 24,696 thousands, slightly increased compared to the first nine months of 2018 (Euro 23,510 thousands), mainly due to the following changes:

- purchases of raw materials and consumables increased by Euro 1,157 thousands, following the increase in development and manufacturing services to third parties
- higher services costs of Euro 810 thousands mainly due to (i) an increase in external development costs for external R&D activities of Euro 641 thousands (ii) higher costs for the proprietary pipeline and for technical, clinical and regulatory consulting services of Euro 226 thousands; (iii) lower costs license and patent fees for Euro 101 thousands, as a result of the non-renewal of patents related to the proprietary product NGR-hTNF
- a decrease in costs for use of third-party assets for Euro 1.032 thousands, mainly following the application, commencing on January 1st 2019, of the IFRS16 accounting standard, which reclassified lease expenses (amounting Euro 1,014 thousands in the first nine months of 2019) and recognized depreciation charges and financial expenses in the income statement.

EBITDA as of September 30th 2019 shows a positive result of Euro 190 thousands (negative for Euro 3,498 thousands in the same period of the previous year) improved by 105% (or by Euro 3,688 thousands). This change is partially due to the adoption, as of January 1st 2019, of the IFRS 16 accounting principles, with the reclassification of lease expenses in the Income Statement (equal to Euro 1,014 thousands in the first nine months of 2019) and the recognition of higher depreciation for Euro 944 thousands and of financial charges for Euro 89 thousands.

The EBITDA improvement is also due to a more than proportional increase in revenues as compared to the one occurred in operating costs, with a 110% impact of operating costs on total revenues, from 127% recorded in the same period of 2018.

EBIT as of September 30th 2019 is negative for Euro 2,341 thousands compared to a loss of Euro 4,628 thousands as of September 30th 2018, improved by Euro 2,286 thousands or 49%, thanks to an increase in revenues from sales (+28%) more than proportional compared to an increase in operating costs (+11%).

Net Result of the first nine months of 2019 is negative for Euro 2.4 million, reduced by more than 50% compared to a loss of Euro 4.9 million as of September 30th 2018.

Net Financial Position as of September 30th 2019 is Euro 2,590 thousands and includes cash and cash equivalent, current financial receivables from corporate bonds and lease payables (current and not current) recognized with the application of the IFRS16, which came into effect on January 1st 2019.



Without the application of IFRS16 accounting standard, Net Financial Position would be Euro 11,418 thousands, compared to a Net Financial Position of Euro 16,466 thousands as of December 31st 2018.

Main events occurred after September 30th 2019

Zalmoxis® (TK) - decision not to further invest in the product

On October 10th the Company, following the communication released on June 27th related to the decision to suspend the enrollment of new patients in phase III study TK008 with Zalmoxis®, informed on its decision to withdraw for commercial reasons the Conditional Marketing Authorization of the product.

This decision took into account the overall results of the interim analysis voluntarily carried out by the Company on the first 90 patients included in the study as part of the review of the product development plan of the product, as well as the following interactions with EMA.

Interim analysis results, albeit in the absence of changes related to the safety profile of the drug, have not shown an advantage of the arm treated with Zalmoxis® compared to the control arm treated with the standard of care, with reference to the primary endpoint of the study, namely 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.

CAR-T CD44v6

CAR-T CD44v6 has entered the clinical trial phase in Italy thanks to the authorization received from AIFA on March 20th 2019.

In addition to the Italian authorities, Czech Republic authorities approved the start of the clinical trial, while Germany and Spain expressed a negative opinion. The lack of harmonized authorization procedures at a European level for clinical trials in innovative cell & gene therapies, together with the time required to finalize the investigation agreements with the clinical centers and to validate the laboratories responsible for the screening of the patients, caused a delay in the start of the enrollment of patients for the study.

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.



Decision not to confirm the request for financing within the tender for the innovation of the MiSE

With reference to the request for financing within the tender for the innovation 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 (i) the delays in the start of the phase I trial (dose escalation) in AML and MM for the above mentioned circumstances, whose good safety outcomes are needed for the start of the clinical trial in solid tumors as well for the commencement of some other projects comprised in the loan; (ii) the fact 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 loan request, reserving the right to submit again the request at a later date.

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 acquired 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 start a clinical trial with CD44v6 CAR-T in solid tumors will be subject to the safety and efficacy results of the aforementioned phase I 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.



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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.

The Official Manager responsible for preparing the Company's financial reports, Salvatore Calabrese, herewith attests, pursuant to Article 154-bis, paragraph 2 of the Legislative Decree 58/1998 ("Testo Unico della Finanza"), that the accounting disclosure contained in this press release matches documentary evidence, corporate books, and accounting records.

In this document Alternative Performance Measures not envisaged by IFRS are used, whose components and meaning, in line with the recommendation CESR/05-178b dated November 3rd 2005, are described below:

- *EBITDA: this is equal to the difference between net revenues and operating cost before depreciation, amortization and impairment of current and non current activities*
- *Net Operating Result or EBIT: defined as the difference between total revenues and costs of Purchases of raw materials and consumables, cost of services, cost for the use of third-party assets, cost of personnel, depreciation, amortization and write-downs. Represents the margin realized before financial management and taxes;*
- *Net Financial Position: represents the sum of cash and cash equivalents, financial receivables and other financial assets and current and non-current financial payables.*

This press release is available on the company's website <http://www.molmed.com>

About MolMed

MolMed S.p.A. is a clinical stage biotech company focused on research, development, manufacturing and clinical validation of innovative therapies. MolMed is the first company in Europe to have obtained the GMP manufacturing authorization for cell & gene therapies ex vivo for its proprietary products as well as for third parties and/or in partnership (Strimvelis, an Orchard gene therapy for the ADA-SCID). With reference to GMP development and manufacturing activities for third parties, MolMed signed numerous partnership agreements with leading European and US companies. MolMed's is also developing a new therapeutic platform based on Chimeric Antigen Receptor (CAR), both autologous and allogeneic; the most advanced product, CAR-T CD44v6, which in March 2019 received the authorization to start human clinical trials in onco-hematologic indications (AML and MM), following an extensive pre-clinical phase. The product, whose innovative spacer incorporated in the CAR protein received in May 2019 the confirmation of grant, is potentially effective also in several epithelial solid tumors. MolMed is also developing a pipeline based on NK (Natural Killer) cells, following a research agreement signed in 2018 with Glycostem. MolMed, founded in 1996 as an academic spin-off of the San Raffaele Scientific Institute, is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana since March 2008. MolMed is headquartered and based in Milan, at the San Raffaele Biotechnology Department (DIBIT) and has an operating unit at OpenZone in Bresso.



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Appendices

- **Income Statement ended September 30th 2019**
- **Net Financial Position as of September 30th 2019**

Income statement ended September 30th 2019

<i>(amounts in Euro thousand)</i>	3 rd quarter 2019	3 rd quarter 2018	1.1.2019- 30.09.2019	1.1.2018- 30.09.2018
Revenues	8,507	7,202	24,820	19,436
Other revenue	4	98	66	576
Total operating revenues	8,511	7,300	24,886	20,012
Purchases of raw materials and consumables	(1,713)	(1,409)	(5,418)	(4,261)
Costs for services	(3,117)	(3,209)	(8,983)	(8,173)
Costs for use of third-party assets	(24)	(365)	(94)	(1,126)
Personnel costs	(3,211)	(3,671)	(10,081)	(9,887)
Other operating costs	(34)	(32)	(120)	(63)
Amortization and depreciation	(855)	(391)	(2,532)	(1,130)
Total operating costs	(8,955)	(9,077)	(27,228)	(24,640)
Operating result	(444)	(1,777)	(2,341)	(4,628)
Financial income	19	13	70	39
Financial charges	(51)	(24)	(127)	(284)
Net financial income (charges)	(32)	(11)	(57)	(245)
Pre-tax result	(476)	(1,788)	(2,398)	(4,873)
Income taxes	-	11	-	-
Profit (loss) for the period	(487)	(1,788)	(2,409)	(4,873)



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Net Financial Position as of 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