

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



Interim Management Report at March 31st, 2020

English translation for convenience

FROM GENES TO THERAPY

MOLMED S.p.A.

Via Olgettina, 58 - 20132 Milan | Phone +39 0221277.1 - Fax +39 02 21277.325

info@MolMed.com - www.MolMed.com

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



INTERIM FINANCIAL REPORT
AT MARCH 31st, 2020

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 excellence in research and development, and manufacturing operations.

...to therapy



Table of contents

General company information	2
Corporate bodies	3
Interim Management Report at March 31 st , 2020	4
1. A history of excellence in R&D and cell & gene manufacturing	7
2. Performance and financial highlights	13
3. Right to depart from disclosure requirements in the event of significant transactions	18
4. Significant events after the reporting period	18
5. Business outlook	18
6. Statement pursuant to the provisions of Article 154-bis, paragraph 2, of Legislative Decree 58/1998	19



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

Chairman	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

Chairman	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 *

Chairman	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

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

Scientific Advisory Board **

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

** Independent advisory body providing advisory support to the Company's research and development program. For further details, reference should be made to the information on the Company's website.

External Auditors

EY S.p.A.



Interim Management Report at March 31st, 2020

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 Interim Management Report at March 31st, 2020 consistently with past practice and in line with Italian and international best practices, reserving the right to reconsider this decision.

Key performance highlights

The following income statement shows the interim EBITDA and EBIT. EBITDA represents the difference between net revenue and operating costs, including non-cash costs such as depreciation, amortization, and impairment of current and non-current assets. EBIT is calculated by deducting non-cash costs associated with the depreciation, amortization, and impairment of current and non-current assets from EBITDA.

(amounts Euro thousand)	1 st quarter 2020	1 st quarter 2019	Change	Change %
Revenues from development and manufacturing activities	9,006	7,891	1,115	14.1%
Other revenue	72	27	45	166.7%
Total operating revenues	9,078	7,918	1,160	14.7%
Total operating costs (amortization and depreciation excluded)	(7,642)	(7,849)	207	(2.6%)
EBITDA	1,436	69	1,367	1981.2%
Amortization and depreciation	(748)	(720)	(28)	3.9%
Total amortization and deprecitaion	(748)	(720)	(28)	3.9%
EBIT	688	(651)	1,339	(205.7%)
Net financial income (charges)	(45)	(21)	(24)	114.3%
Pre-tax result	643	(672)	1,315	(195.7%)
Income taxes	(50)	-	(50)	100.0%
Profit (loss) for the period	593	(672)	1,265	(188.2%)

In the first quarter of 2020, **operating revenues** continued their positive trend, growing by 1,160 thousand Euro or 14.7% year-on-year. Thanks to the expansion in the customer base and the increase in work performed on behalf of existing customers, revenues from development and manufacturing activities on behalf of third parties were up 1,115 thousand Euro from 7,891 thousand Euro, at March 31st, 2019, to 9,006 thousand Euro at March 31st, 2020—a 14.1% rise.

Operating costs less impairment, depreciation, and amortization fell slightly by 207 thousand Euro (or 2.6%) from 7,849 thousand Euro, at March 31st, 2019, to 7,642 thousand Euro, at March 31st, 2020. The change in costs is to be primarily attributed to (i) the lower costs for raw materials, consumables and reagents in the amount of 103 thousand Euro, i.e. 5.9%, following a decreased consumption in reagents used for research and development activities and (ii) a decrease in the expenses related to services in the amount of 219 thousand Euro or 8.0% of which: (a) a lower number of technical advisory services and collaborations for 92 thousand Euro and (b) lower expenses associated with license fees and patents for 167 thousand Euro. These changes followed the strategic corporate decisions that have led to a revision of the proprietary pipeline in the onco-hematology area along with the abandonment of activities for the research and development of



autologous CAR T and allogeneic CAR NK, as well as the withdrawal of the *Conditional Marketing Authorization* for Zalmoxis.

EBITDA showed a 1,367 thousand Euro increase, from 69 thousand Euro, in the first quarter of 2019, to 1,436 thousand Euro, in the first quarter of 2020. This was largely attributable to the growth in revenues and margins associated with development and manufacturing on behalf of third parties—an area in which the Company is a global leader, as showed by the international standing of its customers, their loyalty, and the several projects it works on. In the meantime, a revision of proprietary research projects has made it possible to contain research and development costs, thus with a decrease in operating charges, net of depreciation, amortization and impairment in the amount of 207 thousand Euro, i.e. 2.6%.

The **Net Result** shows a profit of 593 thousand Euro, a net improvement (+188.2%) compared with the first quarter of 2019 that reported a loss of 672 thousand Euro.

Net financial position

(amounts in Euro thousand)	March 31, 2020	December, 31 2019	Variation (a-b)	Variation %
Net financial position - IFRS 16 included	170	1,375	(1,205)	(87.6%)
IFRS 16 application - current	1,204	1,204	-	0.0%
IFRS 16 application - non current	7,026	7,325	(299)	(4.1%)
Net financial position IFRS 16 not included	8,400	9,904	(1,504)	(15.2%)

At March 31st, 2020, the net financial position was down 1,206 thousand Euro (or 87.6%) from 1,375 thousand Euro, at December 31st, 2019, to 170 thousand Euro. The Net financial position is computed in compliance with the indications of the IFRS 16 standard “Leases”, which provides for the recognition, under current and non-current financial liabilities, of payables to lenders for finance leases. The change pertaining to the period is imputable to the use of cash in the operational management performed by the Company in support of the activities carried out during the period, and to the changes in finance lease payables in compliance with the application of the IFRS 16 standard. Net of the effects arising from the adoption of IFRS 16, the net financial position would have amounted to 8,400 thousand, at March 31st, 2020, compared to 9,904 thousand, Euro at December 31st, 2019.

Investments

	31.03.2020 (a)	31.03.2019 (b)	Change	Change %
Investments	217	214	3	1.4%

Average number of employees

	01.01.2020- 31.03.2020	01.01.2019- 31.03.2019
Average number of employees	219	212



Covid19

The Company is committed to manage and to continue to manage this current situation related to the COVID-19 emergency in full compliance with the provisions issued by the central government and the regional authorities. For the management of this emergency, a Crisis Committee has been established and has immediately implemented mitigation actions for the protection of the employees, including additional health-related and hygienic procedures while also promoting remote work.

The pharmaceutical plants of Bresso and Olgettina are opened and functioning, and no relevant interruptions have occurred both in manufacturing activities, due to the unavailability of personnel and/or of raw materials, and in activities related to the supply chain, neither have any recoverability issues emerged. In the meantime the Company is assessing all initiatives aimed at sustaining the continuity of business activities, an essential factor for a company like MolMed which operates in the sector for the supply of advanced therapeutic products. All customers have been promptly notified about these activities in order to provide maximum transparency and the guarantee of business continuity.

During the first quarter, industrial activities were not subject to a slowdown. However, the decision of some customers to discontinue the clinical trials in progress, due to the emergency generated worldwide by COVID-19, will have, in the absence of any future changes, a negative impact on the revenue from activities carried out on behalf of third parties, especially in the second half of 2020, and will produce lower operating results compared with the forward looking trend of the last few quarters .

As a consequence of the COVID-19 emergency and the impact that this situation has had on the management of patients (who require the availability of an intensive care facility) and on some logistic problems related to the management of biological samples, the Company has decided to discontinue, for the period from May 1st until October 31st, 2020, the enrollment of patients with acute myeloid leukemia (AML) and multiple myeloma (MM) for the multicentric clinical trial of Phase I/II *"A Phase I-IIa trial to assess the safety and antitumor activity of autologous CD44v6 CAR T-cells in acute myeloid leukemia and multiple myeloma expressing CD44v6"*.

The Crisis Committee is responsible for managing the activities necessary to guarantee the continuation of the operations of the Company as a going concern, within a scenario that will be constantly changing.



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 recent years, MolMed has been leveraging its distinctive expertise in cell & gene therapies, acquired by working on its products, to develop a business model that combines research and development of proprietary products with development and manufacturing on behalf of third parties. The latter business has consolidated over the last few years, with the double-digit growth in sales bringing the Company to generate profit in the first quarter of 2020, and it has now become MolMed's main business.

Among the first companies in Europe with authorized GMP manufacturing facilities for ex vivo cell and gene therapies, MolMed has become a solid company both in the CDMO (Contract Development & Manufacturing Organization) area, where it boasts important international partnerships, while performing R&D activities for proprietary products, now focusing on a single CAR (Chimeric Antigen Receptor) therapy for the treatment of tumors.

Voluntary full public offer of the ordinary shares of MolMed S.p.A.

On March 17th, 2020, MolMed reported that, with a communication issued pursuant to art. 102 of Italian Legislative Decree no. 58/1998 (“TUF” - Consolidated Finance Act), AGC Inc. had announced its decision for a voluntary public offer of 100% of the ordinary shares of the Company against a payment in cash of 0.518 Euro per ordinary share.

AGC Inc. and Finanziaria d'investimento - Fininvest S.p.A. (“Fininvest”, shareholder of MolMed) executed an agreement, pursuant to art. 122, paragraph 5, letter d)-bis, of the TUF, aimed at governing, inter alia, the commitment of Fininvest to participate in the Offer by contributing 107,173,138 ordinary shares of MolMed, which represent 23.125% of the share capital and the entire shareholding of Fininvest in the capital of MolMed.

On April 12th, 2020, AGC Inc. announced its filing with Consob of the offer document which will be published at the completion of the preliminary inquiry carried out by Consob, pursuant to art. 102, paragraph 4 of the TUF. On April 29th, 2020, AGC Inc. has announced that the approval of the offer document by Consob is scheduled for the second week in May 2020.

GMP development and manufacturing activities on behalf of third parties

Furthermore, MolMed participates in gene and cell therapy projects together with third parties, offering high-level expertise to develop, produce and validate experimental therapies, from the pre-clinical stage to product marketing, in addition to the development of innovative control procedures that meet the requirements of the new advanced cell-based therapies. In particular, MolMed is a state of the art company in terms of competence and experience in clinical manufacturing, according to current GMPs, of viral vectors and genetically modified cells.



Due to its consolidated *leadership* in this field, in recent years MolMed has signed agreements with important market players in the cell and gene therapies industry, both at an academic and non-profit level, such as Boston Children's Hospital and the Telethon Foundation, and mainly with international companies such as GlaxoSmithKline (NYSE: GSK), Orchard Therapeutics (Nasdaq: ORTX), Rocket Pharma (Nasdaq: RCKT), Cellectis (Nasdaq: CLLS), Autolus Therapeutics plc (Nasdaq: AUTL) and Genenta Science for the supply of development, technology transfer and manufacturing services for preclinical and clinical application of cell and gene therapies based on cell transduction with viral vectors. The Company is currently developing and manufacturing over 20 products to treat rare diseases or tumors on behalf of these customers.

In particular, MolMed was involved in the development and validation of the manufacturing process and related analytical methods as well as in the supply of Orchard Therapeutics' Strimvelis™ (CD34 cells + autologous, transduced to express the gene that codes for ADA), and previously of GSK, for both the compassionate use and, subsequently, for commercial use. This is an ex vivo stem cell gene therapy for the treatment of patients suffering from a very rare disease named ADA-SCID (Severe Combined Immunodeficiency due to Adenosine Deaminase Deficiency) which obtained EMA (European Medicines Agency)'s marketing authorization in 2016. In addition, on December 2nd, 2019, Orchard Therapeutics announced it has applied for an authorization from the EMA for OTL-200, a product to treat Metachromatic Leukodystrophy (MLD) patients. MolMed has contributed to the development of the product and, if it obtains marketing authorization, it will become the manufacturer.

The Company continues to search for new partners and customers with the aim of further increasing the number of partnerships in relation to both the manufacturing of both viral vectors and genetically modified cells.

In line with this strategy, on March 6th, 2020, the Company has announced the signing of a multiannual agreement and the start of a new partnership with Autolus Therapeutics pls (Nasdaq: AUTL), a biotech company engaged in the development of "T cell" therapies of the latest generation for the development and supply of viral vectors to be provided to some projects specific to clinical trials and potentially to the market.

On March 18th, 2020, the Company has announced the execution of a new multi-annual agreement and the launch of an additional partnership with a primary biotech American company listed on Nasdaq, whose name is not being disclosed for confidentiality reasons, and engaged in the development of gene and cell therapies for the treatment of rare diseases. Based on this agreement, MolMed shall provide GMP development and manufacturing services for one or more pre-clinical and clinical programs implemented by the customer.

Development

Development activities, conducted by staff with high experience in cell biology, molecular biology and virology, involve design and optimization of processes and analytical methods in order to transfer processes from the lab to GMP production. In this regard, the Company is constantly at work on two fronts: on the one hand, it is developing a technological platform for the large-scale, transient, semi-stable and stable manufacturing of retroviral and lentiviral vectors; on the other hand, it is automating cellular transduction processes and quality control tests. These process improvements allow for a greater production capacity and improved output as well as increased competitive advantage and differentiation, and therefore to expand the portfolio of customers as well as maintain the Company's role as technological co-developer.



Specifically, development efforts focused on the industrial manufacturing process for lentiviral vectors at 200L scale, in order to meet the needs of customers requiring high amounts of lentiviral vectors for products with marketing authorization. This process has already been tested in terms of its final scale; it will be consolidated and transferred from development to GMP manufacturing by the end of 2021.

In 2020, the development of the process for the manufacturing of adeno-associated vectors (AAV), that started in 2019 with a feasibility study to confirm whether it can produce adeno-associated virus vectors in addition to retroviral and lentiviral vectors, will continue. To date, AAVs and Lentiviruses are the two types of vectors most commonly used in ex-vivo and in-vivo gene therapy trials.

GMP production

AIFA (Agenzia Italiana del Farmaco – Italian Medicines Agency) granted MolMed the status of "Pharmaceutical Manufacturing Facility" in relation to the Milan site in 2003 and in relation to the Bresso site in 2017, for the manufacturing of genetically modified cell therapy products to be used in clinical trials and for commercial use.

The Pharmaceutical Manufacturing Facility in Milan, located within San Raffaele's science park, obtained authorization from AIFA in December 2015 to manufacture Strimvelis™, one of the first gene therapies with marketing authorization. The product is distributed by Orchard Therapeutics. The Pharmaceutical Manufacturing Facility includes Grade A, B, C, and D areas for the manufacturing of sterile products in accordance with cGMPs, quality control areas for product testing purposes, and storage areas for raw materials and products, resulting in a total surface area of nearly 1500 square meters.

In order to support both the research on its proprietary pipeline and the projects carried out on behalf of third parties, the Company also completed an important project aimed at expanding its production capacity through the construction of a second Pharmaceutical Manufacturing Facility in the Open Zone scientific park in Bresso (Milan).

In July 2017, AIFA granted this new facility the status of "Pharmaceutical Manufacturing Facility" for the manufacturing of investigational gene therapies and, in 2018, AIFA granted the authorization for the manufacturing of genetically modified cell therapy products to be used in clinical trials and for commercial use.

During 2017 and 2018, AIFA authorized the production area of the Pharmaceutical Manufacturing Facility in Bresso named Stream 1, which includes Grade A, B, C, and D areas for the manufacturing of sterile products (medicinal products and vectors) (approx. 600 square meters). In February 2020, AIFA authorized the production area of the Pharmaceutical Manufacturing Facility in Bresso named Stream 2, which includes Grade A, B, and C areas for the manufacturing of sterile products (vectors). The availability and authorization of the new areas at the Pharmaceutical Manufacturing Facility in Bresso boost the production capacity MolMed can offer to existing and prospective customers, enabling it to continue expanding its business.

On March 12th, 2020, the Company has announced to have received from AIFA (Italian Medicine Agency) GMP authorization, applicable to new spaces at the Bresso site, for the manufacturing of viral vectors to be used in clinical trials based on advanced therapies. The availability of the new spaces at the Bresso facilities will further increase the manufacturing capacity that MolMed can offer to its current and future customers.

1.1 Research and development: therapies for the treatment of high-risk serious tumors

R&D activities are primarily focused on identification, characterization as well as preclinical and clinical development of new therapies for tumors sharing the common trait of severity and the actual need of new therapeutic options.



The Company is thus focusing on cancers for which there are no or very few therapeutic options available (so-called unmet clinical needs). The clinical trials are currently focused on the onco-hematological area but could potentially be expanded to include also solid tumors—always relying on the expertise and experience acquired in cell & gene therapies over the years.

CAR-T CD44v6

CAR-T CD44v6 is an immuno-cell therapy, potentially effective in certain hematological malignancies and a number of solid tumors. It has demonstrated a promising degree of efficacy and safety in experimental animal models. The project is part of the CAR-T family—T cells equipped with chimeric receptors that have already shown great anticancer potential—and the Company acquired it in 2015 under an option agreement with IRCSS Ospedale San Raffaele.

With respect to adoptive cell immunotherapy, engineering T cells with receptors targeting tumor antigens represents an effective strategy—already clinically validated as safe and efficacious—to generate a high number of tumor-specific T-cells in a short period of time. Most clinical trials conducted to date have used CARs targeting the antigen CD19, which is expressed exclusively by B cells and the tumors derived from them. Compared to these CAR-T, CD44v6 CAR targets an original receptor that stands out for the following reasons:

- it has huge therapeutic potential, as it recognizes the variant 6 (v6) of the CD44 antigen (CD44v6), expressed in some hematological malignancies (acute myeloid leukemia and multiple myeloma) as well as many epithelial tumors (breast, lung, colon, pancreas, and head/neck cancer);
- it features a peculiar spacer in the outside of the CAR, targeting the antigen and the intracellular portion, responsible for activating the signal. Such spacer, recognized by specific antibodies, allows to purify CAR-T cells and improve the interaction with the target antigen. This enables the CAR to operate as a high-performing receptor, thus removing the need to include a separate marker gene for cell selection. This particular technology has a pending patent application filed by MolMed in several international territories. In 2019 it has obtained approval by the European Patent Office.
- a potentially low toxicity profile, thanks to the combination with MolMed's proprietary HSV-TK Mut2 suicide gene.

The therapy with the CD44v6 CAR-T involves isolating T cells in patients with tumors expressing the CD44v6 antigen and modifying them in vitro with a retroviral vector to make them express the CD44v6 CAR and the HSV-TK Mut2 suicide gene (fig. 1). The presence of the CD44v6 CAR will enable lymphocytes to recognize and eliminate cancer cells; in the event of adverse reactions, HSV-TK Mut2 suicide gene will allow to eliminate the cells expressing the CD44v6 CAR.

In particular, once engineered, the T cells expressing the CAR are selected and expanded in vitro to obtain the therapeutic dose and then infused into the patient. Before infusion, the patient undergoes lymphodepleting chemotherapy, i.e. a treatment with drugs that, by eliminating part of the patient's T cells, make the space necessary for the T cells expressing the CD44v6 CAR to settle in and remain in circulation.

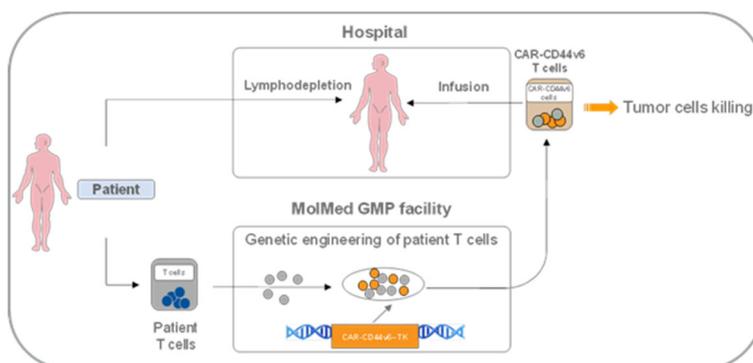


Figure 1. Summary of CAR CD44v6 therapeutic procedure

The lymphocytes infused in vivo into the patient are then guided by the CD44v6 CAR to the tumor site, where they exert their cytotoxic function by destroying neoplastic cells. In the event of undesired reactions, such as the recognition of the patient's normal tissue, the HSV-TK Mut2 suicide gene will be activated to kill the lymphocytes by administering ganciclovir. This suicide gene proprietary technology allows limiting the risks usually associated with cancer immuno-gene therapy.

The product has entered the clinical trial stage in patients with acute myeloid leukemia (AML) and multiple myeloma (MM) with the multicentric phase I/II "A Phase I-IIa trial to assess the safety and antitumor activity of autologous CD44v6 CAR T-cells in acute myeloid leukemia and multiple myeloma expressing CD44v6". The clinical trial is part of the European project EURE-CART (EUROpean Endeavour for Chimeric Antigen Receptor Therapies), of which MolMed is coordinator and sponsor, and received 5,903 thousand Euro in European funding in late 2016—to be shared with the other research centers participating in the project—as part of the funds allocated to new therapies for chronic diseases under the Research and Innovation Framework Program "Horizon 2020".

The clinical trial plan is divided into two phases: the first phase will focus on adult patients suffering from AML and MM and aims to identify the Maximum Tolerated Dose (MTD) among the levels specified in the protocol; the second phase will involve also child patients and pursue the primary goal of assessing the therapeutic activity and safety of CAR-T cells for each pathology in a larger number of patients.

As regards the clinical trial on CAR T CD44v6, at this report date, 6 patients have been enrolled, 5 at the IRCCS Ospedale San Raffaele of Milan and one at Fakultni Nemocnice S Poliklinikou di Ostrava (Czech Republic). Out of these patients, one was treated at the IRCCS Ospedale San Raffaele of Milan with the minimum dose, as per the dose escalation protocol (entry level) of the trial Phase I/II.

It should be noted that, as at May 1st until October 31st, 2020, the enrollment of patients in this clinical trial will be discontinued. This temporary suspension is due to the COVID-19 emergency and its impact on the treatment of patients that need intensive care, in addition to other logistic issues in the management of the biological samples.

The Company intends 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 in vivo efficacy and safety findings expected from the first phase of the dose escalation study in patients with liquid tumors. CD44v6 is an original antigen that has never been previously 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.

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



INTERIM MANAGEMENT REPORT
AT MARCH 31st, 2020

Autologous CAR T and allogeneic CAR NK

The Company, after assessing the scientific evidence emerging from the trials about the products in a pre-clinical phase, decided to discontinue any investment in research and development projects, both for autologous CAR-T with new anti-gene determinants and CAR NK allogeneic, since the time horizon and the financial resources necessary for their further development make its continuation strategically inadvisable.



2. Performance and financial highlights

Accounting standards and basis of measurement

MolMed's Interim Management Report for the period ended March 31st, 2020 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 Interim Management Report has also been prepared in compliance with the Consob Issuers' Regulations no. 11917/98 and subsequent communications.

The accounting standards applied are the same as those used to prepare the annual financial statements at December 31st, 2019. Income figures concern the quarter ending March 31st, 2020 – i.e. the first three months of the annual period ending December 31st, 2020. 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, 2019.

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.

2.1 Financial statements

2.1.1 Income statement – first three months of 2020

(amounts in Euro thousand)

	1 st quarter 2020	1 st quarter 2019	Change	% change
Revenues	9,006	7,891	1,115	14.1%
Other revenue	72	27	45	166.7%
Total operating revenues	9,078	7,918	1,160	14.7%
Purchases of raw materials and consumables	(1,652)	(1,755)	103	(5.9%)
Costs for services	(2,517)	(2,736)	219	(8.0%)
Costs for use of third-party assets	(24)	(11)	(13)	118.2%
Personnel costs	(3,401)	(3,312)	(89)	2.7%
Other operating costs	(48)	(35)	(13)	37.1%
Amortization and depreciation	(748)	(720)	(28)	3.9%
Total operating costs	(8,390)	(8,569)	179	(2.1%)
Operating result	688	(651)	1,339	(205.7%)
Financial income	2	25	(23)	(92.0%)
Financial charges	(47)	(46)	(1)	2.2%
Net financial income (charges)	(45)	(21)	(24)	114.3%
Pre-tax result	643	(672)	1,315	(195.7%)
Income taxes	(50)	-	(50)	100%
Profit (loss) for the period	593	(672)	1,265	(188.2%)



2.1.2 Statement of comprehensive income – first three months of 2020

<i>(amounts in Euro thousand)</i>	March 31, 2020	March 31, 2019	Change (a-b)	Change %
Profit (loss) for the period	593	(672)	1,265	(188.2%)
Other comprehensive income (not subsequently reclassified to the income statement)	-	-	0	0
Profit (loss) actuarial	-	-	-	-
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)	-	-	-	-
Other comprehensive income (subsequently reclassified to the income statement)	-	-	-	-
Total comprehensive income (loss) for the period	593	(672)	1,265	(188.2%)

2.1.3 Net financial position at March 31st, 2020

<i>(amounts Euro thousand)</i>	March 31 st , 2020	December 31 st , 2019
Cash on hand	2	3
Other cash	8,398	9,901
A. Total cash and cash equivalents	8,400	9,904
B. Current financial receivables and other financial assets	-	-
Current financial Debts	(1,204)	(1,204)
C. Current financial debt	(1,204)	(1,204)
D. Net current financial position (A+B+C)	7,196	8,700
Non current financial Debts	(7,026)	(7,325)
E. Non current financial Debts	(7,026)	(7,325)
F. Net financial position (D+E)	170	1,375
G. IFRS 16 effect - current	1,204	1,204
H. IFRS 16 effect - non current	7,026	7,325
I. Posizione finanziaria netta (F+G+H) - esclusi effetti applicazione IFRS 16	8,400	9,904

At March 31st, 2020, the net financial position was down 1,206 thousand Euro (or 87.7%) from 1,375 thousand Euro at December 31st, 2019 to 170 thousand Euro. The Net financial position is calculated in compliance with the indications of the IFRS 16 standard “Leases”, which provides for the recognition, under current and non-current financial liabilities, of payables to lenders for finance leases. The change pertaining to the period is imputable to the use of cash in the operational management performed by the Company in support of the activities carried out during the period, and to the changes in finance lease payables in compliance with the application of the IFRS 16 standard. Net of the effects arising from the adoption of IFRS 16, the net financial position would have amounted to 8,400 thousand at March 31st, 2020, compared to 9,904 thousand Euro at December 31st, 2019.



Note 1 – Sales revenues

(amounts Euro thousand)	1 st quarter 2020	1 st quarter 2019	Change	% change
Revenues from development and manufacturing activities	9,006	7,891	1,115	14.1%
- of wich milestones	337	337	-	0.0%
Total operating revenues	9,006	7,891	1,115	14.1%

Sales revenues amounted to 9,006 thousand Euro at December 31st, 2020, based on recognition at a point in time, increasing by 1,115 thousand Euro (or 14.1%) compared to the previous year period. This change is mainly due to an increase in the activities carried out for the customers in the portfolio, for which the Company was involved in a greater number of projects and activities carried out for the customers acquired over the quarter.

4.8% of sales revenues were generated in Italy (compared to 4.7% in 2019), 86.0% in the European Union (compared to 79.7% in 2019) and 9.2% in non-EU countries (compared to 15.6% in 2019).

Note 2 – Other income

The breakdown of this item, standing at 72 thousand Euro, shows a 45 thousand Euro increase, compared with the same figure at March 31st, 2019 and consists of:

- public contributions to research and development activities, for 53 thousand Euro (28 thousand Euro in the same period of the previous year);
- insurance reimbursements for 19 thousand Euro.

Note 3 – Purchases of raw materials and consumables

This item is broken down as follows:

(amounts in Euro thousand)	1 st quarter 2020	1 st quarter 2019	Change	% change
Processing materials	556	559	(3)	(0.5%)
Reagents	319	257	62	24.1%
General laboratory materials	777	939	(162)	(17.3%)
Total purchases of raw materials and consumables	1,652	1,755	(103)	(5.9%)

Costs for raw materials and consumables, which largely consist of processing materials and reagents used in manufacturing and development activities, fell from 1,755 thousand Euro, at March 31st, 2019, to 1,652 thousand Euro at March 31st, 2020. The difference of 103 thousand Euro, i.e. 5.9%, is primarily due to a lower consumption of reagents in the research and development activities following the discontinuation of pre-clinical development projects.



Note 4 – Costs for services

(amounts in Euro thousand)

	1 st quarter 2020	1 st quarter 2019	Change	% change
Outsourced development costs	720	718	2	0.3%
Consultancy and technical fees	119	211	(92)	(43.6%)
License and patents consultancy fees	23	190	(167)	(87.9%)
Maintenance	297	299	(2)	(0.7%)
Transport and storage of laboratory materials	101	154	(53)	(34.4%)
Utilities	309	300	9	3.0%
Directors and statutory auditors' fees	104	86	18	20.9%
Audit	23	19	4	21.1%
Legal, administrative and managerial fees	201	165	36	21.8%
Listing consultancy fees and other listing costs	13	10	3	30.0%
Supervisory board fees	41	29	12	41.4%
Communications agency fees	44	90	(46)	(51.1%)
IT assistance and other IT costs	102	103	(1)	(1.0%)
Other general and administrative costs	201	188	13	6.9%
Travel, staff training and other personnel costs	219	174	45	25.9%
Total costs for services	2,517	2,736	(219)	(8.0%)

Costs for services declined from 2,736 thousand Euro, at March 31st, 2019, to 2,517 thousand Euro at March 31st, 2020. The change of 219 thousand Euro (or 8.0%) was largely attributable to the:

- decrease of 92 thousand Euro (or 43.6%) in consultancy and technical fees, from 211 thousand Euro, at March 31st, 2019, to 119 thousand Euro, at March 31st, 2020. This change is due to the fact that, over the same period of the previous year, the costs for clinical development and pharmacovigilance incurred for TK and Zalmoxis[®], were higher;
- decrease of 167 thousand Euro (or 87.9%) in costs for license fees and patents, from 190 thousand Euro, at March 31st, 2019, to 23 thousand Euro, at March 31st, 2020, since in the first quarter of 2019, some costs were incurred for the expansion of the proprietary pipeline in the onco-hematology sector.

Note 5 – Costs for use of third-party assets

Costs for use of third-party assets were almost unchanged from 11 thousand Euro, at March 31st, 2019, to 24 thousand Euro, at March 31st, 2020. It should be noted that, starting from January 1st, 2019, the adoption of IFRS 16 generated the reclassification of lease costs and the recognition of depreciation and financial charges.

Note 6 – Personnel costs

These costs are broken down as follows:

(amounts in Euro thousand)

	1 st quarter 2020	1 st quarter 2019	Change	% change
Wages and salaries	2,559	2,480	79	3.2%
Social security contributions	702	701	1	0.1%
Defined contribution plans	134	125	9	7.0%
Other personnel costs	6	6	-	0.0%
Total personnel costs	3,401	3,312	89	2.7%



Personnel costs slightly increased by 2.7% from 3,312 thousand Euro, at March 31st, 2019, to 3,401 thousand Euro at March 31st, 2020. Personnel costs include the fixed fees paid to the Chairman and the Chief Executive Officer and their relevant variable bonuses for 2020 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. The average number of employees in the reporting period and their actual number at period-end are shown below.

	31.03.2020	31.03.2019
Number of employees	217	214
	01.01.2020- 31.03.2020	01.01.2019- 31.03.2019
Average number of employees	219	212

Note 7 – Amortization, depreciation and impairment

Amortization, depreciation and impairment amounted to 748 thousand Euro at March 31st, 2020, increasing by 27 thousand Euro compared to the prior-year period (720 thousand Euro). It must be noted that, following the application, as at January 1st, 2019 of the new IFRS 16 standard, this item includes the recognition of amortization on leased assets.

Note 8 – Financial income and charges

The Company's financial activities generated a negative result of 45 thousand Euro, an increase of 24 thousand Euro compared to March 31st, 2019. The negative result was mainly due to the effect of the recognition of interest expense after the adoption of IFRS 16.

Note 9 – Income taxes

During the period, income taxes, net of previous tax losses, were recognized in the amount of 50 thousand Euro.



Note 10– Changes in equity

	Capital	Share premium reserve	Other reserves	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
<i>(amounts in Euro thousand)</i>							
Balance at 1st January 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	-	-	-	-	-	(672)	(672)
Balance at March 31, 2019	21,819	61,754	223	(11)	(60,190)	(672)	22,923

	Capital	Share premium reserve	Other reserves	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
<i>(amounts in Euro thousand)</i>							
Balance at 1st January 2019	21,819	61,754	223	(6)	(60,190)	(427)	23,173
Allocation of prior year result	-	-	-	-	(427)	427	-
Profit (loss) for the period	-	-	-	-	-	593	593
Balance at March 31, 2019	21,819	61,754	223	(6)	(60,617)	593	23,766

Note 11 – Transactions with related parties

At March 31st, 2020, no transaction with related parties were recorded.

Note 12 – Share-based payments

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

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

On April 27th, the Shareholders' Meeting has approved the Financial Statements for the period ended December 31st, 2019 carrying forward the loss of 427 thousand Euro.

5. Business outlook

The Company, based on its distinctive expertise in the area of gene and cell therapies, demonstrated by the high standing of its customers, their loyalty and the high number of undertaken projects, places the core of its growth in the provision of development and manufacturing services on behalf of third parties, in the sectors of viral vectors and cells that are genetically engineered.

As demonstrated by the agreements executed in the first quarter of the year, the Company is working on expanding the number of its customers and related projects, in the areas of viral vectors and genetically modified cells within the sectors of oncology and rare diseases, as well as in the quantity and scale of the services offered.



In order to offer better services in terms of quantity and quality to current partners and future potential customers, the Company will be increasing its investments in terms of manufacturing scale and technology supporting development and manufacturing on behalf of third parties, and expanding production and support areas.

During the first quarter, industrial activities were not subject to slowdowns. However, the decision of some customers to discontinue the clinical trials in progress, due to the emergency generated worldwide by COVID-19, will have, in the absence of any future changes, a negative impact on the revenue from activities carried out on behalf of third parties, especially in the second half of 2020, and will produce lower operating results compared with the forward looking trend of the last few quarters.

As a consequence of the COVID-19 emergency and the impact on the management of patients (who require the availability of an intensive care facility) in addition to some logistic problems related to the management of biological samples, the Company has decided to discontinue, for the period from May 1st until October 31st, 2020, the enrollment of patients with acute myeloid leukemia (AML) and multiple myeloma (MM) for the multicentric clinical trial of Phase I/II *“A Phase I-IIa trial to assess the safety and antitumor activity of autologous CD44v6 CAR T-cells in acute myeloid leukemia and multiple myeloma expressing CD44v6”*.

With the entry into phase 2 of the COVID 19 emergency, the Company is completing the risk analysis to ensure a full recovery of operational activity in an orderly manner and on the basis of best practices and in compliance with national and regional legislative provisions. The Crisis Committee is operational for the management of the activities necessary to ensure the functioning of the Company with a view to business continuity in a constantly changing scenario.

6. Statement pursuant to the provisions of Article 154-bis, paragraph 2, of Legislative Decree 58/1998

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, May 11th, 2020

[Signed by]

Riccardo Palmisano
CEO

[Signed by]

Salvatore Calabrese
Executive Officer responsible for preparing
company financial reports