

# Half-Year Financial Report at June 30<sup>th</sup>, 2020

#### FROM GENES TO THERAPY



## From genes...

Our mission: focusing on innovative cell and gene therapies that can meet the therapeutic needs in the treatment of tumors and rare diseases, with a clear and solid industrial project based on excellence in research and development, and manufacturing operations

...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: 463,450,672

(100% ordinary shares with no par value)

#### DISCLAIMER

This document may contain forward-looking statements that reflect the current views of the Company on future events based on information available as of today's date. Forecasts and estimates are generally identified by words such as "possible", "should", "forecast", "expected", "estimated", "believe", "intend", "plan", "objective" or by the negative form of these expressions or other variations thereof or by the use of comparable terminology.

Although the Company believes that its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties that are beyond Management's 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, independent

Sabina Grossi

Mario Masciocchi, independent

Alfredo Messina

Elizabeth Robinson, *independent* Raffaella Ruggiero, *independent* 

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

Riccardo Palmisano is the "Director responsible for the internal control and risk management system".

#### Board of Statutory Auditors

Chairman Riccardo Perotta
Statutory Auditors Alessia Bastiani
Michele Milano

Substitute Statutory Auditors Giuliana Maria Converti

Tommaso Casale

Without prejudice to the indications below, the Board of Statutory Auditors, appointed by the Shareholders' Meeting held on April 30<sup>th</sup>, 2019, will remain in office until the Shareholders' Meeting convened to approve the Financial Statements at December 31<sup>st</sup>, 2021. The auditor Alessia Bastiani took over after the auditor Flavia Daunia Minutillo's resignation on June 25<sup>th</sup>, 2020, and will remain in office until the next meeting, which is yet to be scheduled.

#### Control and Risk Management Committee \*

Chairman Mario Masciocchi, independent

Members Sabina Grossi

Elizabeth Robinson, independent

#### Remuneration and Nomination Committee

Chairwoman Raffaella Ruggiero, *independent*Members Laura Iris Ferro, *independent* 

Sabina Grossi

#### Scientific Advisory Board

SAB Chairman Claudio Bordignon
Members Malcolm K. Brenner
Giannietro Dotti

Gianpietro Dotti Mohamad Mohty Miguel-Angel Perales

#### External Auditors

EY S.p.A.

<sup>\*</sup> It also acts as the Committee responsible for transactions with related parties.

<sup>\*\*</sup> 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.



# 1. A history of excellence in cell & gene research, development and 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 and gene therapies, acquired by working on its products, to develop a business model focused on development and manufacturing services on behalf of third parties combined with research and development of proprietary products. This business has consolidated over the last few years, with a double-digit growth in sales, thus bringing the Company to profit, and gradually and finally becoming 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 its main proprietary product (CAR-t CD44v6) for the treatment of tumors.

#### Takeover bid for MolMed's ordinary shares

On March 17<sup>th</sup>, 2020 MolMed disclosed that, with a communication issued pursuant to Article 102 of Italian Legislative Decree 58/1998 (Consolidated Law on Finance), AGC Inc. had announced its decision to take over 100% of MolMed's ordinary shares by consideration in cash equal to 0.518 Euro per ordinary share (the "takeover bid").

AGC Inc. and Finanziaria d'investimento – Fininvest S.p.A. ("Fininvest", shareholder of MolMed) executed a shareholders' agreement, pursuant to Article 122, paragraph 5, letter d)-bis, of the Consolidated Law on Finance, aimed at governing, among other things, the commitment of Fininvest to participate in the bid by contributing 107,173,138 ordinary shares of MolMed, accounting for 23.125% of the Company's share capital and representing the entire shareholding held by Fininvest.

On April 12<sup>th</sup>, 2020 – AGC Inc. declared that it had filed with Consob the bid document relating to the takeover bid launched by AGC Biologics Italy S.p.A. (the "Bidder") for up to 463,450,672 MolMed's ordinary shares (the "Bid Document"), which was published on May 29th, 2020, after completion of Consob's examination in accordance with Article 102, paragraph 4 of the Consolidated Law on Finance.

As of June 30, 2020, no. 145,881,025 shares, equal to 31.477% of the ordinary shares, had been brought to the takeover bid.

On July 6<sup>th</sup>, 2020 – In accordance with Article 2 of Italian Legislative Decree 21/2012, the Italian Presidency of the Council of Ministers has adopted the Decree whereby, in relation to the takeover bid, it has ruled on the application of the following specific rules in regard to AGC and MolMed:

- a) notify the Ministry of Economic Development of any agreement reached for the transfer of intellectual property between MolMed and the AGC Inc. Group companies, in particular as regard the treatment of acute myeloid leukemia and multiple myeloma;
- b) maintain research and development operations in Italy, including research laboratories and relevant manufacturing facilities;



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- c) maintain the employment levels of staff assigned to carry out essential research and development activities as they presently stand;
- d) guarantee the continuation of the current collaborations with Italian and European institutions.

Since the takeover bid is dependent on the absence of any conditions and requirements set by the Italian Presidency of the Council of Ministers in relation to the acquisition of MolMed's control by AGC Biologics Italy S.p.A., with a press release dated July 10<sup>th</sup>, 2020, the Bidder notified, with reference to the rules laid down by the Italian Presidency of the Council of Ministers, that it waives the condition laid down in the Bid Document under paragraph A.1 and wishes to pursue with the takeover bid process in accordance with the terms and conditions of the bid document.

The acceptance period of the takeover bid, agreed with Borsa Italiana S.p.A., started at 8.30 a.m. CEST on June 1<sup>st</sup>, 2020 and ended at 5.30 p.m. CEST on July 24<sup>th</sup>, 2020, both inclusive.

On 24 July 2020 AGC communicated the provisional results of the takeover bid at the end of the subscription period, from which no. 432,081,597 shares, equal to 93.23% of the share capital of MolMed, for a total value of € 223,818,267.25.

In light of the aforementioned provisional results and in consideration of the achievement by the Offeror of a shareholding in excess of 66.667% of the Company's share capital, the condition on the threshold which was, among other things, conditioned by the successful outcome of the takeover bid (as illustrated in letter a), Section A., Paragraph A.1. of the Offer Document) has come true.

The final results of the takeover bid will be announced by the Offeror by the date of payment of the consideration relating to the shares brought in acceptance of the takeover bid, i.e. by Friday 31 July 2020.

With the press release on the final results of the takeover bid, the Offeror will announce the occurrence or non-occurrence of the MAC Condition and, if it has not occurred, the eventual decision to renounce it and will also communicate the methods and times. the procedure through which the Offeror will fulfill the purchase obligation pursuant to article 108, second paragraph, of the TUF and the timing of the subsequent delisting of the MolMed shares by the MTA.

# 2. MolMed's operations: research, development, and manufacturing of cell and gene therapies

#### 2.1 *GMP* development and manufacturing activities on behalf of third parties

Furthermore, MolMed participates in cell and gene 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:



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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<sup>TM</sup> (CD34 cells + autologous, transduced to express the gene that codes for ADA), which previously belonged to GSK, for both compassionate use and, subsequently, 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's marketing authorization in 2016. In addition, in 2019 Orchard Therapeutics announced it had applied for authorization from the EMA for OTL-200, a product to treat Metachromatic Leukodystrophy (MLD) patients. MolMed contributed to the development of this product and, if it obtains marketing authorization, it will become the manufacturer.

#### **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 2019 the Company carried out a feasibility study to confirm whether it can produce adeno-associated virus (AAV) vectors in addition to retroviral and lentiviral vectors. To date, AAVs and Lentiviruses are the two types of vectors most commonly used in ex-vivo and in-vivo gene therapy trials. The feasibility study found that MolMed has the expertise and technological tools required to develop this manufacturing process. Therefore, the development stage has started.

#### 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 cell and gene 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



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accordance with GMPs, 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, it 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 boosts the production capacity MolMed can offer to existing and prospective customers, enabling it to continue expanding the business of GMP development and manufacturing on behalf of third parties.

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

R&D activities, always 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, are now focused on the only proprietary product CAR-T CD44v6.

#### 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 showed 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 cells, CAR CD44v6 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. Thanks to such spacer, recognized by specific
  antibodies, CAR-T cells are purified and the interaction with the target antigen is improved. This



enables the CAR to operate as a high-performing receptor, thus removing the need to include a separate marker gene for cell selection;

 a low toxicity profile, thanks to the combination with MolMed's proprietary HSV-TK Mut2 suicide gene.

The therapy with CAR-T CD44v6 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 CAR CD44v6 and the HSV-TK Mut2 suicide gene (fig. 1). The presence of CAR CD44v6 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 CAR CD44v6.

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 CAR CD44v6 to settle in and remain in circulation.

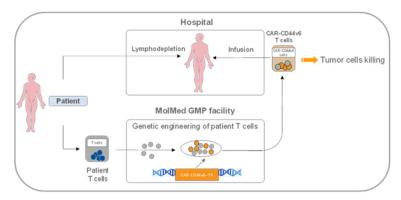


Figure 1. Summary of CAR CD44v6 therapeutic procedure

The lymphocytes infused in vivo into the patient are then guided by CAR CD44v6 to the tumor site, where they exert their cytotoxic function by destroying neoplastic cells. In the event of adverse 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.

As for leukemia, the preclinical findings have confirmed that the CD44v6 CAR-T cells are efficacious and have a better safety profile compared to the CD19 CAR-T cells; the findings concerning solid tumors are encouraging, as showed by a model of human lung adenocarcinoma that brought interesting and very promising properties of the CAR-T CD44v6 project into relief. Specifically, the T-cells express CAR CD44v6 extremely efficiently and migrate mainly towards the tumor's site, where they exert remarkable cytotoxic potential on cancer cells. The analysis conducted immediately after the treatment showed that neoplastic cells within tumor lesions were all but eliminated and replaced by CAR-T cells.

The product has entered the clinical trial stage in patients with acute myeloid leukemia (AML) and multiple myeloma (MM) with the multicenter 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—



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as part of the funds allocated to new therapies for chronic diseases under the Research and Innovation Framework Program "Horizon 2020".

The main outcome expected is the recognition of the cell therapy based on CAR-T cells as a definitive personalized therapy that can defeat neoplastic diseases. To this end, the project will include conducting a multicenter Phase I/IIa clinical trial to demonstrate the safety and efficacy of the immunotherapy based on CD44v6 CAR-T cells in acute myeloid leukemia and multiple myeloma. EURE-CART involves a consortium of renowned partners from four different European Union countries: all of them are world-class leaders in their respective clinical, scientific and industrial sectors.

The clinical trial plan is divided into two phases: the first phase will focus on adult patients suffering from AML and MM and aim 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.

#### 3. Report on operations

#### 3.1 Summary of activities performed in the first half of 2020

#### GMP development and manufacturing activities

During the first six months of 2020, MolMed continued development and manufacturing operations on behalf of third parties regarding both cancer and rare diseases, looking for new partners and customers with the aim of further expanding the number of partnerships with respect to the manufacturing of both viral vectors and genetically modified cells.

In line with this strategy, on March 6<sup>th</sup>, 2020, the Company announced the execution of a multi-year 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 for some projects to be used in clinical trials and potentially available to the market.

On March 18<sup>th</sup>, 2020, the Company announced the execution of a new multi-year 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 cell and gene therapies for the treatment of rare diseases. Based on this agreement, MolMed will provide GMP development and manufacturing services for one or more pre-clinical and clinical programs implemented by the customer.

#### CAR CD44v6

The Company has decided to suspend, for the period from May 1<sup>st</sup> to October 31<sup>st</sup>, 2020, the enrollment of patients involved in the CAR CD44v6 clinical trial. This temporary suspension is due to the COVID-19 emergency and its impact on the management of patients that need intensive care treatment, in addition to other logistic problems in the management of the biological samples.

#### Autologous CAR-T and allogeneic CAR-NK

After assessing the scientific evidence emerging from the trials about the products in a pre-clinical phase, the Company decided to discontinue any investment in research and development projects, both for



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autologous CAR-T with new anti-gene determinants and allogeneic CAR-NK, since the time horizon and the financial resources necessary for their further development make its continuation strategically inadvisable.



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#### 4. Main risks and uncertainties

#### 4.1 Risks associated with external factors

#### Risk of business interruption due to the COVID-19 coronavirus

The outbreak of the novel coronavirus, known as COVID-19, in Wuhan, China and subsequently several other countries—including Italy—has significantly impacted production and sales operations, and therefore the relevant imports/exports as a result of the restrictions placed on the transportation of goods and people.

To protect its employees and ensure business continuity, with the help of the occupational physician, the Company has implemented and is currently maintaining high safety standards and protocols: specifically, it has promoted and extended remote working through August 31<sup>st</sup>, 2020, as well as expanded and enhanced health and hygienic practices. In addition, it set up a Crisis Committee to implement and manage safety measures intended to comply with the emergency orders issued by the relevant Authorities amid an ever-changing landscape.

In the first half of 2020, the manufacturing facilities in Bresso and Olgettina remained always open and operational, and neither manufacturing nor supply chain-related operations experienced any significant interruption: therefore, the results for the first six months of the year were not especially affected by the outbreak of the pandemic.

Although the Company has taken steps to protect its employees and ensure business continuity, it cannot guarantee that these measures will be effective.

Specifically, the hygiene and safety measures put in place cannot rule out the risk that the Company's employees may contract the virus. In addition, there is the risk of potential disruptions to development and manufacturing as well as R&D operations resulting from the absence of personnel placed in preventive quarantine from manufacturing facilities, delays or suspensions in material procurement and logistical supply chains, and disruptions to air travel and transportation.

Considering the above, it is possible that the Company will not be able to promptly fulfill customer orders and conduct its operations, resulting in a substantial negative impact on its business, financial performance, and financial position that cannot currently be estimated.

Moreover, the impact that the COVID-19 pandemic has had so far—and could potentially have—at the international level on the production and sales operations of the Company's customers could cause revenues to decline.

This situation could deteriorate even further in the event of a second wave of the pandemic, which could overshadow the stimulus measures put in place by national governments to help the economy recover.

Finally, the decision of some customers to suspend the clinical trials underway, due to the COVID-19 emergency, may have a negative impact on sales revenues from activities on behalf of third parties in the second half of 2020, and—in the absence of any future changes—it may generate lower operating results compared to those that may be expected following the trend recorded in the last few quarters.

#### Risks associated with products in the clinical development stage

There is no guarantee that the Company will be able to successfully complete the clinical trial of the experimental product CAR-T CD44v6. In particular, as regards the CAR-T CD44v6 multicenter clinical trial, as a consequence of the COVID-19 pandemic and its impact on the management of patients suffering from



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acute myeloid leukemia (AML) and multiple myeloma (MM) (requiring facilities for intensive care treatment) in addition to the logistic management of biological samples, the Company has decided to suspend the enrollment of patients for the period from May 1<sup>st</sup> to October 31<sup>st</sup>, 2020, in agreement with the clinical centers participating in the study.

A potential second wave of the pandemic could cause clinical trials to be delayed further, negatively affecting the Company.

In general, conducting a clinical trial is expensive and time-consuming, and the outcome is uncertain. Clinical trials may be completed after several years and failure can occur at any time during the clinical trial process. Any failure in demonstrating safety and effectiveness of investigational product during clinical trials would stop the development process; this could negatively affect the Company's business, financial situation, financial performance and outlook.

Clinical trials may be delayed or suspended for a variety of reasons, including: delay or failure in obtaining regulatory authorization to commence a clinical trial because of safety or regulatory issues or failure to comply with regulatory guidelines; delay in obtaining clinical materials or manufacturing sufficient quantities for use in clinical trials; delay in obtaining the approval of IRBs for clinical trial protocols; delay in recruiting patients; the clinical trial failing or not being conducted in accordance with applicable laws; unforeseen safety issues; inability to adequately monitor patients during or after treatment or at different clinical sites; inability of clinical trial managers to properly perform their duties, including in terms of complying with applicable laws or meeting expected deadlines; lack of sufficient funding to complete the trials. Should the Company not be able to timely complete the development program and the clinical trials for its products, its business and financial position, results of operations, and cash flows could be negatively affected.

The experimental products under development could still prove to be ineffective or cause side effects during clinical trials and may not obtain proper authorization from relevant authorities or may not obtain it in time in order for them to be sold. In addition, it might happen that the non-randomized Phase II trials, which were successfully completed, do not provide the same positive results in subsequent stages of development. Moreover, clinical trials may be suspended at any time by the Company, or by relevant authorities, in the case of a significant risk to the health of patients. Even after approval by relevant authorities, a product might prove to be unsafe or not to have the expected effects (for example, side effects might emerge after the product is sold on the market or the drug effectiveness may be lower than that assessed during experimental phases), or, in any case, it might not be accepted by the market (which might prefer competitors' products) or, in general, for other reasons which are beyond the Company's control, thus preventing the product's use on a wide scale or forcing the Company to withdraw it from the market. Should the Company not be able to timely complete the development program and clinical trials for its products, its business and financial position, results of operations, and cash flows could be negatively affected.

#### Risks associated with strong competition

The biotechnology and pharmaceutical products markets are characterized by significant competition. This is especially true in the field of oncology. In this context, the Company may face competition from pharmaceutical multinationals and often larger companies that can take advantage of economies of scale and can more effectively and timely develop their products.

With respect to the business of development and manufacturing on behalf of third parties, the investments made by international players in the field of cell and gene therapies are gradually becoming more and more substantial and could jeopardize the Company's ability to compete in this sector and meet growth targets.



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Both in relation to R&D and the sale of products, the Company also faces competition from current and potential competitors benefiting from high financial resources, a significant investment budget and better in-licensing opportunities with regards to new products and technologies.

Moreover, the Company is in competition with companies of similar size and operations to sign out-licensing agreements or partnerships with other biopharmaceutical companies. In the future, these competitors might be able to develop safer, more effective or cheaper products than those developed by the Company. In addition, these companies might be more effective at producing and selling their own products, thanks to resources of their own or of their licensors and/or licensees. The level of competition in the reference market and the presence of organized competitors might therefore cause a loss of market share in the future, with a consequent negative impact on competitive positioning and a drop in expected revenue and profit.

Such circumstances might limit the Company's chances of competing on the market, with potential negative effects on its financial position, results of operations, and cash flows.

#### Risks associated with industry regulations

The Company's activities are subject to strict international, EU and Italian regulations. The Ministry of Health in Italy, the European Medicines Agency (EMA) in Europe, the Food and Drug Administration (FDA) in the United States, and similar institutions in other countries, currently impose restrictions on the production and sale of therapeutic products, which, together with the complex and lengthy authorization process, may cause delays, both in the launch of future trials, and in the sale of the Company's products.

Moreover, the authorized sale of a product in a particular country does not ensure that the product will be authorized in other countries. In fact, it may need to be further tested, thus involving the use of other significant resources. In addition, the discovery of previously unknown problems or failure to comply with applicable provisions, might lead to restrictions on the sale of products, to withdrawal of authorizations or of products from the market, and to the application of sanctions. Furthermore, changes in current regulations may delay drug manufacturing and/or trial process, with a consequent increase in the costs incurred by the Company.

Should these circumstances occur, the Company's business and its financial position, results of operations and cash flows could be negatively affected.



#### *4.2 Strategic and operating risks*

## Risks associated with operations and production capacity of the GMP manufacturing facility and laboratories

MolMed owns two GMP manufacturing facilities formally authorized by the Italian Medicines Agency (AIFA), for the production of cell and gene therapy products. Besides supplying cell therapy for its own clinical trials, these facilities provide cell therapy services to selected customers and partners. In addition, MolMed performs research and development activities at its own laboratories.

These facilities are subject to operating risks, such as breakdowns or delays in manufacturing processes, equipment failure or malfunction, crashes, delays in the supply of raw materials, strikes, natural disasters, the risk of authorizations being revoked, of the introduction of new regulatory measures or environmental regulations, including the risk that the facility is non-compliant with GMP requirements, that may prevent the Company from performing its research and development as well as manufacturing activities, treating patients as part of clinical trials, and promptly processing its customers' orders. In addition, although the Company has taken out relevant insurance, the negative impact of such events might not be fully covered by the policies that the Company has entered into or may exceed the indemnity limits. Should these circumstances occur in the future, they could have negative effects on the Company's business and financial position, results of operations, and cash flows. The Company's GMP facilities are adequate for its current production needs and the business plans envisage revamping activities and an increase in the production capacity aimed at supporting both intensification of the development and manufacturing activities for new cell and gene therapy treatments on behalf of third parties and internal demand. However, should the Company increase the production capacity or the number of products under development in the future, the GMP facility production capacity might reach saturation point, with consequent possible loss of clients/market shares or delays in the clinical trial process and/or in the product time-to-market. The Company constantly monitors this risk and mitigates it by constantly expanding its facilities and production capacity at the new Bresso premises—additional to the registered offices in Milan (via Olgettina). This risk is mitigated through the lease of laboratories in Bresso, as detailed in the Notes.

#### Risks associated with outsourcing and entrusting certain activities to third parties

The Company undertakes research and preclinical and clinical trials on its products as well as manufacturing of proprietary and third-party products based on cooperation agreements. The Company's strategy involves maintaining the current partnerships and signing other agreements with third parties, to perform clinical trials and product development and manufacturing.

In addition, the Company relies on third parties to perform certain research activities, preclinical and clinical studies, and manufacturing operations. These entities may fulfill all or part of their contractual obligations with results not up to par, including in terms of meeting deadlines or the required quality standards, causing delays in the performance of preclinical and clinical studies and negatively impacting MolMed's relationships with its customers. Should these circumstances occur, the Company's business and its financial position, results of operations and cash flows could be negatively affected.

The Company relies on Contract Research Organizations (CROs) or other third parties to design, manage, monitor, and conduct its own clinical trials. Should such entities fail to operate in accordance with the relevant agreements, clinical protocols, or regulatory requirements, this could compromise the quality or accuracy of the data generated. Such circumstances, as well as the need to replace one of the above entities during the study, may lead to significant delays in clinical trials. The Company may not be able to



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timely complete the development program and clinical trials for its products, and as a result, its business and financial position, results of operations, and cash flows could be negatively affected.

#### Risks associated with reliance on key suppliers

The Company relies on single suppliers for certain manufacturing and development operations and may not be able to rapidly replace them if need be. If, for any reason, said suppliers are not able to provide the requested services or materials, or to do so on time, this could result in the Company's failure to perform its contractual obligations with third parties and/or comply with regulations, with negative repercussions on the Company's business and financial position, results of operations and cash flows.

## Risks associated with the reliance of development and manufacturing operations on a limited number of key customers

MolMed's development and manufacturing operations on behalf of third parties are focused on a limited number of key customers. Therefore, a potential shift in their priorities or deterioration in their financial situation could negatively affect the Company's business, financial performance, financial position, and outlook.

In addition, should contractual terms and conditions be no longer acceptable to these key customers, they could ask to renegotiate them, offering less favorable terms and conditions to the Company.

#### Risks associated with license and supply agreements

As part of its operations, the Company has entered into several license agreements with a number of firms, to acquire rights over a range of technologies, patents and manufacturing and supply processes for the development and sale of its own products as well as for the purchase of equipment for its own research and business activities. Should MolMed not be able to maintain the current contract conditions and/or sign new license and/or supply agreements at suitable conditions, or should MolMed's suppliers not be able to provide MolMed with the equipment needed to perform its research and business activities, the Company's business and financial position, results of operations, and cash flows could be negatively affected.

#### Risks associated with the protection of intellectual property rights and industrial secrets

MolMed is committed to protecting intellectual property and actively seeks to protect its inventions through international patents, when appropriate. In addition, MolMed also actively protects its industrial secrets, including those relating to the production of biologically active products. The effectiveness of this intellectual property protection policy is essential for the success of the Company's business. In this regard, it should be noted that it is not possible for the Company to ensure it will be able to develop new patentable products or processes, or that currently pending or future patent applications will be accepted, or that the validity of a Company's patent is not challenged or that a patent does not become invalid, or, finally, that it acquires the right to use third-party patents which are necessary to carry out its business at arm's length. In addition, exclusive rights conferred by a patent might not be sufficiently comprehensive in terms of scope or geographical area, and/or its duration might not be long enough for its purposes. Moreover, patent applications are usually published 18 months after the filing date; therefore, it is impossible to rule out the possibility of the same invention being already developed by others who had previously filed the patent application.

In addition, the Company relies on proprietary and non-patented technologies, processes, know-how and data considered as industrial secrets and protected under confidentiality agreements entered into with its



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employees, consultants and a number of counterparties, including third-party manufacturers. In this regard, it should be noted that it is not possible to ensure: (i) that such agreements or measures aimed at protecting industrial secrets will, in fact, provide adequate protection, or that such agreements will not be breached; (ii) that the Company can effectively enforce remedies in the event of any breach of contract; or (iii) that the industrial secrets of the Company will not become known to the public or will not be developed by competitors. Finally, it should be noted that the protection of intellectual or industrial property or exclusive rights is normally very complex and often leads to legal disputes on ownership. Therefore, during its sales and research and development activities, the Company may be involved in disputes on breach of third-party intellectual or industrial property rights, or could be forced to take legal action against third parties to protect its own rights. Any claims and/or disputes for breach of patent and/or other intellectual or industrial property rights—filed by the Company or against it—could entail significant legal expense, restrictions or a ban on the use of the products involved in the dispute and/or lead to an outlay in order to sell them. Should these circumstances occur in the future, they could have negative effects on the Company's business and financial position, results of operations, and cash flows.

#### Risks associated with reliance on scientific/technical staff

The Company heavily depends on the professional contribution of key scientific and technical staff who actively contribute to the Company's growth and to the development of its strategies. Should MolMed lose any of the key personnel, there would be no assurance that the Company can promptly find adequate substitutes with the same operational and professional skills.

In particular, the Company's business largely depends on the Company's ability to attract and retain its highly qualified scientific and technical staff and experienced top management personnel, also in light of the intense recruitment competition by biotech and pharmaceutical companies, universities and research institutes. Moreover, the Company's ongoing expansion in areas and activities which require greater know-how will make it necessary to recruit staff with a range of competences. The loss of any of the Company's key personnel, or the Company's failure to recruit and retain highly qualified scientific and technical staff and experienced top management personnel or to successfully integrate staff who can manage the Company's growth, may have an adverse effect on its business, and financial position, results of operations, and cash flows.

#### Risks associated with civil liability related to product trials, manufacturing and sale

So far, the Company has never been involved in legal action for its trial, manufacturing and marketing activities. However, the Company is still exposed to such risks, and, despite it has taken out specific insurance, in keeping with market practice and in compliance with current regulations, with indemnity limits which are deemed adequate for its trial activities, should it face legal proceedings, be liable for compensation, and be forced to pay damages exceeding the indemnity limits provided for by its insurance policies, the Company could be required to directly cover the relevant costs.

The Company signs specific contracts with the Italian and foreign clinical centers at which trials are carried out. Although the Company, in line with industry regulations, has taken out insurance for the trials performed at these clinics, it is exposed to the risk of claims by the clinics and their insurers. In addition, contracts signed with clinics and testing facilities generally exclude the Company's liability if the clinical protocol is not complied with. However, should the clinical or testing facilities deviate from the clinical protocols, the Company could be exposed to the risk of being involved in compensation suits and claims for any damage caused to third parties.

Should these circumstances occur, the Company's business and its financial position, results of operations



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and cash flows could be negatively affected.

## Risks associated with the use of dangerous materials and the breach of regulations on environmental and health protection

During its operations, the Company uses dangerous materials and chemical and biological substances requiring special disposal systems which must be set up in compliance with specific provisions on environment, health and safety at workplaces. In this regard it should be noted that, although the safety procedures adopted by the Company for the handling and disposal of such materials are considered to be suitable to avoid or reduce the risks of accidental contamination or workplace injuries, it is impossible to exclude that these events will occur in the future and the Company will be required to pay compensation for any damage caused as a consequence of its operations. Should these circumstances occur, the Company's business and its financial position, results of operations and cash flows could be negatively affected.

#### Pharmacovigilance risks

The Company is subject to pharmacovigilance regulations. Among other things, these require disclosing information on the safety of medicines, especially with respect to adverse reactions, to the competent Regulatory Authorities as and when these may demand. The potential discovery of significant adverse reactions could expose the Company to the risk of restrictions on the prescription of the medicine and, in the most severe cases, the withdrawal of the relevant marketing authorization. To efficiently manage said risk and comply with national laws, the Company has defined specific responsibilities with respect to pharmacovigilance and set up integrated systems to collect, analyze, manage, and disclose the required information to the competent Authorities.

#### Risks associated with managing IT resources and data security

The widespread use of IT tools as part of business operations and the need to connect the Company's IT systems with external IT infrastructure (the web and networks) exposes said systems to potential risks with respect to the availability, integrity, and confidentiality of data as well as the availability and efficiency of IT systems. To ensure effective business continuity, the Company has implemented a disaster recovery and business continuity system to make sure the workstations of the main legacy systems can be immediately replicated. In addition, the active security of the Company's data and applications is guaranteed by multiple physical and logical security layers at both the server and client level. Finally, every year the Company undergoes VAPTs (Vulnerability Assessment and Penetration Tests) as well as additional regular IT security audits conducted by independent experts. These audits have always found that the Company's IT systems are adequately protected. With respect to frauds perpetrated by third parties using IT resources, the Company has introduced a training program to raise awareness among employees about the proper use of the IT resources and applications assigned to them.



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#### 4.3 Financial risks

#### Liquidity risk

The liquidity risk that the Company could be subject to is the failure to obtain adequate financial resources necessary for its operations and for the development of its business. The occurrence of such an event would negatively affect financial performance should the company have to incur additional costs to meet its obligations or, at an extreme, a situation of insolvency that could jeopardize its ability to continue as a going concern.

The Company's business focuses on development and manufacturing activities on behalf of third parties combined with research and development on proprietary products. In line with biotech companies developing new therapeutic products and that have not reached a balanced income and financial position yet, these activities feature negative cash flows. This is due to the fact that at this stage costs must be borne in relation to the testing and development of investigational new drugs, and return is not certain and in any case it is expected in forthcoming years. As for now, costs are not directly correlated to income. Based on the accounting policies adopted, requiring full recognition of research and development costs in the income statement of the year they are incurred, the Company has always recognized a loss since its incorporation, cumulatively generating 211,022 thousand Euro tax losses.

In December 2019, the Company entered into a financing arrangement with the European Investment Bank ("EIB") up to 15,000 thousand Euro over a term of 60 months, aimed at supporting the research and development of the proprietary pipeline as well as the development of, and investments in, facilities. The funds can be drawn down in two tranches of 7,500 thousand Euro. The drawdown is subject to the review of predefined specific financial goals and milestones. At June 30<sup>th</sup>, 2019, the Company had not drawn down any tranche.

In the first half of 2020, the Company recognized a profit of 2,390 thousand Euro compared to the loss of 1,922 thousand Euro of the prior-year period. The change was largely attributable to the impact of sales revenues associated with the steadily growing services performed on behalf of third parties and the redefining of research and development priorities, which led to discontinuing the projects that failed to meet expectations.

Taking account of the above and, in particular, based on the Company's liquidity (of 14,429 thousand Euro at June 30<sup>th</sup>, 2020), the improved results for the reporting period, compared to the last three-year period, and based on the cash flows generated during the first half of 2020 and those projected in the next three years and arising from operations on behalf of third parties, as well as on the credit facility granted by the EIB of up to 15,000 thousand Euro and still unused, the Company deems that the financial resources and equity available are adequate enough to continue its operations for a foreseeable future of at least 12 months from the date of this Report. As at today, no significant uncertainties were reported on the Company's ability to continue as a going concern.

Despite the above, it cannot be ruled out that over the coming years the Company will need to use further financial resources (through risk capital funding or third-party capital), or through the signing of further cooperation agreements, sponsored research or other means.

#### **Currency and interest rate risk**

Currency and interest rate risk consists in the possibility that fluctuations in foreign exchange and interest



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rates could negatively affect the value of assets, liabilities, or expected cash flows. At June 30<sup>th</sup>, 2020, the Company did not have significant exposure to currency fluctuations, because there were no significant receivables or payables in currencies other than the Euro, nor were there any financial instruments subject to currency risk. Contract services agreements are denominated in Euro, even if entered into with counterparties outside the Euro Area. The Company has not entered into derivative contracts. The Company has entered into a financing arrangement with the EIB at a fixed rate, therefore interest rate fluctuations do not affect its financial position.

#### Credit and concentration risk

Credit risk represents the Company's exposure to potential losses resulting from the counterparty's failure to perform its obligations. Concentration risk derives from material exposures to individual counterparties. With respect to the counterparty risk associated with commercial agreements, credit management operations are the responsibility of the business units and the dedicated specialized finance and administration functions, based on formal procedures for assessing and lending to business partners—including debt collection and dispute management. No insolvencies had been declared at the reporting date and, from an operational perspective, the Company continues monitoring the due dates for trade receivables in order to anticipate and deal promptly with positions at higher risk.

As for the current concentration risk, two single-name counterparties account for nearly 70% of sales revenues. Specifically with respect to these counterparties, the Company monitors past due receivables as well as cash receipts and the advance payment of part of the services requested on a monthly basis. At the same time, it is pursuing a series of initiatives aimed at diversifying its customer base by participating in industry conferences and events.

#### 4.4 Legal and Compliance Risks

#### Risks associated with product liability

As any entity operating in the pharmaceutical industry, even though it rigorously complies with applicable laws, the Company may be exposed to the risk of claims for damage caused by its products under development. To cover such potential liabilities, the Company has taken out insurance policies for its products under development with a coverage limit that is considered appropriate and constantly monitored to assess its adequacy. However, damages claims may not be fully covered by the Company's insurance policies or may exceed coverage limits. Should these circumstances occur, the Company's business and its financial position, results of operations and cash flows could be negatively affected.

#### **Compliance risks**

The Company carries out all operational and commercial activities in Italy and abroad in accordance with the laws and regulations applicable where it operates, including laws as well as national and international technical standards applicable to the pharmaceutical industry and governing the research and development, manufacturing, and distribution of medicines as well as medical sales representation. With respect to Italian Legislative Decree 231/2001 on the administrative liability of legal entities, the Company has adopted an Organization, Management and Control Model that is constantly updated to reflect the latest relevant regulatory changes.



### 5. Performance and financial highlights

#### Key performance highlights

The following income statement shows the interim EBITDA and EBIT. EBITDA means earnings before taxes, net financial income and charges, depreciation, and amortization. EBIT means earnings before taxes as well as net financial income and charges.

(amounts Euro thousand)	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019	Change	Change %
Revenues from development and manufacturing activities	20,358	16,313	4,045	24.8%
Other revenue	379	63	316	501.6%
Total operating revenues	20,737	16,376	4,361	26.6%
Total operating costs (amortization and depreciation excluded)	(16,580)	(16,596)	16	(0.1%)
EBITDA	4,157	(220)	4,377	(1989.5%)
Amortization	(1,499)	(1,477)	(22)	1.5%
Devaluation	-	(200)	200	(100.0%)
Total amortization and deprecitaion	(1,499)	(1,677)	178	(10.6%)
EBIT	2,658	(1,897)	4,555	(240.1%)
Net financial income (charges)	(131)	(25)	(106)	424.0%
Pre-tax result	2,527	(1,922)	4,449	(231.5%)
Income taxes	(137)	-	(137)	100.0%
Profit (loss) for the period	2,390	(1,922)	4,312	(224.3%)

In the first half of 2020, **operating revenues** continued their positive trend, growing by 4,361 thousand Euro or 26.6% compared to the prior-year period. Thanks to the expansion in the customer base and the increase in work performed on behalf of existing customers, sales revenues increased by 4,045 thousand Euro (or 24.8%) from 16,313 thousand Euro in the first half of 2019 to 20,358 thousand Euro in the first half of 2020.

Net of amortization, depreciation and impairment, **operating costs** went from 16,596 thousand Euro in the first half of 2019 to 16,580 thousand Euro in the first half of 2020, recording a slight reduction of 16 thousand Euro or 0.1%, mainly due to the combined effect of: (i) a reduction in costs for services of 250 thousand Euro or 4.3%; (ii) an increase in personnel costs of 174 thousand Euro or 2.5%; and (iii) a reduction in costs for raw materials of 89 thousand Euro or 2.4%.

The change in costs for services was largely attributable to (a) the 358 thousand Euro decline in outsourced development costs, (b) the 284 thousand Euro decrease in consulting and technical service fees, and (c) the 167 thousand Euro reduction in license and patent fees, partially offset by the 697 thousand Euro increase in legal and administrative consulting fees attributable to the expenses associated with the takeover bid. The decrease in outsourced development costs, consulting and license fees was the result of the strategic corporate decisions that have led to a revision of the proprietary pipeline in the oncohematology area along with the discontinuation of development activities of autologous CAR-T and allogeneic CAR-NK as well as the withdrawal of the Conditional Marketing Authorization for Zalmoxis.

Personnel costs were up largely because of the 125 thousand Euro allocated to the provision for restructuring risks. This amount was set aside in connection with the reorganization that MolMed carried



out after revising its strategic plans and discontinuing the development of autologous CAR-T *and* allogeneic CAR-NK.

**EBITDA** rose by 4,377 thousand Euro, from a negative 220 thousand Euro in the first half of 2019 to 4,157 thousand Euro in the first half 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. Furthermore, a revision of proprietary research projects has made it possible to reduce research and development costs, thus contributing to a decrease in operating costs.

Amortization, depreciation and impairment costs amounted to 1,499 thousand Euro in the first half of 2020, decreasing by 178 thousand Euro compared to the prior-year period (1,677 thousand Euro).

Income taxes include regional tax on productive activities (IRAP) of 137 thousand Euro. At June 30<sup>th</sup>, 2020, in view of the previous tax losses of 211,022 thousand Euro—some of which accrued in the first three tax periods and are therefore not subject to the limit of use—no provisions were recognized for the Italian corporate income tax (IRES). MolMed recognized a **net profit** for the period amounting to 2,390 thousand Euro. This is an improvement (+224.3%) compared to prior-year figures when the Company recognized a loss of 1,922 thousand Euro.

#### Statement of financial position

The condensed versions of the reclassified statement of financial position and the statement of cash flows are provided below in order to highlight two items: net working capital and net financial position. Therefore, these statements differ from the statement of financial position included in the set of required financial statements, which was prepared by classifying assets and liabilities as current and non-current.

(amounts Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019	Change	Change %
Non-current assets				
Fixed assets and other non-current assets	18,970	22,201	-3,231	-14.6%
Total non-current assets	18,970	22,201	-3,231	-14.6%
Net working capital				
Inventories	2,644	1,830	814	44.5%
Trade receivables and other commercial assets	10,636	9,911	725	7.3%
Tax receivables	2,667	2,528	139	5.5%
Other receivables and current assets	651	542	109	20.2%
Trade payables	(10,297)	(8,230)	(2,067)	25.1%
Tax payables	(137)	(87)	(50)	100.0%
Other liabilities	(3,872)	(3,192)	(680)	21.3%
Provision risk	(256)	(611)	355	100.0%
Total net working capital	2,036	2,691	(655)	(24.3%)
Non-current liabilities				
Other non-current liabilities	(1,941)	(3,094)	1,153	(37.3%)
Total non-current liabilities	(1,941)	(3,094)	1,153	(37.3%)
TOTAL USES	19,065	21,798	(2,734)	(12.5%)
Shareholders' equity	25,563	23,173	2,390	10.3%
Net financial position	6,499	1,375	5,124	372.7%
TOTAL SOURCES	19,065	21,798	-2,733	(12.5%)



At June 30<sup>th</sup>, 2020, non-current assets were down 3,231 thousand Euro (or 14.6%) from 22,201 thousand Euro at December 31<sup>st</sup>, 2019 to 18,970 thousand Euro. The change was largely attributable to the non-recourse factoring of the VAT credit, amounting to 2,601 thousand Euro and included in non-current tax receivables at the end of the prior year.

At June 30<sup>th</sup>, 2020, net working capital was down 655 thousand Euro (or 24.3%) from 2,691 thousand Euro at December 31<sup>st</sup>, 2019 to 2,036 thousand Euro. The decline was largely driven by the increase in payables to suppliers and other payables, which grew at a faster rate than inventories and trade receivables.

#### **Net financial position**

(amounts Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019
	2020	2013
Cash on hand	2	3
Other cash	14,427	9,901
A. Total cash and cash equivalents	14,429	9,904
B. Current financial receivables and other financial assets	-	-
Liabilities to financial leasing entities (IFRS16)	(1,204)	(1,204)
C. Current financial debt	(1,204)	(1,204)
D. Net current financial position (A+B+C)	13,225	8,700
Liabilities to financial leasing entities (IFRS16)	(6,726)	(7,325)
E. Non-current financial debt	(6,726)	(7,325)
F. Net financial position (D+E)	6,499	1,375
G. IFRS16 effects - current	1,204	1,204
H. IFRS16 effects - non current	6,726	7,325
I. I. Net financial position - NO IFRS 16 effects	14,429	9,904

The net financial position was up 5,124 thousand Euro, from 1,375 thousand Euro at December 31st, 2019 to 6,499 thousand Euro at June 30th, 2020. MolMed's net financial position is calculated in compliance with IFRS 16 – Leases with finance lease payables recognized as current and non-current financial payables. The period change is due to the non-recourse factoring and collection of VAT credits to the tune of 2,601 thousand Euro, the partial use of tax credits for research and development purposes, offsetting INPS contributions and IRPEF withholding taxes, which effectively resulted in lesser financial outlay in the amount of 1,004 thousand Euro, the net liquidity generated by the Company's operations supporting the period business and the change in finance lease payables resulting from the application of IFRS 16. Net of the effects arising from the adoption of IFRS 16, the net financial position would have amounted to 14,429 thousand Euro at June 30th, 2020 compared to 9,904 thousand Euro at December 31st, 2019.

Details about changes in equity from January 1<sup>st</sup>, 2020 to June 30<sup>th</sup>, 2020 are provided in the table below:

(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
Balance at January, 1st 2020	21,819	61,754	223	(6)	(60,190)	(427)	23,173
Allocation of prior year result	-	-	-	-	(427)	427	-
Profit (loss) for the period	-	-	-	-	-	2,390	2,390
Balance at June, 30 <sup>th</sup> 2020	21,819	61,754	223	(6)	(60,617)	2,390	25,563



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#### Condensed statement of cash flows:

Below is the condensed statement of cash flows:

(amounts Euro thousand)		1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019	Change	Change %
Opening cash and cash equivalents	Α	9,904	15,507	-5,603	(36.1%)
Cash flow from operating activities before changes in working capital		3,332	(1,103)	4,435	(402.1%)
Total changes in current assets and liabilities		(351)	(2,827)	2,476	(87.6%)
Total cash flow generated (absorbed) by operating activities	В	5,561	(2,361)	7,922	(335.5%)
Total cash flow generated (absorbed) by investing activities	С	(1,036)	(619)	(417)	67.4%
Total cash flow generated (absorbed) by financing activities	D	-	-	-	_
Cash flow generated (absorbed) during the period	E=B+C+D	4,525	(2,980)	7,505	(251.8%)
Closing cash and cash equivalents	F=A-E	14,429	12,527	1,902	15.2%

Cash flows from operating activities before changes in net working capital improved compared to the prioryear period largely because the loss of 1,922 thousand Euro recognized at June 30<sup>th</sup>, 2019 became a profit of 2,390 thousand Euro at June 30<sup>th</sup>, 2020.

Cash flows from operating activities were up 7,922 thousand Euro compared to the first half of 2019 as revenues rose and operating costs remained essentially flat year-on-year.

Cash flows used in investing activities climbed 417 thousand Euro compared to the prior-year period because of the investments made during the first six months of 2020 to expand the facility in Bresso.

#### 6. Covid-19

The Company is committed to manage and to continue to manage the current situation related to the COVID-19 emergency in full compliance with the provisions issued by Italy's Government and regional authorities. A Crisis Committee has been established in order to manage this emergency, and supported by the occupational health doctor, it has immediately implemented mitigation actions for the protection of employees, including additional health-related and hygienic procedures while also promoting remote working until August 31<sup>st</sup>, 2020.

During the first half of 2020, the Bresso and Olgettina facilities were open 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 credit recoverability issues emerged. In the meantime, the Company is assessing all initiatives aimed at sustaining business continuity, an essential factor for a company like MolMed involved in the supply of advanced therapeutic products. All customers have been promptly notified about these activities in order to provide maximum transparency and ensure business continuity.

During the first half of the year, industrial operations were not subject to any slowdown. However, the decision of some customers to suspend the clinical trials underway, due to the global COVID-19 emergency, may have a negative impact on sales revenues from activities on behalf of third parties in the second half of 2020, and—in the absence of any future changes—may generate lower operating results compared to those that may be expected following the trend recorded in the last few quarters. However, the management believes that it will achieve the forecast results foreseen in the 2020 budget and is confident of the medium-



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long term development estimates, which can also be achieved in the event of a hypothetical prolongation or aggravation of the situation deriving from the pandemic.

Furthermore, as a consequence of the COVID-19 emergency and its impact on the management of patients (requiring intensive care treatment) and on some logistic problems related to the management of biological samples, the Company has decided to suspend, for the period from May 1st to October 31st, 2020, the enrollment of patients suffering from acute myeloid leukemia (AML) and multiple myeloma (MM) for the Phase I/II multicenter clinical trial 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 ensure business continuity in order for the Company to continue as a going concern within a constantly changing scenario.

#### 7. Other information

#### Direction and coordination

The Company is not subject to direction and coordination pursuant to Article 2497 et seq. of the Italian Civil Code. The following should be noted:

- Information required by Article 123-bis, paragraph 1, letter i) of the Consolidated Law on Finance Testo Unico sulla Finanza, TUF ("agreements between the company and directors providing for compensation in case of resignation or unfair dismissal or if their employment relationship ends due to takeover") is included in the remuneration report published pursuant to Article 123-ter of the Consolidated Law on Finance.
- Information required by Article 123-bis, paragraph 1, letter I) of the Consolidated Law on Finance ("rules governing appointment and replacement of directors [...] and amendments to company bylaws, if different from supplementary applicable law and regulations") is provided in Chapter 4 of the corporate governance report devoted to the board of directors.

#### Treasury shares

The Company does not directly or indirectly own treasury shares, nor were acquisitions or disposals of said shares made, directly or indirectly, during the period.

#### *Grants and funding schemes*

Because of its particular segment of operations, MolMed enjoys some benefits deriving from funding schemes at European level aimed at supporting and promoting innovation. Starting from 2017, MolMed has sponsored and coordinated EURE-CART (EURopean Endeavour for Chimeric Antigen Receptor Therapies), an EU co-financed project within the Horizon 2020 – Research and Innovation Framework Programme, reserved to the new therapies for chronic diseases (including cancer). In relation to this project, a 5,903 thousand Euro grant was awarded in December 2016. MolMed received 1,995 thousand Euro: this amount will cover a portion of R&D costs over a period of 48 months.

#### Financing

In December 2019, the Company entered into a financing arrangement with the European Investment Bank ("EIB") up to 15,000 thousand Euro over a term of 60 months. The funds can be drawn down in two tranches



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of 7,500 thousand Euro. Each tranche may be divided into two sub-tranches. The drawdown is subject to the review of predefined specific financial goals and milestones. The financing arrangement has a fixed rate and a pre-amortization period of two years. A drop dead fee shall apply in the event of failure to draw down the first tranche within 12 months of the agreement date. Both parties may terminate the financing arrangement early. The funds support the research and development of the proprietary pipeline as well as the development of, and investments in, facilities. At June 30<sup>th</sup>, 2019, the Company had not drawn down any tranche.

#### Government grants - Disclosures as per Article 1, paragraphs 125-129 of Italian Law 124/2017

With respect to the transparency and disclosure requirements for government grants, governed by Article 1, paragraphs 125-129 of Italian Law 124/2017 as supplemented by the 'security' decree-law (113/2018) and the 'simplification' decree-law (135/2018)—which, starting for annual periods beginning on or after January 1<sup>st</sup>, 2019, has introduced a series of disclosure and transparency requirements for those entities that do business with the Public Administration—and based on the interpretation given by Assonime in Circular no. 5 of February 22<sup>nd</sup>, 2019, said regulations are not considered applicable to:

- ✓ subventions, grants, or economic benefits of any kind accessible to all companies that meet certain
  conditions based on predetermined general criteria (e.g. measures in ministerial decrees targeting
  specific industrial sectors and aimed at finalizing activities associated with research and
  development projects);
- ✓ general measures for which all companies are eligible and that are part of the overall framework of the relevant system established by the government (e.g. the ACE (*Aiuto per la Crescita Economica* Aid for Economic Growth)'s mechanism intended to encourage businesses to reinvest profits);
- ✓ European/international public funds;
- ✓ Interprofessional funds for the financing of training courses, as the funds are financed with the fees paid by recipients and must fulfill specific operational transparency requirements (e.g. training courses funded by Fondimpresa).

Considering the above, the Company assessed its situation and concluded it does not fall within the scope of the disclosure requirements in Article 1, paragraphs 125-129 of Italian Law 124/2017.

## 8. Significant events after the reporting period

On July 9<sup>th</sup>, 2020 MolMed and Orchard Therapeutics (Nasdaq: ORTX) announced the extension of the collaboration—launched in April 2018—for a period of five years through to June 2025. MolMed will continue to support activities relating to the development and manufacturing of vectors and medicinal products for various investigational gene therapies based on the ex vivo genetic modification of hematopoietic stem cells, including OTL-200 for metachromatic leukodystrophy (MLD) and OTL-103 for Wiskott-Aldrich Syndrome (WAS) and for additional programs, including OTL-203 for Mucopolysaccharidosis type I (MPS-I).



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#### 9. Business outlook

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

As demonstrated by the agreements executed in the first half of the year, the Company is working on expanding the number of its customers and related projects concerning both viral vectors and genetically modified cells in the fields of oncology and rare diseases, as well as the quantity and scope of the services offered.

In order to offer better services in terms of quantity and quality to current partners and future potential customers, MolMed plans to expand its investments on manufacturing scale and technology supporting development and manufacturing on behalf of third parties, and to extend manufacturing and support areas.

During the first half of 2020, industrial operations were not subject to any slowdown. However, the decision of some customers to suspend the clinical trials underway, due to the global COVID-19 emergency, may have—in the absence of any future changes—a negative impact on sales revenues from activities on behalf of third parties, especially in the second half of 2020, and may generate lower operating results compared to those that may be expected following the trend recorded in the last few quarters.

With the beginning of phase 2 of the COVID-19 emergency, the Company completed its risk analysis to fully and orderly resume operations based on best practices and in compliance with national and regional legislative provisions. The Crisis Committee is responsible for managing the activities necessary to ensure business continuity in order for the Company to continue as a going concern within a constantly changing scenario.



## Condensed Interim Financial Statements at June 30, 2020

## 10. Statement of financial position

(amounts in Euro thousand )	Note	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019
ASSETS			
Tangible assets	1	18,387	18,971
Intangible assets	2	377	423
Financial assets	3	206	206
Tax receivables	4	-	2,601
TOTAL NON-CURRENT ASSETS		18,970	22,201
Inventories	5	2,644	1,830
Trade receivables and other commercial assets	6	10,636	9,911
Tax receivables	7	2,667	2,528
Other receivables and sundry assets	8	651	542
Cash and cash equivalents	9	14,429	9,904
TOTAL CURRENT ASSETS		31,027	24,715
TOTAL ASSETS		49,997	46,916
LIABILITIES AND SHAREHOLDERS' EQUITY			
Capital		21,819	21,819
Share premium reserve		61,754	61,754
Other reserves		217	217
Retained earnings (accumulated losses)		(60,617)	(60,190)
Profit (loss) for the period/year		2,390	(427)
TOTAL SHAREHOLDERS' EQUITY	10	25,563	23,173
Liabilities for pensions and employee severance indemnity (TFR)	11	129	150
Financial debts	12	6,726	7,325
Other liabilities	13	1,812	2,944
TOTAL NON-CURRENT LIABILITIES		8,667	10,419
Provision risk	14	256	611
Trade payables	15	10,297	8,230
Financial debts	16	1,204	1,204
Tax payables	17	137	87
Other liabilities	18	3,872	3,192
TOTAL CURRENT LIABILITIES		15,766	13,324
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY		49,997	46,916



#### 11. Income statement

(amounts in Euro thousand )		1 <sup>st</sup> half 2019	1 <sup>st</sup> half 2018
	Note	1" half 2019	1° haif 2018
Revenues	19	20,358	16,313
Other revenue	20	379	63
Total operating revenues		20,737	16,376
Purchases of raw materials and consumables	21	(3,795)	(3,706)
Costs for services	22	(5,616)	(5,866)
Costs for use of third-party assets	23	(43)	(70)
Personnel costs	24	(7,044)	(6,870)
Other operating costs	25	(82)	(84)
Amortization and depreciation	26	(1,499)	(1,677)
Total operating costs		(18,079)	(18,273)
Operating result		2,658	(1,897)
Financial income		3	51
Financial charges		(134)	(76)
Net financial income (charges)	27	(131)	(25)
Pre-tax result		2,527	(1,922)
Income taxes	28	(137)	-
Profit (loss) for the period		2,390	(1,922)
(amounts in Euro)	1 <sup>st</sup> ha	lf 2020 1 <sup>s</sup>	t half 2019

Basic earnings/(loss) per share 0,0052 (0.0041)
Diliuted earnings/(loss) per share 0,0052 (0.0041)

## 12. Statement of comprehensive income

(amounts in Euro thousand )	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019
Profit (loss) for the period	2,390	(1,922)
Other comprehensive income (not subsequently reclassified to the income statement)		
Profit (loss) actuarial	-	-
Other comprehensive income, net of taxes (not subsequently reclassified to the		
income statement)	-	-
Total comprehensive income (loss) for the period	2,390	(1,922)

<sup>\*</sup> The calculation of basic earnings (loss) per share is based on the net profit/loss of the first half of 2020 and 2019, amounting to a profit of 2,390 thousand Euro and a loss of 1,922 thousand Euro, respectively, and on the weighted average of the ordinary shares outstanding in the two periods equal to 463,450,672. There are no financial instruments that could potentially be converted into dilutive ordinary shares.



## 13. Statement of cash flows

(amounts in Euro thousand)		1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019
Opening cash and cash equivalents	Α	9,904	15,507
Cash flow from operating activities:			
Profit (loss) for the year		2,390	(1,922)
Amortization of assets		1,499	1,477
IFRS16 effetcs		(599)	(626)
Amortization pro-quota Bresso		(167)	(167)
Write down of fixed asset and assets items		-	200
Non monetary costs		125	-
Reversal of non monetary financial income and charges		84	(65)
Cash flow from operating activities before changes in working capital	al	3,332	(1,103)
Changes in current assets and liabilities:			
(Increase) decrease in inventories		(814)	(385)
(Increase) decrease in trade and other receivables		(974)	(3,130)
Increase (decrease) in trade and other payables		2,117	259
Increase (decrease) in other liabilities		(681)	429
Total changes in current assets and liabilities		(351)	(2,827)
(Increase) decrease in non-current tax receivables		2,601	1,969
Increase (decrease) in non current trade liabilities		-	(200)
Increase (decrease) in other liabilities and TFR paid		(21)	(200)
Total cash flow generated (absorbed) by operating activities	В	5,561	(2,361)
Cash flow from investing activities:			
Net (investment) divestment in tangible assets		(1,013)	(547)
Net (investment) divestment in intangible assets		(23)	(72)
Total cash flow generated (absorbed) by investing activities	С	(1,036)	(619)
Total cash flow generated (absorbed) by financing activities	D	-	-
Cash flow generated (absorbed) during the period	E=B+C+D	4,525	(2,980)
Closing cash and cash equivalents	A+E	14,429	12,527

## 14. Statement of changes in equity

(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
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	-	-	-	-	-	(1,922)	(1,922)
Balance at June, 30 <sup>th</sup> 2019	21,819	61,754	223	(11)	(60,190)	(1,922)	21,673
(amounts in Euro thousand)					Retained	·	

(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
Balance at January, 1st 2020	21,819	61,754	223	(6)	(60,190)	(427)	23,173
Allocation of prior year result	-	-	-	-	(427)	427	-
Profit (loss) for the period	-	-	-	-	-	2,390	2,390
Balance at June, 30 <sup>th</sup> 2020	21,819	61,754	223	(6)	(60,617)	2,390	25,563



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#### **Notes**

### 1. General information

MolMed's Condensed Interim Financial Statements for the period ended June 30<sup>th</sup>, 2020 have been prepared in compliance with the International Accounting Standards ("IFRSs") issued by the International Accounting Standards Board ("IASB") and endorsed by the European Union, as well as with the provisions issued pursuant to Article 9 of Italian Legislative Decree 38/2005. Where this document refers to "IFRSs", it is also intended to include the revised International Accounting Standards (IASs) currently in force, as well as all the interpretations issued by the International Financial Reporting Interpretations Committee ("IFRIC"), previously known as Standing Interpretations Committee ("SIC"). These Condensed Interim Financial Statements for the period ended June 30<sup>th</sup>, 2020 have been prepared in accordance with IAS 34 – Interim Financial Reporting.

These Condensed Interim Financial Statements do not include the disclosure required for the preparation of the Annual Financial Statements; and therefore, they should be read together with the Annual Financial Statements for the year ended December 31<sup>st</sup>, 2019. The accounting standards and basis of measurement applied to prepare these Condensed Interim Financial Statements for the period ended June 30<sup>th</sup>, 2020 are the same as those adopted to prepare the Annual Financial Statements for the year ended December 31<sup>st</sup>, 2019, to which reference should be made, except for the new standards, amendments and interpretations applicable on or after January 1<sup>st</sup>, 2020.

This half-year financial report at June 30<sup>th</sup>, 2020 was authorized for issue by the Board of Directors on July 27<sup>th</sup>, 2020.

### 2. Accounting standards and basis of measurement

#### Going concern

The Company's dual business model includes both R&D activities on proprietary products and development and manufacturing services on behalf of third parties which have become prevalent nowadays. In line with biotech companies developing new therapeutic products and that have not reached a balanced income and financial position yet, these activities feature negative cash flows. This is due to the fact that at this stage considerable costs must be borne in relation to the testing and development of investigational new drugs, and return is not certain and in any case it is expected in forthcoming years. As for now, costs are not directly correlated to income.

In the field where it operates, the Company is constantly faced with a highly competitive environment and must compete every day with entities that surpass it in terms of size, stage of development of their products, and financial resources at their disposal, and are thus more attractive on capital markets also thanks to their geographical location. Furthermore, the Company is subject to some uncertainties associated with the field in which it operates (notably, the current product trial stage, for both proprietary products and for third-party products in relation to which it provides development and manufacturing services) regarding both the results that it may actually achieve, and the relevant methods and timings.



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From an accounting perspective, consistently with the policies adopted, requiring full recognition of research and development costs in the income statement of the year they are incurred, the Company has always reported a loss since its incorporation.

The first six months of 2020 ended with positive cash flows and a 2,390 thousand Euro profit, up 4,312 thousand Euro in comparison with a 1,922 thousand Euro loss in the corresponding period of the prioryear, and positive cash flows. The growth of services on behalf of third parties, which caused revenues from development and manufacturing activities on behalf of third parties to rise by 24.8%, mainly contributed to bring the Company to profit in the reporting period. Given the trend in the Company's performance, management believes there is still untapped potential that could further help generate positive cash flows and is working on it.

Finally, in accordance with the three-year plan approved by the Board of Directors in December 2019, the Company will carry on the development of both activities on behalf of third parties and its main proprietary product. Specifically:

- carrying on with investments in clinical research and development activities, aimed at enhancing the peculiar features of the CAR-CD44v6 project;
- looking for new service agreements in relation to development and production activities on behalf of third parties;
- significantly expanding investments aimed at increasing both quantitative and qualitative offer (bioreactors and service types, respectively) to current and potential customers.

It should also be noted that, in December 2019, the Company entered into a financing arrangement with the European Investment Bank ("EIB") up to 15,000 thousand Euro over a term of 60 months aimed at supporting the research and development of the proprietary pipeline as well as the development of, and investments in, facilities. The funds can be drawn down in two tranches of 7,500 thousand Euro. Each tranche may be divided into two sub-tranches. The drawdown is subject to the review of predefined specific financial goals and milestones. At June 30<sup>th</sup>, 2020, the Company had not drawn down any tranche.

Considering the above, and based on the 14,429 thousand Euro in cash and cash equivalents at June 30<sup>th</sup>, 2020, the improvement of the result of the period compared to the prior year, the cash flows generated in the first half of 2020 and those expected in the business plan, as well as on the 15,000 thousand Euro credit facility made available by the European Investment Bank and currently unused, MolMed's management and Board of Directors believe that the Company has sufficient financial resources and equity to continue as a going concern for a foreseeable period of at least 12 months following the approval date of the half-year financial report. Therefore, management and the Board of Directors believe that this conclusion is based on reasonable assumptions and there was no material uncertainty as to the Company's ability to continue as a going concern at the approval date of the half-year financial report.

Specifically, should the Company need to raise spending beyond budgeted levels, or revenue and cash flows fall short of expectations, MolMed will reconsider the priorities of its development programs and potentially postpone some of them, use currently available credit lines, as well as explore all potential options to borrow funds or raise capital as well as grant marketing licenses, if necessary.



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#### Other information

#### Seasonality

The income statement for the period is not significantly subject to seasonal fluctuations in business levels.

#### Taxes

Income taxes for the half year are calculated using the tax rate that would be applicable to the total annual income expected in line with the provisions of IAS 34. Income taxes are recognized in the income statement, except for those relating to items which are directly charged or credited to equity; in this case the tax effect is directly recognized in equity.

Taxable income differs from the figure recognized in the income statement, as it does not include revenues and charges that will be taxable or deductible in future years, as well as the items that will never be taxable or deductible.

Deferred taxes are determined based on the taxes the Company is expected to pay or recover on the temporary differences between the carrying amount of assets or liabilities and their tax value used in calculating taxable income, and they are accounted for using the liability method.

Deferred tax liabilities are generally recognized for all taxable temporary differences, except for those cases in which the Company can monitor the reversal of these temporary differences and it is likely that they will not be reversed in the foreseeable future.

Any deferred tax assets, whether arising from temporary differences and/or accumulated tax losses, are recognized to the extent that it is likely that there will be future taxable income making it possible to use the deductible temporary differences and/or the accumulated tax losses. In this regard, Decree-Law 98/2011 governing urgent provisions for the financial stabilization of the country (Corrective Measure 2011) was converted into Law 111/2011, approved on July 15, 2011. In particular, the Decree-Law amended Article 84 of the Consolidated Law on Income Tax (TUIR) on the possibility to carry tax losses forward, by removing the 5-year time limit set for carrying tax losses forward (meaning that they can be endlessly carried forward), and introducing a quantitative limit to the use of previous tax losses equal to 80% of income generated in the following reporting periods. This 80% quantitative limit is not applicable to tax losses generated in the first three years since the company's incorporation, provided that they relate to a new business.

These assets and liabilities are not recognized if the temporary differences arise from goodwill or initial recognition (not from business combinations) of other assets or liabilities involved in transactions which do not have any impact on accounting or taxable results. The carrying amount of deferred tax assets is reviewed at the end of each reporting period and decreased if it is no longer probable that there will be sufficient future taxable income to allow recovery of all or part of the assets.

Deferred taxes are calculated by using the tax rates that the Company expects to be in force when the asset is realized or the liability is settled, taking account of the rates in force or issued at the end of the reporting period. If the relevant conditions are met, deferred taxes are directly recognized in the income statement, except for those concerning items directly recognized in equity. In this case, deferred taxes are also recognized in equity.

Current and deferred tax assets and liabilities are offset when it is allowed by the law, and they are classified as receivables or payables in the statement of financial position.

Taxes other than income taxes are included in other operating costs.



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#### **Use of estimates**

The preparation of interim financial statements requires management to make estimates and assumptions which have an impact on the amount of revenues, costs, assets and liabilities and on disclosure relating to contingent assets and liabilities at the end of the reporting period. If, in the future, such estimates and assumptions, which are based on management's best measurement, should differ from the real circumstances, they would be appropriately adjusted in the period in which such circumstances change. It should also be noted that some more complex measurement, such as the impairment of non-current assets, is generally fully performed on preparing the annual accounts, when all the necessary information is available, unless there are indications of impairment requiring assets to be tested immediately. At June 30<sup>th</sup>, 2020, there were no indicators of impairment as far as the recoverable amount of assets is concerned. In light of the results of the first half year, the prospects for reaching the 2020 budget and medium-long term estimates of the Company's results.

Accounting standards, amendments and interpretations applicable on or after January 1st, 2020

#### Amendments to IFRS 3: Definition of a business

The amendments to IFRS 3 clarify that to be considered a business, an integrated set of activities and assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output. In addition, the IASB clarified that a business can exist without including all of the inputs and processes needed to create outputs. These amendments had no impact on the Company's financial statements.

#### Amendments to IFRS 7, IFRS 9 and IAS 39: Interest Rate Benchmark Reform

The amendments to IFRS 9 and IAS 39 – Financial Instruments: Recognition and Measurement provide a series of expedients that apply to all hedging relationships directly affected by interest rate benchmark reform. A hedging relationship is affected if the reform generates uncertainties regarding the timing and/or amount of interest rate benchmark-based cash flows of the hedged item or the hedging instrument. These amendments had no impact on the Company's financial statements.

#### Amendments to IAS 1 and IAS 8: Definition of material

The amendments provide a new definition of material that states "information is material if omitting, misstating or obscuring it could reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements, which provide financial information about a specific reporting entity".

Materiality depends on the nature or magnitude of information, or both. An entity assesses whether information, either individually or in combination with other information, is material in the context of its financial statements taken as a whole.

Information is obscured if it is communicated in a way that would have a similar effect for primary users of financial statements to omitting or misstating that information.

These amendments had no impact on the Company's financial statements.



#### 3. Segment reporting

Focusing on biotechnology, MolMed's business is made up of a single operating segment concerning the research, development, clinical validation and manufacturing of innovative cell and gene therapies for the treatment of tumors and rare diseases in relation to both its products in the pipeline and third parties' products.

The essentially uniform nature of the activities performed and the progress of projects under development do not allow to break down business by sector based on risks and benefits.

The CEO is highest-level decision maker with regard to operating issues. The most significant decisions are submitted to the approval of the Board of Directors and of a Scientific Advisory Board (consisting of 5 members), in case of medical/technical issues. Precisely because the research, development and manufacturing activity is considered as a whole, the CEO is responsible for research and development activities as well as for activities carried out on behalf of third parties. Therefore, the CEO is responsible for the operating segment which is the only segment of the Company.

### 4. Notes to the statement of financial position

#### *Note 1 – Tangible assets*

The breakdown and changes in tangible assets at June 30th, 2020 are shown in the table below:

(amounts in Euro thousand)	December 31 <sup>st</sup> , 2019	Purchases	Reclassifications	Disposals	Depreciation and write downs	December June 30 <sup>th</sup> , 2020
Gross book value						
Plant and machinery	1,840	19	8	-	-	1,867
Industrial and commercial equipment	10,628	774	57	-	-	11,459
Leasehold improvements	10,055	109	-	-	-	10,164
Other tangible assets	1,779	85	33	-	-	1,897
Right of use (IFRS16)	9,753	-	-	-	-	9,753
Ass. under construction and payments on account	258	26	(98)	-	-	186
Total gross book value	34,313	1,013	-	-	-	35,326
Accumulated depreciation						
Plant and machinery	(755)	-	-	-	(85)	(840)
Industrial and commercial equipment	(5,658)	-	-	-	(545)	(6,203)
Leasehold improvements	(6,375)	-	-	-	(252)	(6,627)
Other tangible assets	(1,293)	-	-	-	(81)	(1,374)
Right of use (IFRS16)	(1,262)	-	-	-	(634)	(1,896)
Total accumulated depreciation	(15,343)	-	-	-	(1,597)	(16,940)
Net book value						
Plant and machinery	1,085	19	8	-	(85)	1,027
Industrial and commercial equipment	4,970	774	57	-	(545)	5,256
Leasehold improvements	3,680	109	-	-	(252)	3,536
Other tangible assets	486	85	33	-	(81)	523
Right of use (IFRS16)	8,491	-	-	-	(634)	7,857
Ass. under construction and payments on account	258	26	(98)	-	-	186
Total net book value	18,971	1,013	-	-	(1,597)	18,387

<sup>\*</sup> The depreciation shown in the table includes the portion relating to leasehold improvements at the site in Bresso. As detailed in the Notes, it was neutralized in the income statement following the pro rata reversal of the relevant deferred income.

The item "plant and machinery" includes plant and machinery used to develop the Company's products and to provide services. Other tangible assets include furniture, fittings and electronic office equipment.

"Leasehold improvements" include the cost of refurbishing pharmaceutical laboratories and offices. Such costs concern building work and work on the systems, and they are depreciated over the term of the lease agreement, i.e. 12 years starting from January 2015. Based on the agreement signed with the property's owner, the costs necessary to renovate the property and make it fully operational, up to a maximum amount



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of 4,000 thousand Euro, are borne by the property's owner. The Company transferred the costs incurred for extraordinary maintenance work to the owner up to the previously-mentioned amount.

Tangible assets decreased from 18,971 thousand Euro at December 31<sup>th</sup>, 2019 to 18,387 thousand Euro at June 30<sup>th</sup>, 2020.

During the first half of 2020, investments of 1,013 thousand Euro were made in tangible assets. They consist in (i) investments to bring new manufacturing facilities online, including purchases of new equipment used in the manufacturing process, (ii) maintenance and improvement work on the GMP facility, and (iii) investments in the routine replacement of laboratory equipment.

The most significant changes in the period include:

- the 774 thousand Euro increase in industrial and commercial equipment;
- the 105 thousand Euro increase in leasehold improvements.

Depreciation amounted to 1,597 thousand Euro at June 30<sup>th</sup>, 2020, compared to 1,391 thousand Euro recognized in the prior-year period. The depreciation includes the portion relating to leasehold improvements at the facility in Bresso, totaling 167 thousand Euro. This was neutralized in the income statement following the pro rata reversal of the relevant deferred income, as the costs of said improvements were charged to the site's owner up to an amount of 4,000 thousand Euro.

At June 30, 2020, no impairment indicators were identified, in light of the results obtained in the first half of the year, the prospects for reaching the 2020 budget and medium-long term estimates of the Company's results.

## *Note 2 – Intangible assets*

The breakdown and changes in intangible assets at June 30th, 2020 are shown in the table below:

(amounts in Euro thousand)	December 31 <sup>st</sup> , 2019	Purchases	Reclassifications	Disposals	Depreciation and write downs	June 30 <sup>th</sup> , 2020
Patents and intellectual property rights	86	-	-	-	(10)	76
Concessions, licenses and trademarks	321	23	-	-	(59)	285
Assets under construction	16	-	-	-		16
Intangible assets	423	23	-	-	(69)	377

Purchases of intangible assets, amounting to 23 thousand Euro, mainly include software licenses, while amortization totaled 69 thousand Euro.

#### *Note 3 – Financial assets*

Non-current financial assets of 206 thousand Euro were in line with the prior-year figures. They consist of guarantee deposits on leased facilities.

## *Note 4 – Tax receivables (non-current)*

Non-current tax receivables were zero at June 30<sup>th</sup>, 2020 compared to 2,601 thousand Euro at December 31<sup>st,</sup> 2019. This decrease is due to non-recourse factoring of 2019 VAT credits. Such credit was collected in April 2020.

#### *Note 5 – Inventory*

Inventory at June 30<sup>th</sup>, 2020 is broken down as follows:



(amounts in Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019	Change	% change
Processing materials	1,080	667	413	62.0%
Reagents	1,321	958	363	37.9%
General materials	243	205	38	18.6%
Total inventories	2,644	1,830	814	44.5%

Consisting of reagents and materials used in the Company's laboratories, inventory increased by 814 thousand Euro or 44.5%, from 1,830 thousand Euro at December 31<sup>st</sup>, 2019 to 2,644 thousand Euro at June 30<sup>th</sup>, 2020.

The increase was driven by greater purchases of materials in connection with rising production volumes as well as the decision to move purchases forward to ensure the continuity of manufacturing processes at a time when factors of production are in short supply.

The line item is reported net of a 291 thousand Euro provision for obsolete inventory (182 thousand Euro at December 31<sup>st</sup>, 2019). The amount set aside during the period was mainly associated with the depreciation of processing materials and reagents.

#### Note 6 – Trade receivables

The breakdown of trade receivables and other commercial assets at June 30th, 2020 is as follows:

(amounts in Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019	Change	% change
Trade receivables	4,971	4,433	538	12.1%
Prepayments	260	506	(246)	(48.6%)
Invoices to be issued	5,405	4,972	433	8.7%
Total trade receivables and other commercial assets	10,636	9,911	725	7.3%

Trade receivables and other commercial assets were up 725 thousand Euro or 7.3% from 9,911 thousand Euro at December 31<sup>st</sup>, 2019 to 10,636 thousand Euro at June 30<sup>th</sup>, 2020. The increase reflects the growth in sales revenues from services rendered on behalf of third parties and the billing and collection trends in relation to the services provided. Receivables are shown net of a bad debt provision equal to 278 thousand Euro. No changes occurred involving this provision during the period.

## *Note 7 – Tax receivables (current)*

Tax receivables at June 30th, 2020 are broken down as follows:

(amounts in Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019	Change	% change
VAT receivables	1,845	700	1,145	163.6%
Tax credit R&D costs	822	1,826	(1,004)	(55.0%)
Withholding taxes	-	2	(2)	(100.0%)
Total tax receivables	2,667	2,528	139	5.5%

Current tax receivables amounted to 2,667 thousand Euro at June 30<sup>th</sup>, 2020, thus increasing by 139 thousand Euro or 5.5% compared to the amount of 2,528 thousand Euro recognized at December 31<sup>st</sup>, 2019.

Current tax receivables included 1,845 thousand Euro in VAT credits accruing during the reporting period and 1,826 thousand Euro in the research and development tax credit for the year 2019, of which 822 thousand Euro have not yet been utilized to offset other taxes in accordance with applicable law.



## Note 8 – Other receivables and sundry assets

Other receivables and sundry assets at June 30th, 2020 are broken down as follows:

(amounts in Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019	Change	% change
Prepayments relating to costs not pertaining to the period	573	352	222	63.0%
Other receivables	78	190	(112)	(58.8%)
Total other receivables and sundry asset	651	542	110	20.3%

Other receivables and sundry assets amounted to 651 thousand Euro at June 30<sup>th</sup>, 2020, thus increasing by 109 thousand Euro or 20.1% compared to the amount of 542 thousand Euro recognized at December 31<sup>st</sup>, 2019. They consist of 573 thousand Euro advances to suppliers for research and development activities, including:

- ✓ prepayments of 384 thousand Euro relating to operating costs incurred for contracts with "advance billings" and maintenance and assistance fees for information services and other minor amounts;
- ✓ insurance premium costs of 189 thousand Euro.

## *Note 9 – Cash and cash equivalents*

Cash and cash equivalents are broken down as follows:

(amounts in Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019	Change	% change
Bank and post office accounts	14,427	9,901	4,526	45.7%
Cash on hand	2	3	(1)	(33.3%)
Total cash and cash equivalents	14,429	9,904	4,525	45.7%

At June 30<sup>th</sup>, 2020 cash and cash equivalents amounted to 14,429 thousand Euro (9,904 thousand Euro at December 31<sup>st</sup>, 2019), including 14,427 thousand Euro of bank deposit accounts and 2 thousand Euro of cash on hand. The above amounts are unencumbered by liens or restrictions or significant transaction costs.

### *Note 10 – Equity*

Equity totaled 25,563 thousand Euro at June 30<sup>th</sup>, 2020. Its breakdown is as follows:

(amounts in Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019	Change	% change
Share capital	21,819	21,819	-	0.0%
Share premium reserve	61,754	61,754	-	0.0%
Other reserves:	0	0	-	0.0%
Actuarial valuation reserve	(6)	(6)	-	0.0%
Other	223	223	-	0.0%
Retained earnings (accumulated losses)	(60,617)	(60, 190)	(427)	0.7%
Profit (loss) for the year	2,390	(427)	2,817	(659.7%)
Total shareholders' equity	25,563	23,173	2,390	10.3%



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## Share capital

At June 30<sup>th</sup>, 2020, the fully paid-in share capital amounted to 21,819 thousand Euro and consisted of 463,450,672 ordinary shares with no par value.

Shareholder	No. of shares (*)	%
Fininvest S.p.A. (*)	107,173,138	23
Cicogne Found (*)	9,206,000	2
Other	347,071,534	75
Total	463,450,672	100.00

<sup>\*</sup> based on the Company's figures at April 27th, 2020

#### Share premium reserve

Share premium reserve totaled 61,754 thousand Euro at the end of the reporting period. No changes occurred in the first half of 2020.

#### Other reserves

Other reserves are broken down as follows:

#### a) Actuarial valuation reserve

The actuarial valuation reserve was negative to the tune of 6 thousand Euro at June 30<sup>th</sup>, 2020, and it was unchanged compared to the previous year.

#### *b)* Other reserves

Other reserves of 223 thousand Euro mainly consist of the following:

- a 45 thousand Euro reserve for unexercised rights relating to the 2014 share capital increase including income arising from the sale of such rights;
- a 178 thousand Euro reserve for unexercised rights relating to the 2015 share capital increase including income arising from the sale of such rights.

## Retained earnings (accumulated losses)

This item totaled 60,617 thousand Euro at June 30<sup>th</sup>, 2020. The 427 thousand Euro change compared to the period ended December 31<sup>st</sup>, 2019 is attributable to the recognition of the loss for 2019 as accumulated losses, as per the Shareholders' Meeting resolution of April 27<sup>th</sup>, 2020.



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## Main equity items

(amounts in Euro thousand)	Balance at December June 30 <sup>th</sup> 2020	Purpose of use	Amount available
December			
Reserves			
-Share premium reserve	61,754	A,B	61,754
-Other reserves			
- Actuarial valuation reserve	(6)	-	-
- Unexercised rights 2014 reserve	45	A,B	45
- Unexercised rights 2015 reserve	178	A,B	178
-Retained earnings (accumulated losses)	(60,617)	-	-

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A: for share capital increase

B: for coverage of losses

C: for distribution to shareholders

## *Note 11 – Liabilities for pensions and employee severance indemnity (TFR)*

This item includes all liabilities for pension schemes and other employee benefits following termination of the employment relationship or payable when certain requirements are met. It consists of accruals relating to the employee severance indemnity (TFR) pertaining to Company's staff. Liabilities for pensions and employee severance indemnity totaled 129 thousand Euro at June 30<sup>th</sup>, 2020 (150 thousand Euro at December 31<sup>st</sup>, 2019). Changes in the period are as follows:

(amounts in Euro thousand)	June 30 <sup>th</sup> ,	December 31 <sup>st</sup> ,
	2020	2019
Opening balance	150	143
Uses	(21)	-
Financial loss	-	2
Actuarial (gain)/loss	-	5
Total liabilities for pensions and employee severance indemnity (TFR)	129	150

Under IAS 19, the employee severance indemnity has been considered as a "defined benefit plan", determined on the basis of actuarial calculations performed by an external consultant in accordance with international accounting standards.

#### *Note 12 – Financial payables (non-current)*

Non-current financial payables of 6,726 thousand Euro were recognized at June 30<sup>th</sup>, 2020, as a consequence of the adoption of IFRS 16 – Leases starting from 2019. The standard sets out a comprehensive model for the identification of lease arrangements and their treatment in the financial statements of the lessee. Assets held under a lease (including an operating lease) shall be recognized as assets in an entity's statement of financial position and the relevant financial payable shall be accounted for (both the current and non-current portion).

## *Note 13 – Other liabilities (non-current)*

Other non-current liabilities amounted to 1,812 thousand Euro at June 30<sup>th</sup>, 2020. This item includes the deferred income relating to costs incurred for the Bresso facility. Based on the agreement signed with the property's owner, the costs to renovate the property and make it fully operational, up to a maximum amount



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of 4,000 thousand Euro, shall be borne by the owner. The Company transferred the costs incurred for extraordinary maintenance work to the owner. Costs are recorded as leasehold improvements and deferred income arising from the owner's contribution is also recognized. The relevant recognition in the income statement is based on the lease duration.

The Company reclassified most of the deferral as non-current following the formal delivery of the offices in 2014 and the laboratories in 2015. The event triggered the beginning of the depreciation period, estimated at 12 years based on the lease agreement. The Company continued recognizing 333 thousand Euro, representing the depreciation for the next 12 months, as current liabilities.

The 167 thousand Euro decrease in the period is due to the reclassification of the depreciation relating to the January-to-June 2020 period from long to short term.

#### *Note 14 – Provisions for risks and charges (current)*

Provisions for risks and charges (current portion) declined from 611 thousand Euro at December 31<sup>st</sup>, 2019 to 256 thousand Euro at June 30<sup>th</sup>, 2020. They consist of:

- restructuring risk provision to the tune of 196 thousand Euro. MolMed had initially recognized this provision in 2019 following a functional reorganization at an amount of 551 thousand Euro. The provision at June 30<sup>th</sup>, 2020 reflected the expected outflows associated with the Company's restructuring in the wake of the reorganization caused by the decision to stop investing in the research and development of both autologous CAR-T and allogeneic CAR-NK;
- commercial risk provision: it was set aside for a contingent liability associated with the insolvency proceedings of a cleaning services supplier that directors deemed likely to occur and totals 60 thousand Euro. This item did not change compared to the previous period.

Below are the changes occurred during the period:

(amounts in Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019
Opening balance	611	_
write-off (used)	(480)	
Provison	125	611
Provison for risk and charges (current)	256	611



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## *Note 15 – Trade payables*

Trade payables amounted to 10,297 thousand Euro at June 30<sup>th</sup>, 2020, compared to 8,230 thousand Euro at December 31<sup>st,</sup> 2019, and are broken down as follows:

(amounts in Euro thousand)	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019	Change	% change
Trade payables	7,865	6,226	1,639	26.3%
Deferred income concerning revenues pertaining to future periods	2,432	2,004	428	21.4%
Total trade payables	10,297	8,230	2,067	25.1%

At June 30<sup>th</sup>, 2020, payables to suppliers included 6,587 thousand Euro due in Italy, 1,143 thousand Euro due in other European Union countries and 133 thousand Euro due in other countries (mainly in USD).

Deferred income mainly refers to revenues from cell and gene therapy services to be provided by the Company in 2020. The 2,432 thousand Euro deferred income was recognized with respect to invoices that, as per the relevant agreements, were issued to customers prior to the actual rendering of the services, and will be recognized in the income statement as revenues when the service will be rendered.

## *Note 16 – Financial payables (current)*

Current financial payables of 1,204 thousand Euro at June 30<sup>th</sup>, 2020 consist in the current portion of the payables recognized after the adoption of IFRS 16 – Lease starting from 2019.

#### *Note 17 – Tax payables (current)*

Current tax payables amounted to 137 thousand Euro at June 30<sup>th</sup>, 2020 and represented the Company's IRAP liability for the first half of 2020.

#### *Note 18 – Other liabilities*

This item is broken down as follows:

(amounts in Euro thousand)	June 30 <sup>th</sup> ,	December 31 <sup>st</sup> ,	Change	% change
	2020	2019		
Amounts due to employees for holidays and bonuses	1,596	1,408	188	13.4%
Amounts due to social security institutions	634	676	(42)	(6.2%)
Tax payables	406	382	24	6.3%
Other payables	903	305	598	196.1%
Deferred income (Bresso)	333	421	(88)	(20.9%)
Total other liabilities	3,872	3,192	680	21.3%

Amounts due to employees for remuneration, holiday and bonus pay increased by 188 thousand Euro, from 1,408 thousand Euro at December 31<sup>st</sup>, 2019 to 1,596 thousand Euro at June 30<sup>th</sup>, 2020.

Amounts due to social security institutions and tax payables consist of withholding taxes and social security contributions on employee salaries and on the remuneration of freelance consultants for the month of June 2020, but paid to the authorities the following month.

Other payables totaled 903 thousand Euro, up 598 thousand Euro from December 31st, 2019, and mainly included:

 625 thousand Euro in payables for third-party contributions, consisting in the advance payment received from the European Community for the EURECART project less the receivables for grants accrued at June 30<sup>th</sup>, 2020 and relating to work already performed and accounted for;



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Payables due in relation to other remuneration to be paid by the Company concerning the amount owed to the former Chairman of the Board of Directors for the award of 800 thousand Euro in one-off gross compensation during the third quarter of 2018 following the termination of his employment with the Company on September 24<sup>th</sup>, 2018 and the 24-month non-compete agreement signed on January 26<sup>th</sup>, 2017. Said compensation is to be paid in installments over 24 months, resulting in a 278 thousand Euro residual payable at June 30<sup>th</sup>, 2020 net of the installments already paid.

Accrued liabilities and deferred income relate to the current amount of 333 thousand Euro: the depreciation for the next 12 months of an amount equal to 4,000 thousand Euro, recorded as leasehold improvements and charged to the owner of the property in the Open Zone park in Bresso. Based on the agreement signed with the property's owner, the costs to renovate the property and make it fully operational, up to a maximum amount of 4,000 thousand Euro, shall be borne by the owner. The Company transferred the costs incurred for extraordinary maintenance work to the owner.

Costs are recorded as fixed assets and deferred income arising from the owner's contribution is also recognized. The relevant recognition in the income statement is based on the lease duration. The Company reclassified most of said deferral as non-current following the formal delivery of the offices in 2014 and the laboratories in 2015. The event triggered the beginning of the depreciation period, estimated at 12 years based on the lease agreement.

## 5. Notes to the income statement

#### *Note 19 –Revenues*

(amounts Euro thousand)	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2020 1 <sup>st</sup> half 2019		% change	
Revenues from development and manufacturing activities	20,358	16,313	4,045	24.8%	
- of which Milestones	475	675	(200)	(29.6%)	
Total revenues	20,358	16,313	4,045	24.8%	

Revenues amounted to 20,358 thousand Euro at June 30<sup>th</sup>, 2020, based on recognition at a point in time, increasing by 4,045 thousand Euro or 24.8% compared to the prior-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 period.

3.5% of sales revenues were generated in Italy (compared to 4.8% in the prior-year period), 17.3% in the European Union (compared to 86.0% in the prior-year period) and 79.1% in non-EU countries (compared to 9.2% in the prior-year period).



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#### Note 20 – Other income

The breakdown of this item, standing at 379 thousand Euro, shows a 316 thousand Euro increase, compared with the same figure at June 30<sup>th</sup>, 2019 and consists of:

- public contributions to research and development activities to the tune of 269 thousand Euro (63 thousand Euro in the prior-year period);
- insurance reimbursements of 23 thousand Euro;
- 87 thousand Euro resulting from the exemption from paying the balance of the Italian regional tax on productive activities (IRAP) for the year 2019, in accordance with Italian Law Decree 34/2020 ("Relaunch").

## *Note 21 – Purchases of raw materials and consumables*

This item is broken down as follows:

(amounts Euro thousand)	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019	Change	% change
Processing materials	1,336	1,092	244	22.4%
Reagents	1,667	1,973	(306)	(15.5%)
General laboratory materials	677	641	36	5.6%
Slow moving materials	115	-	115	100.0%
Total purchases of raw materials and consumables	3,795	3,706	89	2.41%

Costs for raw materials and consumables, which consist of process materials and reagents used in manufacturing and development activities, increased from 3,706 thousand Euro at June 30<sup>th</sup>, 2019 to 3,795 thousand Euro at June 30<sup>th</sup>, 2020. The change of 89 thousand Euro or 2.4% was attributable to:

- the 244 thousand Euro increase (+22.4%) in the consumption of processing materials associated with the rising value of production;
- the decline (-15.5%, 306 thousand Euro) in the consumption of reagents, mainly driven by MolMed's decision to scale back research and development after discontinuing pre-clinical development projects during the period;
- the amount set aside for slow-moving materials previously purchased to support research and development operations.



## *Note 22 – Costs for services*

(amounts Euro thousand)	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019	Change	% change
Outsourced quality control	1,290	712	578	81.2%
Outsourced development costs	167	1,103	(936)	(84.9%)
Consultancy and technical fees	232	516	(284)	(55.1%)
License and patents consultancy fees	81	266	(185)	(69.6%)
Maintenance	631	536	95	17.7%
Transport and storage of laboratory materials	235	276	(41)	(14.8%)
Utilities	584	562	22	3.8%
Directors and statutory auditors' fees	217	191	26	13.7%
Audit	42	41	1	1.9%
Legal, administrative and managerial fees	934	237	697	294.0%
Listing consultancy fees and other listing costs	52	38	14	35.8%
Supervisory board fees	70	61	9	14.1%
Communications agency fees	72	118	(46)	(39.3%)
IT assistance and other IT costs	275	255	20	7.8%
Other general and administrative costs	461	537	(76)	(14.1%)
Ttravel, staff training and othe personnel costs	275	417	(142)	(34.1%)
Total costs for services	5,616	5,866	(250)	(4.3%)

Costs for services declined from 5,866 thousand Euro at June 30<sup>th</sup>, 2019 to 5,616 thousand Euro at June 30<sup>th</sup>, 2020. The change of 250 thousand Euro or 4.3% was mainly attributable to:

- outsourced quality controls, increasing by 587 thousand Euro or 81.2%, from 712 thousand Euro at June 30<sup>th</sup>, 2019 to 1,290 thousand Euro at June 30<sup>th</sup>, 2020. This was largely driven by the expansion of outsourced quality controls on third-party operations as a result of rising revenues from operations on behalf of third parties;
- outsourced development costs, decreasing by 936 thousand Euro or 84.9%, from 1,103 thousand Euro at June 30<sup>th</sup>, 2019 to 167 thousand Euro at June 30<sup>th</sup>, 2020. This was mostly attributable to the decline in outsourced research and development costs associated with the proprietary pipeline following the decision to halt research and development on autologous CAR-T and allogeneic CAR-NK.
- consulting and technical fees, decreasing by 284 thousand Euro or 55.1%, from 516 thousand Euro at June 30<sup>th</sup>, 2019 to 232 thousand Euro at June 30<sup>th</sup>, 2020. The reduction was largely driven by the decline in clinical and regulatory consulting fees as well as IRB fees following the Company's decision to suspend the clinical trials of TK and CD44v6 CAR-T cells;
- costs for license fees and patents, decreasing by 185 thousand Euro or 69.6%, from 266 thousand Euro at June 30<sup>th</sup>, 2019 to 81 thousand Euro at June 30<sup>th</sup>, 2020. This reflected the reduction in outsourced license and patent fees in the wake of the changes made to the Company's strategy, which caused proprietary pipeline research projects to be discontinued;
- costs for legal and administrative consulting services, increasing by 697 thousand Euro or 294.0%, from 237 thousand Euro at June 30<sup>th</sup>, 2019 to 934 thousand Euro at June 30<sup>th</sup>, 2020. This was largely attributable to the rise in legal and consulting fees incurred for the fairness opinion provided to the Board of Directors with respect to the takeover bid price;
- costs for training, travel and other personnel costs, decreasing by 142 thousand Euro or 34%, from 417 thousand Euro at June 30<sup>th</sup>, 2019 to 275 thousand Euro at June 30<sup>th</sup>, 2020. This was mainly



driven by the decline in travel, training, canteen, and conference expenses in the wake of the lockdown triggered by the COVID-19 pandemic.

## *Note 23 – Costs for use of third-party assets*

Costs for use of third-party assets decreased by 27 thousand Euro, from 70 thousand Euro at June 30<sup>th</sup>, 2019 to 43 thousand Euro at June 30<sup>th</sup>, 2020.

#### *Note 24 – Personnel costs*

These costs are broken down as follows:

(amounts Euro thousand)	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019	Change	% change
Wages and salaries	5,158	5,142	16	0.3%
Social security contributions	1,447	1,457	(10)	(0.7%)
Defined contribution plans	263	256	7	2.8%
Stock option costs	125	-	125	100.0%
Other personnel costs	51	15	36	240.0%
Total personnel costs	7,044	6,870	174	2.5%

Personnel costs increased by 2.5% from 6,870 thousand Euro at June 30<sup>th</sup>, 2019 to 7,044 thousand Euro at June 30<sup>th</sup>, 2020. The 174 thousand Euro increase was largely attributable to the 125 thousand Euro the Company set aside in connection with the reorganization after discontinuing the development of proprietary projects during the period.

Personnel costs also 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 30<sup>th</sup>, 2019 and following the appointment of corporate bodies on the same date.

Please also refer to note 31 Potential Liabilities, Commitments and Other guarantees for the information related to the one-off extraordinary emolument approved by the Board of Directors, in the event of a successful tender offer, due to the significant activity carried out by the President and the CEO, from the moment of their establishment, in terms of creating value for the Company.

At June 30<sup>th</sup>, 2020, the exact number of employees was 223 (compared to 215 at June 30<sup>th</sup>, 2019), while during the first half of 2020 the average number of employees was 219 (215 in the first half of 2019). The breakdown by position is as follows:

	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019
Executives	6	9
Middle management	31	35
Clerical staff	179	167
Technicians	3	4
Total	219	215



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## *Note 25 – Other operating costs*

The item "other operating costs", amounting to 82 thousand Euro at June 30<sup>th</sup>, 2020, is in line with the prioryear figure (84 thousand Euro).

#### Note 26 – Amortization, depreciation and impairment

These costs are broken down as follows:

(amounts Euro thousand)	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019	Change	% change
Amortization of intangible assets	69	86	(17)	(19.8%)
Depreciation of tangible assets	1,430	1,391	39	2.8%
Write-downs	-	200	(200)	(100.0%)
Total amortization, depreciation & write-downs	1,499	1,677	(178)	(10.6%)

Amortization, depreciation and impairment amounted to 1,499 thousand Euro at June 30<sup>th</sup>, 2020, decreasing by 178 thousand Euro compared to the prior-year period (1,677 thousand Euro).

The line item was down compared to the first half of 2019 mainly because during that period the Company had written down a tax credit previously recognized as a non-current tax receivable by 200 thousand Euro. This item was recognized net of the relevant depreciation on leasehold improvements at the facility in Bresso totaling 167 thousand Euro and charged to the site's lessor. This was neutralized in the income statement following the pro rata reversal of the relevant deferred income. For further details, reference should be made to **Note 13 and 28.** 

## *Note 27 – Financial income and charges*

This item is broken down as follows:

(amounts in Euro thousand)	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019	Change	% change
FINANCIAL INCOME:				
Interest and other financial income	-	50	(50.00)	(100.0%)
Exchange gains	2	1	1.00	100.0%
Total financial income	2	51	(49.00)	(96.1%)
FINANCIAL CHARGES:				
Exchange losses	(4)	(4)	-	0.0%
Finacial charges (IFRS16)	(81)	(45)	(36)	80.0%
Other charges	(48)	(27)	(21)	77.8%
Total financial charges	(133)	(76)	(57.00)	75%
Total financial income (charges)	(131)	(25)	(106.00)	424%

The Company's financial activities generated a negative amount of 131 thousand Euro, increasing by 106 thousand Euro compared to June 30<sup>th</sup>, 2019. This was mainly attributable to the recognition of interest expense associated with the application of IFRS 16 as well as the absence of financial income from investments that were discontinued after December 2019.

#### *Note 28 – Income taxes*

At the reporting date, MolMed recognized a 137 thousand Euro provision for the Italian regional tax on productive activities ("IRAP"). In accordance with Italian Law Decree 34/2020 ("Relaunch"), the Company did not pay the 2019 IRAP balance and the 40% estimated IRAP payment for 2020.

At 30 June 2020, income taxes are calculated using the tax rate that would be applicable to the total



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expected annual income.

At the end of the previous year, the tax losses to be carried forward totaled 211,022 thousand Euro and the theoretical deferred tax assets totaled 50,645 thousand Euro. In accordance with the relevant accounting standards, during the period the Company did not recognize deferred tax assets.

## *Note 29 – Basic and diluted earnings (loss) per share*

The basic earnings (loss) per share are detailed below:

(amounts in Euro)	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019	
Basic earnings/(loss) per share	0,0052	(0.0041)	
Diliuted earnings/(loss) per share	0,0052	(0.0041)	

As required under IAS 33, diluted earnings (loss) per share take into account the effects of all dilutive potential ordinary shares. There were no dilutive financial instruments at June 30<sup>th</sup>, 2020.

Calculation of basic earnings (loss) per share is based on the net profit/loss of the first half of 2020 and 2019, amounting to a profit of 2,390 thousand Euro and a loss of 1,922 thousand Euro, respectively, and on the weighted average of the ordinary shares outstanding in the two periods equal to 463,450,672.

## 6. Other notes

#### *Note 30 – Net financial position*

(amounts Euro thousand)	June 30 <sup>th</sup> ,	December 31 <sup>st</sup> ,	Change	Change %
	2020	2019	Onlango	onungo 70
Cash on hand	2	3	(1)	(33.3%)
Other cash	14,427	9,901	4,526	45.7%
A. Total cash and cash equivalents	14,429	9,904	4,525	45.7%
B. Current financial receivables and other financial assets	-	-	-	-
Liabilities to financial leasing entities (IFRS16)	(1,204)	(1,204)	-	-
C. Current financial debt	(1,204)	(1,204)	-	-
D. Net current financial position (A+B+C)	13,225	8,700	4,525	52.0%
Liabilities to financial leasing entities (IFRS16)	(6,726)	(7,325)	599	(8.2%)
E. Non-current financial debt	(6,726)	(7,325)	599	(8.2%)
F. Net financial position (D+E)	6,499	1,375	5,124	372.7%
G. IFRS16 effects - current	1,204	1,204	-	-
H. IFRS16 effects - non current	6,726	7,325	(599)	(8.2%)
I. I. Net financial position - NO IFRS 16 effects	14,429	9,904	4,525	45.7%

The net financial position was up 5,124 thousand Euro, from 1,375 thousand Euro at December 31<sup>st</sup>, 2019 to 6,499 thousand Euro at June 30<sup>th</sup>, 2020. MolMed's net financial position is calculated in compliance with IFRS 16 – Leases with finance lease payables recognized as current and non-current financial payables. The period change is due to the net liquidity generated by the Company's operations supporting the period business, the non-recourse factoring and collection of VAT credits to the tune of 2,601 thousand Euro, the partial use of tax credits for research and development purposes, offsetting INPS contributions and IRPEF withholding taxes, which effectively resulted in lesser financial outlay in the amount of 1,004 thousand Euro, and the change in finance lease payables resulting from the application of IFRS 16. Net of the effects arising from the adoption of IFRS 16, the net financial position would have amounted to 14,429 thousand at June



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30<sup>th</sup>, 2020 compared to 9,904 thousand Euro at December 31<sup>st</sup>, 2019.

#### *Note 31 – Contingent liabilities, commitments, and guarantees*

## Contingent liabilities

With respect to CAR-T CD44v6, under existing agreements the Company is to pay a third party a fee amounting to 2% of the sales of the product and 20% of the proceeds from licensing the product to third parties. At the date of preparation of these interim financial statements, the above conditions did not occur.

On April 30<sup>th</sup>, 2019, the Board of Directors decided to award the CEO an amount equal to his fixed remuneration, totaling 450 thousand Euro per year, for the remainder of his term in office or until the approval of the financial statements as at December 31<sup>st</sup>, 2021 only in the event of termination under "good leaver" circumstances. The following are regarded as "good leaver" circumstances: (i) removal from the position of director without just cause; (ii) resignation as board member in the event the CEO is substantially divested of his powers, resulting in a substantive alteration of his relationship with the Company, without just cause. At the date of preparation of these interim financial statements, the above conditions did not occur.

On April 14<sup>th</sup>, 2020, at the proposal of the Remuneration and Nomination Committee and in accordance with the Company's Remuneration Policy, in recognition of the substantial work performed by the Chairman and the Chief Executive Officer since their respective appointment in terms of value created for the Company, the Board of Directors has authorized, a one-off payment amounting to 1,300 thousand Euro and 1,000 thousand Euro, respectively, subject to the success of the takeover bid.

Subject to the completion of the takeover bid on July 24<sup>th</sup>, 2020, the Company shall pay an amount equal to 2.5% of the bid price to the investment bank that assisted it.

At 30 June 2020, only n. 145,881,025 shares, equal to 31.477% of the ordinary shares, had been made to the takeover bid (compared to a minimum required equal to 66.667% of the ordinary shares), therefore in consideration of the fact that none of the three conditions set by the buyer in the Document of Offer had occurred, at June 30, 2020 there were significant uncertainties in relation to the onset of the above obligations, which therefore were considered a potential liability.

## *Note 32 – Commitments and guarantees*

The guarantees outstanding at June 30<sup>th</sup>, 2020 were unchanged from the end of the prior year and largely referred to guarantees for lease payments.

## *Note 33 – Transactions with related parties*

At June 30th, 2020, no transactions with related parties were recorded.

#### *Note 34 – Share-based payments*

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

## *Note 35 – Significant non-recurring events and transactions*

Pursuant to Consob Communication 15519 of July 27th, 2006 and Consob Communication DEM/6064293 of July 28th, 2006 it should be noted that, during the period, the Company did not enter into any significant non-recurring transactions.



## *Note 36 – Transactions resulting from atypical and/or unusual events*

Pursuant to Consob Communication of July 28, 2006, it should be noted that, during the period, the Company did not enter into any atypical or unusual transactions. The Communication defines as atypical or unusual transactions those transactions that may raise doubts as to the accuracy/completeness of the information in the Financial Statements, the existence of conflicts of interest, the safeguarding of the business net assets and of the minority shareholders, due to their significance/importance, the counterparties involved in the transaction, the subject of the transaction, the way the transfer price was determined and when the event/transaction takes place (close to year end).

## *Note 37 – Fees due to Directors and Statutory Auditors*

Fees due to MolMed's Directors and Statutory Auditors are shown in the following table:

(amounts in Euro thousand)	1 <sup>st</sup> half 2019	1 <sup>st</sup> half 2019	Change	Change %
Directors' fee	660	631	29	4.6%
Statutory auditors' fee	73	52	21	40.6%
Total Directors' and Statutory auditors' fee	733	683	50	7.3%

## *Note 38 – Information on financial risks*

The Company constantly monitors the financial risks to which it is exposed, in order to detect the potentially negative effects in advance and take the necessary action to mitigate them. The following section provides qualitative and quantitative disclosure on the effects that these risks may have on the Company.

The Company has recognized financial assets and liabilities in the financial statements relating solely to trade receivables and payables as well as liabilities deriving from leasing contracts, in application of IFRS 16.

The quantitative data reported in the following paragraphs should not be considered as forecasts; specifically, the sensitivity analysis on market risks is unable to reflect the complexity of the market and the reactions that may result from any estimated changes.

## Capital management

The Company manages its capital with the aim of pursuing the best interests of its stakeholders while also maintaining a sound capital structure.

### Market risk

Market risk is the risk of fluctuations in the fair value or the cash flows of a financial instrument following variations in the market price due to changes in exchange or interest rates, or in the price of equity-related financial instruments.

#### Interest rate risk

The Company has not recognized any financial payables—except for those recognized under IFRS 16—or receivables. Available cash was invested in current account deposits and bonds. Their yield depends on the trend in short-term interest rates. In order to limit the risk of counterparties' default in performing their obligations, investments were made at top-flight banks and financial institutions with high credit ratings, in order to diversify the counterparty risk.



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#### **Currency risk**

The Company's exposure to fluctuations in exchange rates is marginal, since there are no significant debit or credit positions in foreign currency, or financial instruments subject to currency risks. Financial assets are denominated in Euro. The Company does not use instruments aimed at hedging against the currency risk.

#### Credit risk

This is the risk that a client or counterparty causes a loss by defaulting on an obligation and it is primarily related to financial transactions. Given the nature of the Company's business, and the relevant asset structure, the Company is subject to limited credit risk. The maximum credit risk relating to the Company's current assets, including cash and cash equivalents, other financial assets, tax receivables, trade receivables and other assets, is equal to the value of these assets in the event that the counterparty becomes insolvent. There are no significant amounts past due. It should also be noted that all the main counterparties consist in leading financial institutions and widely recognized companies. At the current date, there are no insolvency situations and, operationally, normal monitoring of the commercial credit schedule continues in order to anticipate and intervene promptly on those credit positions that present a greater degree of risk.

With regard to concentration risk, currently two single name counterparties represent around 70% of revenues. In particular, for these counterparties, the Company monitors the state of the past due and collections and the advance payment of part of the services requested monthly. At the same time, through participation in congresses and sector events, a series of initiatives are underway aimed at diversifying the customer portfolio.

#### Liquidity risk

Liquidity risk is the inability to obtain, under reasonable conditions, the financial resources necessary for the operations and business development.

The company currently presents commitments for financial liabilities deriving from leasing contracts, for a total of Euro 7,930 thousand, of which Euro 6,726 thousand are to be paid beyond 12 months.

The two main factors that determine the Company's liquidity are, on the one hand, the resources generated or absorbed by the operating and investing activities and, on the other hand, the characteristics of the financial investments in terms of their maturity and renewal, as well as market conditions. The Company has implemented a series of policies and processes designed to optimize the management of financial resources and reduce liquidity risk:

- keeping an adequate level of cash and cash equivalents;
- constant monitoring of cash flows arising from the Company's operations and of the net financial position, in order to promptly implement the necessary actions;
- monitoring of prospective liquidity conditions related to corporate planning.

Cash and cash equivalents amounted to 14,429 thousand Euro at June 30<sup>th,</sup> 2020.

For further information, reference should be made to the section "Going concern" in these Notes, and to the section "Financial risks" in the Report on Operations.



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## Note 39 – Significant events after the reporting period

For further information on significant events after the reporting period, reference should be made to paragraph *6. Significant events after the reporting period*.

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

During the Board of Directors' meeting of November 12<sup>th</sup>, 2012, based on the amendments to Articles 70 and 71 of the Issuers' Regulations introduced by Consob Resolution no. 18214 of May 9<sup>th</sup>, 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.

## 8. Certification of Condensed Interim Financial Statements pursuant to Article 81-ter of Consob Regulation no. 11971 of May 14th, 1999 and subsequent amendments and additions

The undersigned, Mr. Riccardo Palmisano, CEO, and Mr. Salvatore Calabrese, Executive Officer responsible for preparing MolMed's financial reports, having taken into account the provisions of Article 154-bis, paragraphs 3 and 4, of Italian Legislative Decree no. 58 of February 24<sup>th</sup>, 1998, hereby certify the following:

- the adequacy in relation to the characteristics of the Company; and
- the effective implementation of the administrative and accounting procedures for the preparation of the Company's Condensed Interim Financial Statements for the period ended June 30<sup>th</sup>, 2020;

assessment of the adequacy of the administrative and accounting procedures used for the preparation of the Condensed Interim Financial Statements for the period ended June 30<sup>th</sup>, 2020 is based on a process defined in keeping with the Internal Control – Integrated Framework model issued by the Committee of Sponsoring Organizations of the Treadway Commission which is a reference framework generally accepted internationally.

It is also stated that:

the Condensed Interim Financial Statements for the period ended June 30th, 2020:

- a) were prepared in compliance with the applicable international accounting standards endorsed by the European Union pursuant to Regulation (EC) 1606/2002 of the European Parliament and Council of July 19<sup>th</sup>, 2002, as subsequently amended and supplemented;
- b) are consistent with the entries in accounting books and records;
- c) provide a true and fair view of the financial position, results of operations and cash flows of the issuer.



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The Interim Report on Operations includes a reliable analysis of the important events which occurred in the first six months of the year and their impact on the Condensed Interim Financial Statements, as well as a description of the main risks and uncertainties to which the Company is exposed for the rest of the year. The Interim Report on Operations also includes reliable disclosure on significant transactions with related parties.

Milan, July 27th, 2020

[Signed by]

Riccardo Palmisano CEO [Signed by]

Salvatore Calabrese Executive Officer responsible for Preparing company financial report



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## Indipendent Auditors' Report



## MolMed S.p.A.

Review report on the interim condensed financial statements

(Translation from the original Italian text)



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# Review report on the interim condensed financial statements (Translation from the original Italian text)

To the Shareholders of MolMed S.p.A.

#### Introduction

We have reviewed the interim condensed financial statements, comprising the statement of financial position, the income statement, the statement of comprehensive income, the statement of changes in equity, the statement of cash flows and the related explanatory notes of MolMed S.p.A. as of 30 June 2020. The Directors of MolMed S.p.A. are responsible for the preparation of the interim condensed financial statements in conformity with the International Financial Reporting Standard applicable to interim financial reporting (IAS 34) as adopted by the European Union. Our responsibility is to express a conclusion on these interim condensed financial statements based on our review.

## Scope of Review

We conducted our review in accordance with review standards recommended by Consob (the Italian Stock Exchange Regulatory Agency) in its Resolution no. 10867 of 31 July 1997. A review of interim condensed financial statements consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (ISA Italia) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion on the interim condensed financial statements.

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim condensed financial statements of MolMed as of June 30, 2020 are not prepared, in all material respects, in conformity with the International Financial Reporting Standard applicable to interim financial reporting (IAS 34) as adopted by the European Union.

Milan, July 29, 2020

EY S.p.A.

Signed by: Luca Pellizzoni, Statutory Auditor

This report has been translated into the English language solely for the convenience of international readers

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